



EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

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Directorate D: Food Safety; production and distribution chain
Unit D.3: Chemical and physical risks; surveillance

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**Guideline developed within the Standing Committee on the Food Chain and Animal Health
on the Preparation and Presentation of Complete Dossiers for the Inclusion of Active
Substances in Annex I of Directive 91/414/EEC (Article 5.3 and 8.2)**

INTRODUCTION

On 1 – 2 October 2001, member state representatives meeting as the Legislation Working Group agreed that from **31st December 2004**, all dossiers submitted by notifiers wishing to have active substances included in Annex I to Directive 91/414/EEC (the Directive), or other interested parties wishing to have other information taken into account by the relevant regulatory authorities should be presented in OECD-format.

For chemical substances, applicants and interested parties should use the 'OECD guidelines and criteria for industry for the preparation and presentation of complete dossiers and of summary dossiers for plant protection products and their active substances in support of regulatory Decisions in OECD countries (Revision 2, May 2005)'.

For microbial pesticides, applicants and interested parties should use the 'OECD Guidance for Industry Data Submissions for Microbial Pest Control Products and their Microbial Pest Control Agents (Dossier Guidance for Microbials), February 2004, Series on Pesticides No. 23'.

The OECD guidance documents are based on and are consistent with the previous European Commission Guidance Document 1663/VI/94 Rev 8 (2 April 1998) and have been approved by the OECD Working Group on pesticides.

To help member states, industry and other interested parties to understand any differences between the existing EU format and the OECD format for microbials, a document that compares the two numbering systems has been prepared as background document to this guidance.

As regards the dossier format for chemicals, Revision 2 of the OECD Dossier Guidance is fully consistent with the existing EU format. However, in order to facilitate the handling of dossiers submitted earlier, a document that compares the two numbering systems has also been prepared for chemicals as background document to this guidance.

These documents are available from the SANCO home page under [Guidance Documents for the implementation of Council Directive 91/414/EEC](#). For chemical substances, please refer to "[Comparison List A](#)" and for microbials, "[Comparison List B](#)".

This document provides guidance to Member States and to industry on the submission of dossiers to support the inclusion of an active substance in Annex I. In particular, this document provides guidance on the number and format of dossiers, addresses to which they should be submitted and general contact points. For guidance on the submission of dossiers to support national authorizations, prospective applicants should consult the competent authorities of the relevant member states. In preparing Annex III submissions, the OECD guidelines should be followed from 1 July 2006. This document has been conceived as an opinion of the Commission Services and elaborated in co-operation with the Member States. The Commission also had comments received from ECPA/IBMA available to it. This document does not, however, produce legally binding effects and by its nature does not prejudice any measure taken by a Member State, nor any case law developed by the European Court of Justice with regard to the interpretation of Directive 91/414/EEC and the legislation made under it.

Article 8 (2) of the Directive provides that the Commission will set out all the provisions necessary

for the implementation of the review programme for existing active substances. For new active substances it is also in the interest of all parties involved to provide similar guidance. Therefore the Commission and the Member States expect that the approach proposed in this document will also be followed for new active substances.

When preparing dossiers for submission, applicants and other interested parties are advised to consult the most recent texts of data requirements as set out in Annexes II and III of the Directive. These can be obtained from the SANCO home page under [Guidance Documents for the implementation of Council Directive 91/414/EEC](#).

Where additional or more detailed guidance is required on technical points, applicants and other interested parties are advised to refer to the Guidance documents which can be obtained from the SANCO home page under [Guidance Documents for the implementation of Council Directive 91/414/EEC](#). If necessary, they should contact the designated authority of the Member State to which the documentation is to be submitted.

1 FORMAT

The OECD formatting guidelines are available on the OECD homepage: (http://www.oecd.org/document/59/0,2340,en_2649_34383_1916347_1_1_1_1,00.html)

Note: 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 whenever the related dossier of the applicant/main notifier has been submitted in OECD format, i. e. latest from 31st December 2004 onwards.

The essential components of the dossier are as follows:

(Advice on how a dossier should be compiled and structured is available in the OECD guidance document - http://www.oecd.org/document/59/0,2340,en_2649_34383_1916347_1_1_1_1,00.html)

Document	
A	Statement of the context in which the dossier is submitted
B	Task force information: Where in the context of Article 8 (2) of Directive 91/414/EEC and Commission Regulations made pursuant to that Article, there is an obligation on notifiers of particular existing active substances to <i>take all reasonable steps to present collectively the dossiers</i> concerned and, where it is not possible to so present the dossiers - a claim that all reasonable steps were taken to present the dossiers collectively, and documentation to justify the claim made
C	Where requested, copies of existing or proposed label(s) and where relevant leaflets (see Article 16 (2) of the Directive) for each of the preparations for which an Annex III dossier is submitted and in addition, labels and leaflets relevant to the uses on the basis of which import tolerances are supported or proposed. Where relevant, a translation of the texts of labels and leaflets submitted.
D1	Details of the intended uses (GAPs) (uses that are being supported by the applicant, for which data have been provided or for which data are to be provided by a specified date) and conditions of use (GAPs), on both food and feed crops and on non food and feed crops in the territory of the EU, supported in relation to the proposed inclusion of the active substance in Annex I. Link to template
D2	Details of registered uses (GAPs) in EU Member States and an indication of whether, or not, actually used. The listing provided should include those uses which are currently authorized but which are not being supported by the applicant. The information provided with respect to actual use, should identify those authorizations that are not currently availed of (some uses or all uses), and further should describe those instances where the rate and manner of use in practice is more restrictive than is provided for in the existing authorization (e.g. authorized uses of a plant protection product for which the product is not currently commercialized; uses for which the maximum authorized application rate is seldom if ever availed of).

Document	
D3	<p>Details of supported uses (GAPs) in exporting countries (non-EU Member States)</p> <p>Details of the intended uses (GAPs) that are being supported by the applicant on both food and feed crops which are imported in significant quantities into the territory of the EU from non-EU Member States and for which import tolerances are required.</p>
E1	Details of existing EU MRLs. Where relevant, details of MRLs established by Member States and details of MRLs established by the CAC or proposed by the CCPR, should also be provided.
E2	Where an import tolerance is required, a listing of the MRLs established for the active substance in countries that export the plants and plant products concerned and in addition, where relevant, a listing of MRLs and import tolerances established in non-EU OECD countries, should be provided.
F	Where relevant, in the case of existing active substances, a copy of each notification submitted to the Commission in the context of the programme of work undertaken for the examination of existing active substances pursuant to Article 8 (2) of the Directive.
G	<p>Unless a dossier in accordance with Annex II is submitted for every formulant included in the preparation (ingredient other than active substance):</p> <p>A statement as to whether the substance is permitted in food, animal feeding stuffs, medicines or cosmetics in accordance with Community legislation.</p>
H	<p>Unless a dossier in accordance with Annex II is submitted for every formulant included in the preparation (ingredient other than active substance):</p> <p>A copy of the safety data sheet prepared in accordance with Directive 67/548/EEC.</p>
I	<p>Unless a dossier in accordance with Annex II is submitted for every formulant included in the preparation (ingredient other than active substance):</p> <p>Where requested, other available toxicological and environmental data.</p>
J	Where relevant and desired, a statement to indicate the data and information involving industrial and commercial secrets for which confidentiality is requested, in accordance with Article 14 of Directive 91/414/EEC. To facilitate the secure handling of such information, it should be included in a separate file, where it is feasible to do so (e.g. details of manufacturing processes, detailed specifications of active substance and preparations and individual medical records). The file should be identified as containing industrial and commercial secrets.
K	<p>Individual test and study reports in accordance with the requirements of 91/414/EEC. Separate dossiers should be provided for the active substance and formulated products. Where dossiers are submitted that concern more than one formulation, a separate Annex III dossier must be provided for each plant protection product. Dossiers for additional plant protection products should be identified and numbered as indicated below.</p>
	KIIA - Individual test and study reports for the active substance
...	KIIIA1 - Individual test and study reports for the 1 st formulated product
...	KIIIA2* - Individual test and study reports for the 2 nd formulated product
	<p>Note: For dossiers that contain data from supervised residue trials (Annex point IIA 6.3) for more than one crop, it is recommended that the data are organized as follows:</p> <p>IIA 6.3.1 Crop 1 (e.g. wheat)</p> <p>IIA 6.3.2 Crop 2(e.g. oilseed rape)</p> <p>IIA 6.3.3 Crop 3</p> <p>IIA 6.3.4 Crop 4, etc.</p>
L- N	A summary, evaluation and assessment of the dossier of data submitted by the applicant, prepared in accordance with the tiered structure outlined below: Where dossiers are submitted that concern more than one formulation, a separate Annex III dossier must be provided for each plant protection product. Dossiers for additional plant protection products should be identified and numbered as indicated below.
L	Reports (Tier 1 Summaries) as to the quality of the individual tests and studies submitted and a list of study reports and documents submitted.
	LIIA - Tier 1 Summaries for the active substance
	LIIIA1 - Tier 1 Summaries for the 1 st formulated product
	LIIIA2* - Tier 1 Summaries for the 2 nd formulated product
	Reference lists for the active substance, 1 st formulated product and from 2 nd formulated product* (sorted according annex points and authors)

(*) Where a data package contains more than one Annex III dossier.

Document	
M	Tier 2 summaries. Comprehensive summaries and assessments of individual tests and studies' and groups of tests and studies, as appropriate, in the light of relevant evaluative and decision making criteria.
	MIIA - Tier 2 Summaries for the active substance
	MIIIA1 - Tier 2 Summaries for the 1 st formulated product
	MIIIA2* - Tier 2 Summaries for the 2 nd formulated product
N	Tier 3 Summary. An overall summary and assessment of the application in the light of relevant evaluative and decision making criteria, the conclusion reached by the applicant on the basis of the data and information submitted. This summary should include a complete list of regulatory end points and a key to the metabolites and breakdown products identified in animal metabolism studies, crop metabolism studies and appropriate studies conducted with soil, water, sediment etc.
O	A completed set of the forms for checking the completeness of the dossier. 1: for Doc. A – J 2: for Doc. L – N (for active and formulated products together, possibility to include more than one FL is already included) 3: for Doc. KIIA (for active substance) 4: for Doc. KIIIA1 (for 1 st formulated product) for Doc. KIIIA2* (for 2 nd formulated product)

(*) Where a data package contains more than one Annex III dossier.

2 CADDY-FORMAT

Several Member States, the European Food Safety Authority (EFSA) and the Commission request that dossiers be submitted in electronic form. Such dossiers will only be accepted if they are compiled in accordance with the Format Specification for CADDY Document Interchange Format for Pesticides Registration Applications. The RMS will check the format of electronic submissions to ensure that they comply with the CADDY format. Submissions in electronic form will inter alia reduce the number of paper copies to be submitted. Further information on CADDY is available from the CADDY website at <http://caddy.ecpa.be/>. Note: In order to harmonise the submission and to avoid compatibility problems, it is recommended that the standard “**table of contents**” that is available on the CADDY website is used in all CADDY dossiers.

Dossiers for new and existing active substances should be submitted to the European Commission and to EFSA in the form of a signed covering letter plus an electronic version of the remainder of the dossier.

3. NUMBER OF DOSSIERS TO BE SUBMITTED

Information on the number of copies of dossiers relating to existing and new active substances is available on the DG SANCO home page

For new active substances: [Number of dossier to be submitted - New active substances.](#)

For existing active substances: [Number of dossier to be submitted - Existing active substances.](#)

4. ADDRESSES AND CONTACT POINTS

The addresses to which the dossier(s) should be sent are available on the DG SANCO home page under: [Contact Points](#)

5. COMPLETENESS CHECK

Electronic versions of the Completeness Check Forms are available on the DG SANCO home page. They should be used for new active substances as well as for dossiers of existing active substances. For chemical pesticides, please use "[Completeness Check Forms A](#)"; for microbial pesticides, please use "[Completeness Check Forms B](#)".

Notes:

These forms must be used by all notifiers from **1st January 2005**. The forms use the OECD numbering system and include certain data requirements that do not apply to notifications for the inclusion of an active substance in Annex I of 91/414/EEC. Notes in the completeness check forms indicate where this is the case.

To help applicants and notifiers to check the completeness of their dossiers, the EU numbering system has also been included in the forms for ease of reference. However, from 1 January 2005 dossiers should be presented using the OECD numbering system.