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HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

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

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Commission services.*

Guidance document on the preparation of dossiers and draft assessment reports for substances covered in the fourth stage of the review programme referred to in Article 8(2) of Council Directive 91/414/EEC

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.

Introduction

This guidance has been developed in order to assist notifiers and rapporteur Member States in preparation of the dossiers and Draft Assessment Reports required by the Commission Regulation dealing with the 4th stage of the review programme.

It intends to give guidance on the way the information should be presented in the dossier and how it should be presented in the draft assessment reports. In certain cases, where guidance has already been developed this is referred to.

A number of specific types of substance are covered by this stage to which different requirements apply.

Questions regarding the preparation of dossiers should be addressed to the rapporteur Member State identified in the Commission Regulation dealing with the 4th stage of the review programme.

A. Requirements for substances listed in Part A of the Commission Regulation

Dossier

The following information should appear in the dossier:

1 IDENTITY OF THE ACTIVE SUBSTANCE

As specified in Annex II of Directive 91/414/EEC section 1

2 FURTHER INFORMATION ON THE ACTIVE SUBSTANCE

As specified in Annex II of Directive 91/414/EEC section 3

3 IDENTITY OF THE PLANT PROTECTION PRODUCT

As specified in Annex III of Directive 91/414/EEC section 1

4 DATA ON APPLICATION

As specified in Annex III of Directive 91/414/EEC section 3

It should be noted that the dossier include a limited range of representative uses of the active substance, in respect of which the data submitted by the notifier in the dossier shall demonstrate that for one or more preparations, the requirements set out in Article 5 of Directive 91/414/EEC for inclusion of the active substance in Annex I to Directive 91/414/EEC, can be met;

The information on representative uses should be presented in the format provided in Appendix 1.

5 FURTHER INFORMATION ON THE PLANT PROTECTION PRODUCT

As specified in Annex III of Directive 91/414/EEC section 4

6 INFORMATION ON THE PROVISION OF COLLECTIVE DOSSIERS

Where for any active substance listed in Annex I there are several notifications, the notifiers concerned shall take all reasonable steps to submit these dossiers collectively. Where a dossier is not submitted by all notifiers concerned, it shall mention the efforts made and the reasons why certain notifiers have not participated.

For active substances notified by more than one notifier those notifiers shall for each study involving vertebrate animals, detail the attempts made to avoid duplication of testing and give, if applicable, the reasons for conducting a duplicate study.

7 COPY OF NOTIFICATION

A copy of the notification; in the case of a joint application made by several producers, a copy of the notifications made in accordance with Article 4 or 5 of Regulation (EC) No 1112/2002 and the name of the person designated by the producers concerned as being responsible for the joint dossier and the processing of the dossier in accordance with this Regulation;

8 SUPPORTING INFORMATION

- (a) all available and relevant information on the active substance and the plant protection product (where applicable) (including evaluations from other OECD countries) especially on possible risks to human and animal health and the environment including that available from searching the literature and identifying the data bases searched and search terms used.
- (b) for any ongoing studies not yet fully completed information on the study and a projected date of completion.

The dossier shall physically contain the individual test and study reports.

The information should be ordered according to Annex II and III of 91/414/EEC.

In general the information should be in English language.

A reference list in the format given in SANCO/4713/2001, 6.12.2001 - Detailed instruction for industry for submission on reference lists, (www.europa.eu.int/comm/food/fs/ph_ps/pro/wrkdoc/reference_en.pdf) should be provided.

9 CONFIDENTIAL INFORMATION

Confidential information (as defined in Article 14 of Directive 91/414/EEC) should be submitted separately and identified as such.

The following guidance document may assist in the preparation of dossiers for plant extracts and certain chemical substances:

GUIDANCE DOCUMENT CONCERNING THE DATA REQUIREMENTS FOR PLANT PROTECTION PRODUCTS MADE FROM PLANTS OR PLANT EXTRACTS (Sanco/10472/2003 –rev.5, 6.7.2004)

Or

GUIDANCE DOCUMENT CONCERNING THE DATA REQUIREMENTS FOR CERTAIN CHEMICAL ACTIVE SUBSTANCES AND PLANT PROTECTION PRODUCTS CONTAINING SUCH SUBSTANCES (Sanco/10473/2003 –rev.4, 6.7.2004)

Draft assessment reports

Based on the submitted and relevant information, these should be prepared as far as possible following the Guidelines and Criteria for the Evaluation of Dossiers and for the Preparation of Reports to the European Commission by Rapporteur Member States Relating to the Proposed

Inclusion of Active Substances in Annex I of Directive 91/414/EEC Document 1654/VI/94 rev. 7 of 22.4.98

B. Requirements for substances listed in Part B of the Commission Regulation

Further guidance on data requirements can be found in OECD , document, Guidance for Registration Requirements for Pheromones and other Semiochemicals Used for Arthropod Pest Control Series on Pesticides No. 12 ENV/JM/MONO(2001)12 - [www.oelis.oecd.org/olis/2001doc.nsf/LinkTo/env-jm-mono\(2001\)12](http://www.oelis.oecd.org/olis/2001doc.nsf/LinkTo/env-jm-mono(2001)12)

Further guidance on the preparation of dossiers and draft assessment reports can be found in

OECD Guidance For Industry Data Submissions for Pheromones and Other Semiochemicals and their Active Substances (Dossier Guidance for Pheromones and Other Semiochemicals) Series on Pesticides No. 16 - www.oecd.org/document/48/0,2340,en_2649_34383_2085104_119820_1_1_1,00.html

OECD Guidance for Country Data Review Reports for Pheromones and other Semiochemicals and their Active Substances (Monograph Guidance for Pheromones and other Semiochemicals) Series on Pesticides No. 17 www.oecd.org/document/48/0,2340,en_2649_34383_2085104_119820_1_1_1,00.html

C. Requirements for substances listed in Part C of the Commission Regulation

Detailed data requirements have been established in Annex IIB and IIIB of Directive 91/414/EEC.

Further guidance on the preparation of dossiers and draft assessment reports can be found in:

OECD Guidance for Industry Data Submissions for Microbial Pest Control Products and their Microbial Pest Control Agents Feb 2004 Series on Pesticides No 23-
www.oecd.org/document/48/0,2340,en_2649_34383_2085104_119820_1_1_1,00.html

OECD Guidance for Country Data Review Reports on Microbial Pest Control Agents (Monograph Guidance for Microbials), Series on Pesticides No 22
www.oecd.org/document/48/0,2340,en_2649_34383_2085104_119820_1_1_1,00.html

D. Requirements for substances listed in Part D and E of the Commission Regulation

In principle the biocides dossier guidance and guidance on Draft Assessment Reports can be followed

E. Requirements for substances listed in Part F of the Commission Regulation

Standard dossier and draft assessment reports are required.

As from 31st December 2004, all dossiers should be submitted in OECD-format on the basis of the OECD dossier guidance. The OECD formatting guidelines are available on the OECD homepage:

(http://www.oecd.org/document/55/0,2340,en_2649_34383_33650359_1_1_1_1,00.html)

As discussed at the Working Group 'Plant Protection Products' (legislation) on 2 and 3 December 2002, draft assessment reports (Monographs) prepared by the rapporteur Member States have to be submitted according to the OECD guidance (http://www.oecd.org/document/12/0,2340,en_2649_34383_33650316_1_1_1_1,00.html) whenever the related dossier of the applicant/main notifier has been submitted in OECD format, i. e. latest from 31st December 2004 onwards.

Appendix 1

Crop and/or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks: (m)
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between applications (min)	kg as/hL min max	water L/ha min max	kg as/ha min max		

Remarks: (a) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (e.g. fumigation of a structure)
 (b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
 (c) e.g. biting and suckling insects, soil born insects, foliar fungi, weeds
 (d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
 Codes - GIFAP Technical Monograph No 2, 1989
 (f) All abbreviations used must be explained
 (g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
 (h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated

(i) g/kg or g/l
 (j) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
 (k) The minimum and maximum number of application possible under practical conditions of use must be provided
 (l) PHI - minimum pre-harvest interval
 (m) Remarks may include: Extent of use/economic importance/restrictions