



**EUROPEAN COMMISSION**  
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

Directorate E - Food Safety: plant health, animal health and welfare, international questions  
**E1 - Plant health**

**Sanco/10472/2003 –rev.5**  
**6.7.2004**

## **Draft working document**

# **CONCERNING THE DATA REQUIREMENTS FOR ACTIVE SUBSTANCES OF PLANT PROTECTION PRODUCTS MADE FROM PLANTS OR PLANT EXTRACTS**

**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 the context of the 4<sup>th</sup> stage of the review programme of existing active substances and for applications for new 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 active substances of plant protection products made from plants or plant extracts.

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 4<sup>th</sup> 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 4<sup>th</sup> 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. Annexes II and III to Directive 91/414/EEC lay down the information and studies that have 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.

## 1. Definitions in the framework of this document

The plants used in plant protection products in the framework of this document are live or dried plants and live or dried parts of plants, including fruits and seeds but excluding genetically modified plants.

*Active substance : definition see Article 2 point 4 of Directive 91/414/EEC*

### ***Plant protection products made from plants or plants extracts***

Product intended for use in plant protection which contains plants, plant extracts and possibly formulants.

### ***Plant extracts***

An extract is obtained from a solution achieved by treating plants or parts of them, with a solvent, which is further concentrated through evaporation, distillation or some other process. Only soft extraction with water and/or ethanol (excluding other solvents) are covered in the framework of this document.

## 2. DATA SET REQUIREMENTS

This document provides initial guidance for submission of dossiers for active substances of plant protection products made from plants and/or plant extracts included in the reference list. These are included in the list because they are considered to present reduced risk based on long-term experience and a sufficient database.

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

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 relevant available information (studies, publications, evaluations done in OECD countries, other relevant uses other 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.

For active substances of plant protection products or plant extracts prepared with plants or plant extracts which are not included in the reference list as well as plant extracts prepared with other solvents than water and/or ethanol, Applicants are invited to contact first the competent authorities and to submit to them all relevant 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.

For inclusion of an active substance into Annex I sufficient information has to be submitted for both the active substance and for one or more preparations for a limited range of representative uses. It is not exceptional that in the case of plant extracts the active substance is used as such and is therefore to be considered as being also the plant protection product. It is therefore not always possible to differentiate clearly between the data requirements for the active substance and for the plant protection product. Therefore the following guidance has not been separated in requirements of Annex II (active substance) and Annex III (plant protection product) but has to be interpreted on a case by case basis.

In a tiered approach, two categories are identified:

### Category 1 :

**Active substances of plant protection products made from one or several plants included in the reference list and mixed with water and plant protection products possibly with formulants added.**

- **Category 2 :**

**Active substances of plant protection products prepared with one or several ethanol/water based extracts made of plants included in the reference list and plant protection products possibly with formulants added**

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## A. Tier 1 Data requirements for Category 1

**Active substances of plant protection products made from one or several plants included in the reference list and mixed with water and plant protection products possibly with formulants added.**

### **PLANT NOMENCLATURE**

Applicable in all instances.

#### Description

Latin name of the plant and its author. Common names.

Genus, species, sub-species, variety or chemotype, if necessary.

Geographic origin.

Natural state: cultivated or wild.

Growth stage.

Organ or part of the plant sampled.

If the plant protection product is not obtained directly from the plant itself, specify the processing used;

#### Origin of the plant

Name and address of grower (where relevant) and/or region of origin.

Growing conditions.

Place, time and conditions of harvest.

Length of storage and storage conditions.  
Any change of origin must be considered in advance before being accepted.

## *1 IDENTITY OF THE PLANT PROTECTION PRODUCT*

### Particulars relating to the plant protection product manufacturer

Name and address of applicant.  
Name of contact person.  
Name and address of the manufacturer.  
Place of manufacture.  
Name of contact person.

### Plant protection products specifications

Establish a chemical profile :

- Description of the known active plant protection substances. Provide the active substances' concentration range.
- For the other substances, provide a percentage of the total weight (or a percentage range).

If any active substance has been identified the following information are required :

- Chemical name according to IUPAC, and other information about identity (CAS N°, structural formula, ISO name).
- Physico-chemical properties: vapour pressure, partition coefficient, hydrolysis, photolysis.

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

If the active substance(s) is (are) not identified, define a representative marker\*.

*\* i.e. a chemical naturally present in a known proportion in the plant in order to identify the plant protection product.*

Analysis report of 5 batches of different manufacture, collected over several periods.

### Manufacture of the plant protection product

Precise description of the manufacturing process: methods, stages, operating conditions.

Detection and identification of possible contaminants such as heavy metals, toxins, pesticides.

Assessment of microbiological quality : detection and quantification of the plant and animal and human pathogens (depending on the type and origin of the plant, and the plant protection product's manufacture and storage).

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Full list of ingredients :

The plant protection product's trade name, physical state and function must be specified.

Example: plant protection product manufactured directly from a plant

A precise quantity of the plant, or an upper and lower limit must be submitted.

	<b>Quantity</b>
Plant (whole or part)	[    ] g/kg or g/l (expressed as fresh weight and dry weight or as a weight interval)
Other ingredients (incl. CAS N°)	[    ] g/l or g/kg
Water	[    ] g/l

## 2 *PHYSICAL AND CHEMICAL PROPERTIES OF THE PLANT PROTECTION PRODUCT*

Type of formulation.

Appearance (physical state, colour, and odour).

pH.

Oxidising properties.

Relative density.

Suspensibility.

Persistent foaming.

Particle size distribution for powders.

Compatibility with the packaging.

Plant protection product's stability in storage:

-with monitoring in all cases of its physical, chemical and micro-biological properties and of the active substances that have been identified.

-the wrapping and packaging must be specified. The stability trials are to be carried out under normal conditions on 3 batches of the same formula, using the dose and wrapping that will be used when the product is marketed

## 3 *DATA ON APPLICATION*

Field of use

Effect on harmful organisms, expected mode of action.

Details of intended use (crops, parasites).

Application rate .

Method of application

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

#### 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 plant protection product).

#### 5 *ANALYTICAL METHODS*

- If the substances are identified :  
Validated method for analysing the identified active substance in the plant protection product,
- If the active substances are not identified, a validated method of analysis of the marker in the plant protection product should be available.
- 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 in the plant protection product, validated methods of analysis must be provided.

#### 6 *EFFICACY DATA*

The dossier for product authorisation should contain information on efficacy and selectivity.

#### 7 *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 of sufficient quality to enable an evaluation of the plant protection product, taking into account the endpoints relevant for the intended use of the product 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). In case the plant used in the plant protection product is also used in food and feed information on oral toxicity may be waived.

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

In the case where formulants are added in the plant protection product, the safety data sheets of the formulants must be provided.

Based on available information on the formulants 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 plant itself. In cases where relevant residues of the active substance or other components of toxicological relevance occur in/on the treated plants used as a food or feed item, supervised field trials must be carried out.

Depending on the results, further studies (e.g., processing, feeding) might be necessary.

When relevant a dietary risk assessment for the consumer is required.

#### 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 etc..

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 formulants are added in the plant protection product, the safety data sheets of the formulants must be provided.

Based on available information on the formulants 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 Directive 67/548/EEC or 1999/45/EC [1] the following studies must be provided: acute effects on fish, daphnia and algae.

#### 11 *SUMMARY AND EVALUATION OF POINTS 9 AND 10*

## 12 CLASSIFICATION AND LABELLING

If applicable, proposals for the classification and labelling are mandatory [1].

### **B. Tier 1 Data requirements for Category 2**

**Active substances of plant protection products prepared with one or several ethanol/water based extracts made of plants included in the reference list and plant protection products possibly with formulants added**

#### **PLANT NOMENCLATURE**

Applicable in all instances.

##### Description

Latin name of the plant and its author. Common names.

Genus, species, sub-species, variety or chemotype, if necessary.

Geographic origin.

Natural state: cultivated or wild.

Growth stage.

Organ or part of the plant sampled.

If the plant is not used in its natural state, specify the processing used and the macro- and microscopic characteristics of the resulting product.

##### Origin of the plant

Name and address of grower (where relevant) and/or region of origin.

Growing conditions.

Place, time and conditions of harvest.

Length of storage and storage conditions.

Any change of origin must be considered in advance before being accepted.

### *1 IDENTITY OF THE PLANT PROTECTION PRODUCT*

#### Particulars relating to the plant protection product manufacturer

Name and address of applicant.

Name of contact person.

Name and address of the manufacturer.

Place of manufacture.

Name of contact person.

#### Extract specifications

A chemical profile is required :

Description of known active plant-protection substances. Provide a concentration range for the active substances.

For the identified active substance(s) the following information are required :

- Chemical name according to IUPAC, and other information about identity (CAS N°, structural formula, ISO name).
- Physico-chemical properties such as vapour pressure, partition coefficient, hydrolysis and photolysis including pH-effect.

For other substances, provide a percentage of the total weight.

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

Analysis report of 5 batches of different manufacture, collected over several periods.

#### Manufacture of the extract

Precise description of the manufacturing method : methods, stages, operating conditions, type and quantity of the solvents used.

#### Plant protection product specifications

Precise description of the manufacturing process of the plant protection product : methods, stages, operating conditions.

Detection and identification of possible contaminants such as heavy metals, toxins, pesticides.

Assessment of microbiological quality : detection and quantification of the plant and animal and human pathogens (depending on the type and origin of the plant, and the plant protection product 's manufacture and storage).

#### Full list of ingredients:

The plant protection product's trade name, physical state and function must be specified.

Example: A precise quantity or an upper and lower limit corresponding to a defined quantity of plant-protection substances must be submitted.

	<b>Quantity</b>
Extract of [       ] prepared from: <ul style="list-style-type: none"> <li>• Plant(s) [       ] g/kg</li> <li>• Solvent [specify solvent composition, indicating content in g/l or g/kg] (includ. CAS N°)</li> </ul>	[       ] g/l or g/kg of extract corresponding to [       ] g/l or g/kg of active substance
Other ingredients	[       ] g/l or g/kg

Type of formulation.  
Appearance (physical state, colour, and odour).  
pH.  
Explosiveness, flash point, self-combustibility.  
Oxidising properties.  
Volatility.  
Viscosity.  
Surface tension.  
Relative and overall densities.  
Suspensibility.  
Persistent foaming.  
Compatibility with the packaging.

Plant protection product's stability in storage:

-with monitoring in all cases of physical, chemical and micro-biological properties and content of the identified active substances.

-the wrapping and packaging must be specified. The stability trials are to be carried out under normal conditions on 3 batches of the same formula, using the dose and wrapping that will be used when the product is marketed.

### 3 *DATA ON APPLICATION*

Field of use  
Effect on harmful organisms, expected mode of action.  
Details of intended use (crops, parasites).  
Application rate .  
Method of application  
Number and timing of applications and the protection period where relevant.

### 4 *FURTHER INFORMATION ON THE EXTRACT*

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 plant protection product).

### 5 *ANALYTICAL METHODS*

- Validated method for analysing the identified active substance in the plant protection product must be provided.

- 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 in the plant protection product, validated methods of analysis must be provided.
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- Validated method for analysing of the active substances in the treated plant if residue studies are required and MRLs have been established.

## 6 *EFFICACY DATA*

Applicable if the extract is used directly as a plant protection product.  
The dossier should contain information on efficacy and selectivity.

## 7 *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 of sufficient quality to enable an evaluation of the plant protection, taking into account the endpoints relevant for the intended use of the product as listed in Annex III to the Directive 91/414/EEC (i.e. acute oral, dermal, inhalation toxicity, cutaneous and eye irritation and skin sensitisation). In case the plant used in the plant protection product is also used in food and feed information on oral toxicity may be waived.

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

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 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 plant itself. In cases where relevant residues of the defined active substance or other components of toxicological relevance occur in/on the treated plants used as a food or feed item, supervised field trials must be carried out.

Depending on the results, further studies (e.g., processing, feeding) might be necessary.

When relevant a dietary risk assessment for the consumer is required.

#### 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 OF THE WATER ETHANOL EXTRACT*

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

Data available on the extract 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 Directive 67/548/EEC or 1999/45/EC [1] the following studies must be provided: acute effects on fish, daphnia and algae.

#### 11 *SUMMARY AND EVALUATION OF POINTS 9 AND 10*

#### 12 *CLASSIFICATION AND LABELLING OF THE WATER ETHANOL EXTRACT*

If applicable, proposals for the classification and labelling are mandatory [1].

## [1].REFERENCE LIST

This list contains:

A) **all edible parts of plants used for animal or human feed** and in addition other parts of plants mentioned in this table such as:

<u>common name of the plant</u>	<u>genus and species</u>	<u>Parts of the plant to be used</u>
artichoke	<i>Cynara scolymus</i>	edible parts
basil	<i>Ocimum basilicum</i>	whole plant
black pepper	<i>Piper nigra</i>	fruit
carvi	<i>Carum carvi</i>	Fruit
chives	<i>Allium schoenoprasum</i>	Clove
coriander	<i>Coriandrum sativum</i>	fruit
elder	<i>Sambucus nigra</i>	Bark + flower + fruit
garden sage	<i>Salvia officinalis</i>	whole plant
garlic	<i>Allium sativum</i>	Clove
Horse tail	<i>Equisetum arvensis</i>	leaf
laurel	<i>Laurocerassus officinalis</i>	leaf
mint	<i>Menta spicata</i>	whole plant
olive	<i>Olea sativa europea</i>	Oil
onion	<i>Allium cepa</i>	bulb
oil seed-rape	<i>Brassica napus</i>	oil
sesame	<i>Sesamum indicum</i>	seed
soybeans oil	<i>Soja hispida</i>	oil
squash	<i>Cucurbita pepo</i>	seed
sunflower	<i>Helianthus annuus</i>	oil
tomato	<i>Lycopersicum esculentum)</i>	fruit

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white mustard	<i>Sinapis alba</i>	seed
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**B) A list of parts of plants currently authorised as herbal drugs in European pharmacopoeia and known traditionally for plant protection properties (2).**

<u>common name of the plant</u>	<u>genus and species</u>	<u>part(s) of the plant to be exclusively used</u>
bladder wrack	<i>Fucus vesiculosus</i> L	thallus
feverfew	<i>Chrysanthemum parthenium</i>	whole plant
lavander	<i>Lavendula officinalis</i>	whole plant
nettle	<i>Urtica dioica, membranacea, pillulifera</i>	whole plant
rhubarb	<i>Rheum rhabarbarum , officinale</i>	rhizome only
sweet chamomille	<i>Anthemis nobilis</i>	whole plant

This list has been established on the basis of available information including literature, evaluation done in OECD countries, European pharmacopoeia, weight of evidence which indicates that the plant is not harmful to human, animal and environment.

## REFERENCES

- 1 Directive 1999/45/EC of the European Parliament and of the Council of 31 May 1999 concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations (Official Journal of the European Communities L 200 , 30/07/1999, P. 1- 68).  
Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances.
- 2 French official document for the submission of a dossier for medicines containing herbal drug(s) (AFSSAPS) : Agence Française de Sécurité SANitaire des Produits de Santé.