



EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

Directorate D - Food Safety: Production and distribution chain
Unit D.3 - Chemicals, contaminants and pesticides

SANCO/10696/2004– rev 5
15 April 2005

**Guidance document on
preparation of Review Report for review Stage 2 substances
and new active substances considered by EFSA**

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

For existing active substances in stage 2 of the review programme a review report is required by Commission Regulation 451/2000 (as amended by Regulation 1490/2002).

At the latest six months after receipt of the EFSA conclusion the Commission has to submit a draft review report. Where the Commission presents a draft directive to include an active substance in Annex I or a draft decision addressed to Member States to withdraw an active substance it shall at the same time present the conclusions of the Standing Committee's examination in the format of a finalised review report to be noted in the summary record of the meeting. It is also a requirement that the finalised review report, excluding any parts which refer to confidential information contained in the dossiers and determined as such in accordance with Article 14 of Directive 91/414/EEC, shall be made available for public information.

This guidance document describes the format of the review report for stage 2 review substances and new substances where peer reviewed by EFSA and the procedure for preparing the draft review report.

Background

The Review Reports that have been prepared for substances evaluated prior to the creation of EFSA not only explain the basis of the conclusion on the active substance but also contain the critical end points, the list of essential studies for which data protection has been claimed by the notifier/applicant, the list of uses supported by available data and three background documents:

Background document A	Draft Assessment Report (DAR) from the rapporteur Member State (RMS).
Background document B	Full report of the former ECCO Peer Review
Background document C	All documents (except original studies) which were also considered, or evolved in the context of further evaluation, assessment, negotiation and decisions.

Following the creation of EFSA for second list substances and new active substances the risk assessment is peer reviewed by EFSA who present their conclusions in a form which has been to be agreed with the Commission.

The EFSA conclusion contains a summary of the risk assessments and its conclusions. The draft assessment report including any addenda and the peer review report are background documents A and B to the conclusion respectively. Appendix 1 to the conclusion contains the list of endpoints for the active substance and the representative formulation.

Structure and contents of the Draft Review Report

Given that the EFSA conclusion now contains information which previously formed part of the review report and considering that the EFSA conclusion is publicly available the review report need only contain a reference to these elements rather than repeat them.

However certain end points could be considered to fall between risk assessment and risk management in particular those that require the inclusion of a safety factor, since deciding on such a safety factor is both a scientific and policy decision. These end points, (usually ADI, AOEL, ARfD) should be mentioned again in the review report.

In addition in certain cases the EFSA conclusion might present risk management options e.g. the setting of reference doses with and without the use of human data, or the use of different risk assessment guidance documents. In these circumstances the review report will need to identify which risk management approach has been taken to support the decision and the reasons for this.

Finally additional documentation may be submitted after the EFSA conclusion is finalised. This should also be accounted for in the review report.

The structure of the review report is presented at Appendix 1.

Appendix 2 gives an overview on the structure of the complete documentation for 2nd stage substances.

Procedures for preparation of the draft review report

The initial draft is prepared by the Commission (or their contractors if available). The Commission request the RMS to check facts before distributing it to all Member States.

The text of the review report is finalised by the Commission during the discussions on the substances in the relevant Commission meetings.

The list of studies relied upon with a view to Annex I inclusion of existing active substances is prepared in accordance with the procedure in guidance document SANCO/10435/2004.

Appendix 1



EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

Directorate D - Food Safety: Production and distribution chain
Unit D.3 - Chemicals, contaminants and pesticides

[as stage 2]

SANCO/XXXX/05 – rev. X

[date]

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THE VIEWS OF THE COMMISSION SERVICES**

DRAFT

Review report for the active substance [as stage 2]

Finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on
[date]

in view of the inclusion of [as stage 2] in Annex I of Directive 91/414/EEC

1. Procedure followed for the re-evaluation process

This review report has been established as a result of the re-evaluation of [as stage 2], made in the context of the work programme for review of existing active substances provided for in Article 8(2) of Directive 91/414/EEC concerning the placing of plant protection products on the market, with a view to the possible inclusion of this substance in Annex I to the Directive.

Commission Regulation (EC) No 451/2000⁽¹⁾ laying down the detailed rules for the implementation of the second and third stages of the programme of work referred to in Article 8(2) of Council Directive 91/414/EEC, as last amended by Regulation (EC) No 1490/2002⁽²⁾, has laid down the detailed rules on the procedure according to which the re-evaluation has to be carried out. [as stage 2] is one of the existing active substances covered by this Regulation.

In accordance with the provisions of Article 4 of Regulation (EC) No 451/2000, [applicant] notified to the Commission of their wish to secure the inclusion of the active substance [as stage 2] in Annex I to the Directive.

In accordance with the provisions of Article 5 of Regulation (EC) No 451/2000, the Commission, designated [rapporteur Member State] as rapporteur Member State to carry out the assessment of [as stage 2] on the basis of the dossiers submitted by the notifiers. In Regulation

¹ OJ No L 55, 29.02.2000, p.25.

² OJ No L 224, 21.8.2002, p.23.

(EC) No 703/2001³ the Commission specified furthermore that the deadline for the notifiers with regard to the submission to the rapporteur Member States of the dossiers required under Article 6(2) of Regulation (EC) No 451/2000, as well as for other parties with regard to further technical and scientific information was 30 April 2002.

[applicant] each submitted by the deadline a dossier to the rapporteur Member State which did not contain substantial data gaps, taking into account the supported uses. Therefore [applicant] was considered to be the main data submitter.

In accordance with the provisions of Article 8(1) of Regulation (EC) No 451/2000, [rapporteur Member State] submitted on [date] to the EFSA the report of their examination, hereafter referred to as the draft assessment report, including, as required, a recommendation concerning the possible inclusion of [as stage 2] in Annex I to the Directive. Moreover, in accordance with the provisions of Article 8(2) of Regulation (EC) 451/2000, the Commission and the Member States received also the summary dossier on [as stage 2] from [main data submitter], on [date]. In accordance with the provisions of Article 8 of Regulation (EC) No 451/2000, the EFSA organised the consultation on the draft assessment report by all the Member States as well as by [main data submitter] being the main data submitters, on [date] by making it available.

The EFSA organised an intensive consultation of technical experts from a certain number of Member States, to review the draft assessment report and the comments received thereon (peer review).

In accordance with the provisions of Article 8 (7) of Regulation 451/2000 the EFSA sent to the Commission its conclusion on the risk assessment [reference]. This conclusion refers to background document A (draft assessment report) and background document B (EFSA peer review report).

In accordance with the provisions of Article 8 (7) of Regulation (EC) No 451/2000, the Commission referred on [date] a draft review report to the Standing Committee on the Food Chain and Animal Health, for final examination. The draft review report was finalised in the meeting of the Standing Committee on [date].

The present review report contains the conclusions of the final examination by the Standing Committee. Given the importance of the conclusion of the EFSA, and the comments and clarifications submitted after the conclusion of the EFSA (background document C), these documents are also considered to be part of this review report.

2. Purposes of this review report

This review report, including the background documents and appendices thereto, has been developed and finalised in support of the Directive **2005/./EC** concerning the inclusion of [as stage 2] in Annex I to Directive 91/414/EEC, and to assist the Member States in decisions on individual plant protection products containing [as stage 2] they have to take in accordance with the provisions of that Directive, and in particular the provisions of article 4(1) and the uniform principles laid down in Annex VI.

³ OJ No L 98, 7.4.2001, p. 6.

This review report provides also for the evaluation required under Section A.2.(b) of the above mentioned uniform principles, as well as under several specific sections of part B of these principles. In these sections it is provided that Member States, in evaluating applications and granting authorisations, shall take into account the information concerning the active substance in Annex II of the directive, submitted for the purpose of inclusion of the active substance in Annex I, as well as the result of the evaluation of those data.

In accordance with the provisions of Article 8(9) of Regulation (EC) No 451/2000, Member States will keep available or make available this review report for consultation by any interested parties or will make it available to them on their specific request.

The information in this review report is, at least partly, based on information which is confidential and/or protected under the provisions of Directive 91/414/EEC. It is therefore recommended that this review report would not be accepted to support any registration outside the context of Directive 91/414/EEC, e.g. in third countries, for which the applicant has not demonstrated to have regulatory access to the information on which this review report is based.

3. Overall conclusion in the context of Directive 91/414/EEC

This section will need to be elaborated where the EFSA conclusion offered alternative outcomes.

The overall conclusion from the evaluation is that it may be expected that plant protection products containing [as stage 2] will fulfil the safety requirements laid down in Article 5(1)(a) and (b) of Directive 91/414/EEC. This conclusion is however subject to compliance with the particular requirements in sections 4, 5, 6 and 7 of this report, as well as to the implementation of the provisions of Article 4(1) and the uniform principles laid down in Annex VI of Directive 91/414/EEC, for each [as stage 2] containing plant protection product for which Member States will grant or review the authorisation.

Furthermore, these conclusions were reached within the framework of the uses which were proposed and supported by the main data submitter and mentioned in the list of uses supported by available data (attached as Appendix II to this review report).

Extension of the use pattern beyond those described above will require an evaluation at Member State level in order to establish whether the proposed extensions of use can satisfy the requirements of Article 4(1) and of the uniform principles laid down in Annex VI of Directive 91/414/EEC.

The following reference values have been finalised as part of this re-evaluation:

ADI value
ARfD value
AOEL value

With particular regard to residues, the review has established that the residues arising from the proposed uses, consequent on application consistent with good plant protection practice, have no harmful effects on human or animal health. The Theoretical Maximum Daily Intake (TMDI; excluding water and products of animal origin) for a 60 kg adult is **XX** % of the Acceptable Daily Intake (ADI), based on the FAO/WHO European Diet (August 1994).

Additional intake from water and products of animal origin are not expected to give rise to intake problems.

Estimates of acute dietary exposure of adults and toddlers revealed that the Acute Reference Dose (ARfD) would not be exceeded (European diet - XX % or XX % for respectively adults or children). The review has identified several acceptable exposure scenarios for operators, workers and bystanders, which require however to be confirmed for each plant protection product in accordance with the relevant sections of the above mentioned uniform principles.

The review has also concluded that under the proposed and supported conditions of use there are no unacceptable effects on the environment, as provided for in Article 4 (1) (b) (iv) and (v) of Directive 91/414/EEC, provided that certain conditions are taken into account as detailed in section 6 of this report.

4. Identity and Physical/chemical properties

The main identity and the physical/chemical properties of [as stage 2] are given in Appendix I.

The active substance shall comply with the FAO specification and there seem not to be reasons for deviating from that specification; the FAO specification is given in Appendix I of this report.

The review has established that for the active substance notified by the main data submitter none of the manufacturing impurities considered are, on the basis of information currently available, of toxicological or environmental concern.

[In accordance with the provisions of Article 13(5) of Directive 91/414/EEC, the RMS is also satisfied, on the basis of the information currently available, that the substances notified by the other data submitter(s) [XXX] and [XXXX] do not, in the meaning of Article 13(2) and (5) of the Directive, differ significantly in degree of purity and nature of impurities from the composition registered in the dossier submitted by the main data submitter.]

5. Endpoints and related information

In order to facilitate Member States, in granting or reviewing authorisations, to apply adequately the provisions of Article 4(1) of Directive 91/414/EEC and the uniform principles laid down in Annex VI of that Directive, the most important endpoints were identified during the re-evaluation process. These endpoints are listed in the conclusion of the EFSA, and at section 3 of this report.

6. Particular conditions to be taken into account on short term basis by Member States in relation to the granting of authorisations of plant protection products containing [as stage 2]

On the basis of the proposed and supported uses (as listed in Appendix II), the following particular issues have been identified as requiring particular and short term attention from all Member States, in the framework of any authorisations to be granted, varied or withdrawn, as appropriate:

- Member States should pay particular attention to the protection of [species]. Risk mitigation measures should be applied, where appropriate.

7. List of studies to be generated

No further studies were identified which were at this stage considered necessary in relation to the inclusion of [as stage 2] in Annex I under the current inclusion conditions.

Some endpoints however may require the generation or submission of additional studies to be submitted to the Member States in order to ensure authorisations for use under certain conditions. This may particularly be the case for

- [studies]

8. Information on studies with claimed data protection

For information of any interested parties, the rapporteur Member State will keep available a document which gives information about the studies for which the main data submitter has claimed data protection and which during the re-evaluation process were considered as essential with a view to annex I inclusion. This information is only given to facilitate the operation of the provisions of Article 13 of Directive 91/414/EEC in the Member States. It is based on the best information available but it does not prejudice any rights or obligations of Member States or operators with regard to its uses in the implementation of the provisions of Article 13 of the Directive 91/414/EEC and neither does it commit the Commission.

9. Updating of this review report

The information in this report may require to be updated from time to time in order to take account of technical and scientific developments as well as of the results of the examination of any information referred to the Commission in the framework of Articles 7, 10 or 11 of Directive 91/414/EEC. Any such adaptation will be finalised in the Standing Committee on the Food Chain and Animal Health, in connection with any amendment of the inclusion conditions for [as stage 2] in Annex I of the Directive.

APPENDIX I**Identity, physical and chemical properties**

[AS STAGE 2]

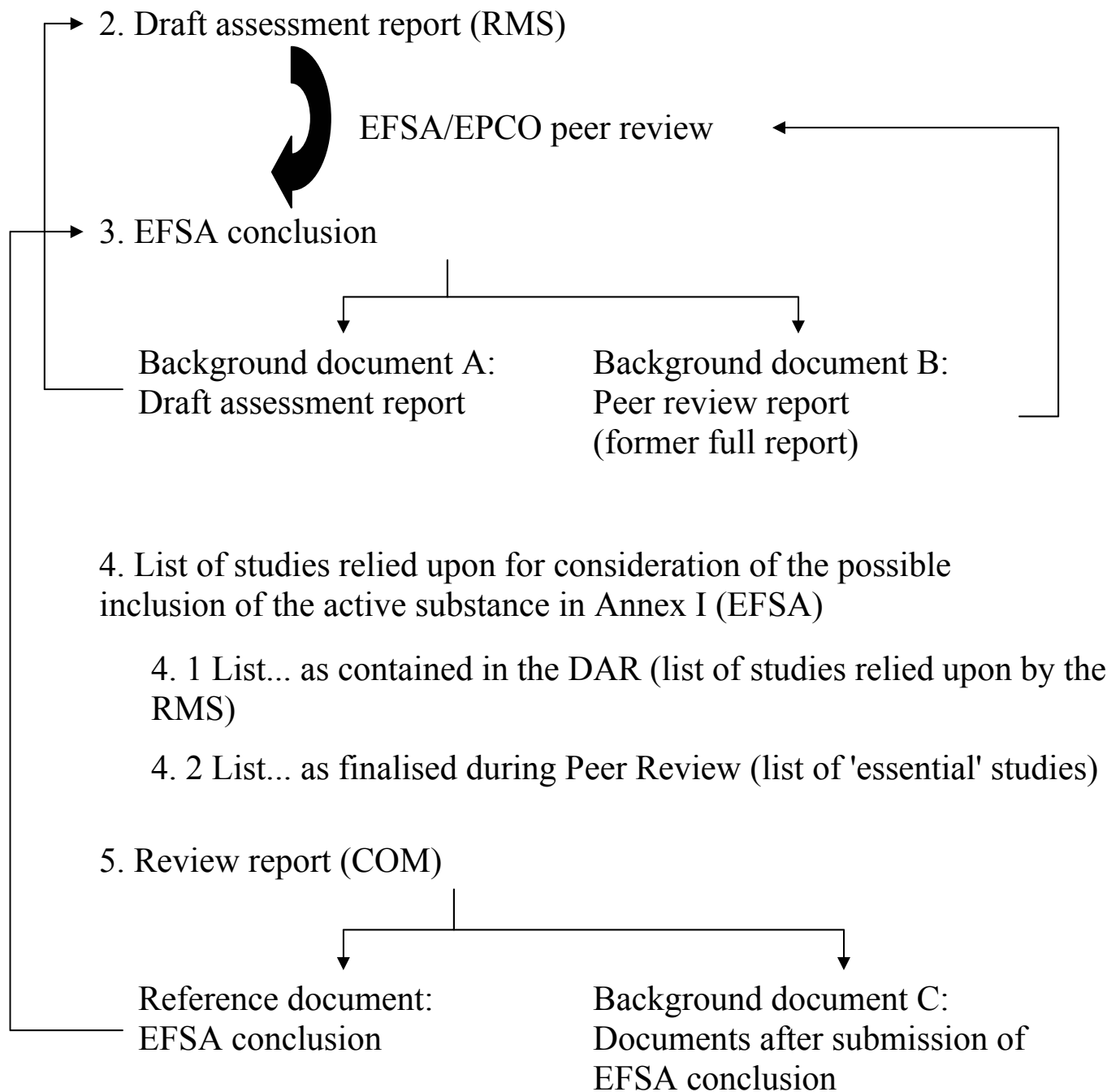
Common name (ISO)	
Chemical name (IUPAC)	
Chemical name (CA)	
CIPAC No	
CAS No	
EEC No	
FAO SPECIFICATION	
Minimum purity	
Molecular formula	
Molecular mass	
Structural formula	

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)
- (e) GCPF 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

Documentation for 2nd stage active substances

1. Dossier (notifier/applicant)



6. List of studies relied upon for which data protection has been claimed by main data submitter (RMS)