



EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

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

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Guideline developed within the Standing Committee on Plant Health concerning instructions for industry on dossier submission

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 the active substances included in the second stage of the review programme, Commission Regulation (EC) No 451/2000 provides in its Article 6(4) that Member States shall determine the number of copies and the format of the dossiers to be submitted by notifiers and that in determining the format of the dossiers, they shall take the utmost account of the recommendations made by the Commission in the framework of the Standing Committee on Plant Health. It is anticipated that similar provisions would apply for the active substances of the third phase of the review programme.

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.

This document therefore provides guidance to Member States and to industry on the submission of dossiers, in particular on the number and format of dossiers, addresses to which they should be submitted and general contact points. It has been conceived as an opinion of the Commission Services and elaborated in co-operation with the Member States. It 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.

1 Format

1.1 EU-Format

The dossier should be submitted in accordance with the format foreseen in Document 1663/VI/94 Rev. 8 of 22 April 1998:

Guidelines and Criteria for the Preparation and Presentation of the Complete Dossiers and of Summary Dossiers for the Inclusion of Active Substances in Annex I of the Directive 91/414/EEC (Article 5.3 and 8.2). This document is available on:

[Formatting of dossiers](#)

1.2 OECD-Format

As from **31st December 2004**, all dossiers should be submitted in OECD-format on the basis of the OECD dossier guidance. For new active substances dossiers in the OECD format are acceptable already at an earlier stage.

The OECD formatting guidelines are available on the OECD homepage: (<http://www1.oecd.org/ehs/pesticid.htm>)

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.

1.3 CADDY-Format

Several Member States 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 Version 1.1 Document Interchange Format for Pesticides Registration Applications September 23, 1997 or a more recent version. 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.

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

2 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.

3 Adresses and contact points

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

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4 Completeness Check

An electronic version of the Completeness Check is available on the DG SANCO home page and should be used by all notifiers from **1st April 2002**. Notifiers are free to use this electronic version already earlier.

The same form should be used for new active substances as well as for dossiers of existing active substances.

[Completeness check evaluation forms](#)

5 Reference list of studies

Templates for the reference lists to be used as part of the dossier are available on the DG SANCO home page. These forms enable both simplify completion by the notifier and facilitate electronic data transfer. After completion of these DOC-files data can easily be transferred into RTF-, XLS- or MDB-files.

[Instruction reference list](#)