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**CONCERNING THE DATA REQUIREMENTS
FOR CERTAIN CHEMICAL ACTIVE
SUBSTANCES AND
PLANT PROTECTION PRODUCTS
CONTAINING SUCH SUBSTANCES**

**COMMISSION WORKING DOCUMENT - DOES NOT NECESSARILY REPRESENT THE
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This document has been conceived as a working document of the Commission Services, which was elaborated in co-operation with the Member States. It does not intend to produce legally binding effects and by its nature does not prejudice any measure taken by a Member State within the implementation prerogatives under Annex II, III and VI of Council Directive 91/414/EEC, nor any case law developed with regard to this provision. This document also does not preclude the possibility that the European Court of Justice may give one or another provision direct effect in Member States.

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Introduction

This document is intended to provide initial guidance for notifiers and Member States in particular in the context of the 4th stage of the review programme of existing active substances under Council Directive 91/414/EEC concerning the placing of plant protection products on the market. The aim of this document is to propose on a weight of evidence basis a tiered approach to the data requirements for specific active substances and plant protection products containing such active substances.

This document has not been finalized in the Standing Committee on the Food Chain and Animal Health.

It is intended that it would be used by the relevant Rapporteur Member States designated in the context of the 4th stage of the review programme and that it might be updated as a result of their experience.

This document is without prejudice to the provisions included in the Regulation on the 4th stage of the review programme.

It does not prejudice the authority of Member States in national authorisations, nor does it prejudice the application of other Community legislation in force. Nonetheless, the document still provides some recommendations, which might be helpful in maintaining harmonised assessment schemes and decision making in Member States.

It is the responsibility of the applicant to provide the data and information required by Directive 91/414/EEC. Annexes II and III to Directive 91/414/EEC lay down the information and studies that had to be submitted as a minimum for active substances and plant protection products. However the introduction to the Annexes II and III provides that the applicant can provide a justification, which is acceptable to the competent authority, where particular data and information would not be necessary owing to the nature of the product or its proposed uses or where it is not scientifically necessary, or technically possible to supply information and data.

DATA SET REQUIREMENTS

This document is intended to provide initial guidance (minimum expected data set, tier 1) for submission of dossiers for plant protection products made from chemical substance(s), included in Annex I part A (with exception of plant extracts) to the Regulation on the 4th Stage and of similar new active substances.

The minimum expected data set depends on the chemical substance(s) used, the nature of the product and the intended uses. This document intends to define which data should in principle be submitted to allow a risk assessment. If necessary however supplementary data can be requested on a case-by-case basis by the competent authorities (Tier 2) in order to enable to finalize the risk assessment.

For plant protection products prepared with chemical substance(s) which are not included in Annex I – part A (with exception of plant extracts) to the Regulation on the on the 4th Stage, the requirements of Directive 91/414/EEC annexes II et III must be fulfilled. However, before

submitting an annex II and III dossier, applicants are invited to contact first the competent authorities and to submit to them all available information in accordance with guidance given by the competent authorities. The authorities will also for such products perform a first risk assessment based on the available data and will identify, where appropriate, further information to be submitted.

When reference is made in this document to particular information or studies that have to be submitted, the provisions of Annexes II and III to the Directive apply.

All available information (studies, publications, evaluations done in OECD countries, other uses than pesticides etc.) must be presented in the dossier and the summary dossier, and must be of sufficient quality to allow an assessment of possible risks of the proposed use. All information must be physically submitted by the notifier/applicant; this implies as well that all the original references identified by the literature search must be submitted.

• **TIER 1 DATA REQUIREMENTS ON THE ACTIVE SUBSTANCE**

1 IDENTITY OF THE ACTIVE SUBSTANCE

Name and address of applicant.

Name and address of manufacturer.

Place of manufacture or place of mining (if extracted).

Common names proposed, ISO name or synonyms, IUPAC/CA name.

Chemical name as in annex I to Directive 67/548/EEC.

Manufacturer's code number(s).

Existing CAS, CIPAC, EEC, numbers.

Molecular formula, molecular mass and structural formula.

Method of manufacture where relevant.

Content (g/kg) of pure a.s.

-Inactive isomers where relevant :

Common names proposed, ISO name or synonyms IUPAC/CA name.

Existing CAS, CIPAC, EEC, numbers.

Molecular formula, molecular mass and structural formula.

Maximum content in (g/kg).

-Impurities and additives :

Common names proposed, ISO name or synonyms IUPAC/CA name.

Existing CAS, CIPAC, EEC numbers.

Molecular formula, molecular mass and structural formula.

Maximum content in (g/kg).

For any toxic substances that are relevant for human, animal health and environment provide a maximum content limit.

Analysis report of 5 batches for each manufacturing location.

2 PHYSICAL AND CHEMICAL PROPERTIES OF THE ACTIVE SUBSTANCE

Melting point (of purified a.s.).

Vapour pressure (of purified a.s.) and Henry's Law constant where relevant.
Description of the physical state, colour and odour of both purified a.s. and a.s. as manufactured .
Solubility in water.
Solubility in organic solvents.
Stability in water, hydrolysis rate if relevant.
Dissociation in water of purified a.s. (pKa values).

Explosive properties, flash point, flammability, self-combustibility, oxidizing properties, surface tension of the a.s. as manufactured where relevant.

3 *FURTHER INFORMATION ON THE ACTIVE SUBSTANCE*

Function.
Field of use.
Effect on harmful organisms, expected mode of action.
Details of intended use (crops, parasites) if relevant.
Application rate.
Application method.
Recommended methods and precautions concerning handling, storage, transport or fire if relevant
Emergency measures in the case of an accident.

4 *ANALYTICAL METHODS*

Validated method for analysing the purity of the active substance and where appropriate impurities of the active substance and additives.

A validated method for analysing the active substance in water, soil and air can be judged necessary if exposure of the concerning compartment is likely and the contribution compared to natural background levels is substantial.

If any toxic substances that are relevant for human or animal health and the environment are detected, validated methods of analysis must be provided.

5 *TOXICOLOGICAL STUDIES*

Provide all toxicological information available, including studies, publications, evaluations done in OECD countries, other uses than pesticides etc.

The information provided must be sufficient to enable an evaluation of the active substance. Taking into account the end points as listed in Annex II of Directive 91/414/EC.

6 *RESIDUES IN OR TREATED PRODUCTS FOOD AND FEED*

The extent of exposure due to the use as plant protection product, must be compared to the exposure due to consumption of the active substance itself. If the exposure due to the use as plant protection product is relatively large, residue data will be needed.

Provide where relevant the information submitted in the framework of EU legislation in human foodstuffs or animal feeding stuffs substances.

7 *FATE AND BEHAVIOUR IN THE ENVIRONMENT*

If exposure of water, soil or air is likely to occur available information from literature on natural background levels should be provided. If there is a substantial increase more information may be required based on expert judgement.

8 *ECOTOXICOLOGICAL STUDIES OF THE ACTIVE SUBSTANCE*

Provide all ecotoxicological information available, including studies, publications, evaluation done in OECD countries etc.

Based on the evaluation of the available information, further ecotoxicological data on the plant protection product may be required based on expert judgment.

If classification according to Directive 67/548/EC [1] is applicable, the following studies must be provided: acute effects on fish, daphnia and algae.

9 *SUMMARY AND EVALUATION OF POINTS 7 AND 8*

10 *CLASSIFICATION AND LABELLING OF THE ACTIVE SUBSTANCE*

If applicable, proposals for the classification and labelling are mandatory [DIR 67/548 EEC].

- **TIER 1 DATA REQUIREMENTS ON THE PLANT PROTECTION PRODUCT**

1 IDENTITY OF THE PLANT PROTECTION PRODUCT

Name and address of applicant.
Name of contact person.
Name and address of the manufacturer.
Place of manufacture.
Name of contact person.
Trade name of the plant protection product
Content expressed:
 technical active substance.
 pure active substance.
 formulants.
For each formulants or components in formulants:
 Chemical name EEC or IUPAC/CA name
 Existing CAS, CIPAC, EEC numbers.
 Structure or structural formula.
 Trade name.
Function of each formulant.
Type of preparation
Function

2 PHYSICAL AND CHEMICAL PROPERTIES OF THE PLANT PROTECTION PRODUCT

Appearance (physical state, colour, and odour).
pH value and acidity or alkalinity.
Explosive properties and oxidising properties where relevant.
Flash point and other indications of flammability auto-flammability where relevant.

Relative density where relevant.
Storage stability.

Suspensibility, spontaneneity of dispersion, dilution stability where relevant.

For solids products : size distribution of particles, dust content, particle size of dust, friability and attrition characteristics of granules.

3 *DATA ON APPLICATION*

Field of use.

Effect on harmful organisms, expected mode of action.

Details of intended use (crops, parasites).

Application rate.

Application method.

Number and timing of applications and the protection period where relevant.

Concentration of active substance in material used

4 *FURTHER INFORMATION ON THE PLANT PROTECTION PRODUCT*

Packaging (description, type, capacity, size, materials, seal).

Methods for cleaning the equipment used to apply the product.

Re-entry periods, required waiting periods or other precautions for protecting man, animals and the environment.

Recommended procedures and precautions for product handling, storing and transporting, or in the event of a fire.

Emergency procedures in the event of an accident.

Destruction or decontamination procedures (depending on the kind of ingredients in the preparation).

5 *ANALYTICAL METHODS*

Validated method for determining the content of active substance(s) in the plant protection product.

6 *EFFICACY DATA*

The dossier should contain information on efficacy and selectivity.

7 *TOXICOLOGICAL STUDIES*

Provide all toxicological information available, including studies, publications, evaluation done in OECD countries, other uses than pesticides etc..

The information provided must be sufficient quality to enable an evaluation of the plant protection product, taking into account the endpoints as listed in Annex III to the Directive 91/414/EC (i.e. acute oral, dermal, inhalation toxicity, cutaneous and eye irritation and skin sensitisation).

Depending on the outcome of the evaluation additional information can be required on a case by case basis.

Data available on the active substance(s) could be used in a case by case approach.

In the case where formulant(s) are added in the plant protection product, the safety data sheets of the formulant(s) must be provided.

Based on available information on the formulant(s) and the amount added in the plant protection product, further toxicological data may be required based on expert judgement.

Risk assessment for the operator and worker must be addressed and personal protective equipment where relevant indicated.

8 *RESIDUES IN OR ON TREATED PRODUCTS, FOOD AND FEED*

The extent of exposure due to the use as plant protection product, must be compared to the exposure due to consumption of the active substance itself. If the exposure due to the use as plant protection product is relatively large, residue data will be needed.

9 *FATE AND BEHAVIOUR IN THE ENVIRONMENT*

If exposure of water, soil or air is likely to occur available information from literature on natural background levels should be provided. If there is a substantial increase more information may be required based on expert judgement.

10 *ECOTOXICOLOGICAL STUDIES*

Provide all ecotoxicological information available, including studies, publications, evaluations done in OECD countries, other uses than pesticides etc.

Data available on the active substance(s) could be used in a case by case approach.

Based on the evaluation of the available information, further ecotoxicological data on the plant protection product may be required based on expert judgment.

In the case where formulant(s) are added in the plant protection product, the safety data sheets of the formulant(s) must be provided.

Based on available information on the formulant(s) and the amount added in the plant protection product, further ecotoxicological data may be required based on expert judgement.

If required for classification according to the Directive 1999/45/EC [1], the following studies must be provided: acute effects on fish, daphnia and algae.

11 SUMMARY AN EVALUATION OF POINTS 9 AND 10

12 CLASSIFICATION AND LABELLING

If applicable, proposals for the classification and labelling are mandatory [DIR 99/45/EEC].