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**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**

FOREWORD

These guidelines are intended to provide guidance as to the format and presentation of the documentation to be prepared by Rapporteur Member States and to be submitted to the Commission, in the context of applications for the inclusion of both existing and new active substances in Annex I to Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market¹.

The current draft of the guidelines was prepared by the Commission with the benefit of the comments on earlier drafts of the document made by experts from the competent authorities of the Member States during the course of the European Commission Pilot Project Meetings (ECPPM) and the first two rounds of the European Commission Co-ordination (ECCO) meetings organized by the Biologische Bundesanstalt für Land und Forstwirtschaft (BBA) and the Pesticides Safety Directorate (PSD). In preparing this current draft, the Commission also had the benefit of the comments provided in the context of the Joint EU-OECD Meeting on guidance documents for industry data submissions (dossiers) and country data review reports (monographs), which was held in Dublin on 25 and 26 September 1997. Finally, the Commission had available to it comments provided by ECPA and by GCPF.

It is envisaged that the text of these guidelines will be further reviewed with the benefit of experience gained by the competent authorities of the Member States in the examination of dossiers submitted in the context of the first stage of the programme of work referred to in Article 8 (2) of Directive 91/414/EEC.

These guidelines have been conceived as an opinion of the Commission services and were elaborated in co-operation with the Member States. Being guidelines, they are not intended to have legally binding effects. Given its nature, this document does not prejudice any measures taken by a Member State or by the Commission in the implementation of the measures concerned, nor any case law produced by the European Court of Justice.

¹ OJ No L 230, 19. 8. 1991, p. 1

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1 GENERAL INTRODUCTION

- 1.1 In the interest of avoiding wastage of scarce and expensive evaluative resources, dossiers should be checked for completeness before any detailed evaluation of them is undertaken. The *Guidelines and criteria for the preparation and presentation of complete dossiers and of summary dossiers for the inclusion of active substances in Annex I of Directive 91/414/EEC (Article 5.3 and 8.2)*², require that applicants complete and submit a set of forms designed to facilitate the checking of dossiers for completeness, by the competent authorities of the Member States.
- 1.2 Evaluations and assessments of dossiers prepared by Rapporteur Member States, are to be used by the Standing Committee on Plant Health (SCPH) and by the Commission as a basis for decision making with respect to the possible inclusion of individual active substances in Annex I of Directive 91/414/EEC. In addition, in those instances where particular issues relating to the possible inclusion of an active substance in Annex I are referred by the Commission to the Scientific Committee for Pesticides, the evaluations and assessments prepared by Rapporteur Member States, together with other relevant documentation, including the studies evaluated by the Rapporteur Member State, will be used by that Committee in formulating its opinion.
- 1.3 In the interest of ensuring efficiency and economy in the use of the resources necessary for the evaluation of the draft monographs by other Member States and by the Commission, it is necessary that their general lay-out and format be standardized. In order to ensure a consistently high standard in the documentation concerned, it is necessary that guidance be provided and where relevant criteria be specified, for their preparation. While requiring standardization in general lay-out, subject matter, terminology and units of measurement, the competent authorities of the Member States nevertheless are required to use expert judgement in preparing the documentation concerned. It is especially important that the competent authorities of the Member States treat these guidelines as providing a degree of flexibility.
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.
- 1.4 For each active substance, the documentation to be prepared by Rapporteur Member States should consist of a monograph, containing a concise statement of the purpose for which it was prepared, a statement of the conclusions reached and a statement of the rationale used in reaching those conclusions, as well as proposals for the decision to be taken by the Commission. Those elements of each monograph form the report of the Rapporteur Member State to the Commission.
A supporting text consisting of a detailed summary, evaluation and assessment of the data base concerned, together with a reference list, should be annexed to each monograph.
- 1.5 Monographs should reflect, the results of all test and study reports and other relevant information submitted by applicants and other interested parties, where appropriate, taking account of any other relevant information available to the Rapporteur Member State. The evaluations and assessments contained in monographs should reflect relevant Community evaluative and decision making criteria.
- 1.6 It is especially important that points of weakness identified in assessing the data base evaluated be fully described, regardless of whether the point concerned arises as a result of:-
- (i) evidence as to compliance with any particular decision making criterion not being clear;
 - (ii) a particular test or study or group of tests or studies being of questionable quality; or

² Commission Document 1663/VI/94, rev 7.7, 1 March 1998

- (iii) the results of a particular test or study or group of tests or studies being equivocal in nature.

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- 1.7 The tiered approach specified for the preparation of monographs in these guidelines is designed to facilitate efficiency in the use of evaluative resources and to facilitate decision making, in particular:-
- (i) evaluation and assessment of the documentation concerned by Member States other than the Rapporteur Member State concerned;
 - (ii) evaluation and assessment of the documentation concerned by the committees established or convened by the Commission for that purpose; and
 - (iii) decision making by the Commission.
- 1.8 Each monograph considered by the SCPH and the Commission, of necessity will contain certain information provided in confidence in accordance with Article 14 of Directive 91/414/EEC. Where in accordance with those provisions, and those of Council Directive 90/313/EEC³, it is accepted that particular information for which confidentiality has been claimed (Document J as submitted by the applicant) be treated as confidential, that information shall not be included in any version subsequently published or otherwise made available to interested parties. All such confidential information should be included in an Annex to each monograph to facilitate its removal from the final publication version.
- 1.9 In each instance that, in the context of the provisions of Article 8 (2) of Directive 91/414/EEC and Commission Regulations made pursuant to that Article, there was a failure to collectively present the complete dossier, the monograph prepared by the Rapporteur Member State concerned, should include in an Annex, information relating to the assessments made as to whether or not the steps taken by the notifiers concerned were reasonable. That information will not be included in any version of the monograph subsequently published.
- 1.10 Standard Units, Terms and Abbreviations:-
- (i) Standard Units - the English language version of Standard International Units must be used in reporting and summarizing tests and studies, although other units, if desired or considered relevant, may be used in parentheses⁴;
 - (ii) Standard Terms and Standard Abbreviations - in the interest of avoiding confusion, standard technical terms and abbreviations as specified in Appendix 1 and 2, must be used - these Appendices will be further developed as required. Where terms and abbreviations not listed are used, a concise explanation of each such term or abbreviation must be provided in the text, when it is used for the first time. In addition, a listing of all such additional terms and abbreviations should be provided as an Annex to the monograph. The listing should comprise two parts, the first part should contain the list of terms and abbreviations which have general application, while the second part should contain the list of terms and abbreviations which are of specific relevance to the active substance concerned.

³ OJ No L 158, 23. 6. 1990, p 56

⁴ Particular attention is drawn to the requirement to use metric units - *e.g.* in the case of application rates as kg active substance/ha, content of active substance in formulations as g/kg or g/l, content of residues as mg/kg, doses in feeding studies as mg/kg body weight.

1 General Introduction

- 1.11 As well as providing at least two hard copies of each monograph to the Commission, Rapporteur Member States should also provide the draft monograph in electronic form. Details of the recommended format to be used with respect to pagination, presentation of tables, diagrams and references are provided in Appendix 3.
- 1.12 Monographs, taken together with other documentation developed during the course of the decision making process, when made available to interested parties, will ensure transparency with respect to the basis for decisions made by the Community, for each individual active substance.

2 **CHECKING DOSSIERS FOR COMPLETENESS**

2.1 **Introduction**

2.1.1 The guidance provided herewith, is for use by the competent authorities of Rapporteur Member States in checking dossiers for completeness, regardless of whether such dossiers have been submitted in support of applications for inclusion of existing or new active substances in Annex I, and regardless of whether the dossiers have been submitted in the context of the review or renewal of any such inclusion.

2.1.2 In the case of new active substances being evaluated for possible inclusion in Annex I, in accordance with Article 6 (2) of the Directive, Member States receiving an application for its inclusion in Annex I, when satisfied that the dossier submitted complies with the requirements of Annex II and Annex III of the Directive, must then require that the applicant forward copies of the dossier to the other Member States and the Commission. It is evident that the competent authority of the Member State concerned must examine the dossier, to ensure that the requirements of the Directive relating to the studies and information to be provided have been respected, before requiring that the applicant send copies of the dossier to the other Member States and the Commission. Although free to commence the detailed examination of the dossier once the check for completeness has been carried out, the competent authority concerned is not required to commence that examination until it has been designated Rapporteur for the active substance concerned.

2.1.3 The process of checking dossiers for completeness consists of:-

- (i) verification that the relevant evaluation forms have been correctly completed by the applicant, and if not correctly completed, correction of the forms;
- (ii) assessment of a representative selection of the *Tier I* quality checks submitted, using Evaluation Form 5 as set out in Part 5 of Appendix 11 to the *Guidelines and criteria for the preparation and presentation of complete dossiers and of summary dossiers for the inclusion of active substances in Annex I of Directive 91/414/EEC (Article 5.3 and 8.2)*²; and
- (iii) assessment of the extent and significance of any deficiencies noted in dossiers, as reflected in the completed or corrected forms, as appropriate.

2.1.4 For each new active substance for which an application has been made for its inclusion in Annex I of the Directive, a copy of the correctly completed or corrected forms, as appropriate, should be provided to the Commission for the purposes of the decision to be made in accordance with Article 6 (3) of the Directive - *i.e.* whether or not the content of the dossier satisfies the requirements of Annex II and Annex III and its format and presentation conform to that prescribed in the *Guidelines and criteria for the preparation and presentation of complete dossiers and of summary dossiers for the inclusion of active substances in Annex I of Directive 91/414/EEC (Article 5.3 and 8.2)*².

2.1.5 Additional information relating to the initial examination of dossiers in order to check them for completeness, as well as information relating to the detailed examination of dossiers, can be found in the relevant Commission working documents:-

- (i) for new active substances in Commission document 1663/VI/95⁵; and




⁵ Commission Document 1663/VI/95, Working document for the guidance of the Member States with regard to the implementation of Article 6 of Directive 91/414/EEC for new active substances, developed in the Working Group "Pesticides" (legislation) of the Standing Committee on Plant Health

- (ii) for active substances included in the re-evaluation programme in Commission document 1614/VI/95⁶.

Since the two Commission documents referred to are subject to regular updating, readers are advised to ensure that they consult the currently valid versions.

2.2 Suggested approach

2.2.1 The nature and extent of the check for completeness to be conducted by the competent authorities of Member States should be such that:-

- (i) it is conducted by a scientific secretariat, not by administrative personnel - although specialist evaluators can be involved in the process of checking dossiers for completeness, it is not necessary that they be so involved;
- (ii) it includes an exercise to correct the relevant evaluation forms, or to verify that they have been correctly completed by the applicant, as appropriate;
- (iii) with respect to the overall content of dossiers, it is limited to checks to ensure that -
 -  the required supporting documentation has been provided (Documents A to J, as specified in the relevant guidelines²),
 -  all test and study reports required in accordance with the requirements of Annex II and Annex III have been provided or, in the case of particular test and study reports, either a justification for non provision, or an undertaking to provide them at a future specified date, have been provided,
 -  summaries and evaluations of the Annex II and Annex III data and information provided, and an overall assessment and conclusions, as specified in the relevant guidelines², have been provided;
- (iv) it includes checks to ensure that the requirements of the relevant guidelines², relating to the preparation of *Tier I* checks as to the quality of individual tests and study reports, have been complied with. A limited number of the *Tier I* checks as to the quality of test and study reports from each of the six sections of dossiers should be examined - it is not necessary that a systematic examination of all *Tier I* checks, be carried out; and
- (v) it includes checks to ensure that the *Tier I* lists of study reports and documents have been provided and have been correctly compiled (Document L - reference list).

2.2.2 In the case of testing as to the physical and chemical properties of active substances and testing as to the physical, chemical and technical properties of preparations, and in the case of information relating to analytical methods, *Tier I* checks as to quality are not required. The relevant *Tier II* summaries can be examined to ensure that all test and study reports and information required have been provided. In the case of supervised trials residues data and soil dissipation studies, summaries of the studies rather than *Tier I* checks as to their quality are required.

2.2.3 For other types of tests and studies, it is generally sufficient to ensure that the *Tier I* checks as to quality, have been submitted for all the individual tests and studies concerned. Where particular

⁶ Commission Document 1614/VI/95, Draft working document concerning Articles 6 and 7 of Regulation (EEC) N° 3600/92

tests and studies are not provided, it is necessary to examine the relevant *Tier II* summaries and evaluations, to confirm whether or not justifications for non provision, or undertakings to provide the test and study reports concerned at future specified dates, have been provided. During the course of checking of dossiers for completeness, it is neither necessary nor appropriate that the validity of particular justifications be evaluated. It is sufficient to establish that a full justification was, or was not, provided ⁷. The validity of particular justifications provided will be assessed during the detailed examination of the dossier.

2.2.4 A representative selection of the *Tier I* quality checks submitted from each of the six sections of dossiers, should be examined using Evaluation Form 5 as set out in Part 5 of Appendix 11 to the *Guidelines and criteria for the preparation and presentation of complete dossiers and of summary dossiers for the inclusion of active substances in Annex I of Directive 91/414/EEC (Article 5.3 and 8.2)* ². It is not necessary that a systematic examination of all *Tier I* checks, be carried out, unless on the basis of the examination of a representative selection of them, it becomes apparent that there are serious deficiencies in the quality of the documentation submitted.

2.2.5 Where on completion of the check for completeness of a dossier for a new active substance, it is clear that there are significant deficiencies in the dossier such that a basis has not been provided to permit a decision to be made as to whether or not the active substance concerned could be included in Annex I, the applicant should be informed of the deficiencies and be given an opportunity to complete the dossier. Until the deficiencies in the dossier have been rectified, the applicant should not be required to forward copies of the dossier to the other Member States and the Commission. Once satisfied that the dossier is complete, a copy of the completed evaluation forms should be provided to the Commission. The detailed evaluation of the dossier by specialists need not be undertaken until, in accordance with Article 6 (3) of the Directive, the Commission has decided that the requirements of Annex II and Annex III have been satisfied.

2.2.6 Although the approach suggested for the checking of dossiers for completeness for existing active substances, is identical to that suggested for new active substances, a different approach to that described in paragraph 2.2.5 is required where on completion of the check, it is established that there are deficiencies in the dossier or dossiers submitted for a particular active substance, since Article 7 (1) (c) of Commission Regulation (EEC) No 3600/92, includes provision for the:-

- (i) postponement of the decision to include, or not, any particular active substance in Annex I pending the receipt and evaluation of additional studies and information; or
- (ii) suspension of the marketing of particular active substances with the option of reconsidering the possible inclusion of the active substance in Annex I on the receipt and evaluation of additional studies and information.

Accordingly, in the case of an existing active substance, the dossier should be submitted for examination by specialist evaluators, even where it is incomplete, unless the deficiencies in the dossier are such that it is obvious that the proposal made by the applicant for the inclusion of the active substance in Annex I, has not been substantiated. In cases where on the basis of checking for completeness it is apparent that none of the dossiers submitted for a particular existing active substance, warrant consideration by specialist evaluators, a detailed report must be submitted to the Commission (*cf* paragraph 2.1.6).

2.2.7 The forms to be completed by applicants and to be used by the competent authorities of Member States in checking dossiers for completeness are provided in Appendix 11 to the *Guidelines and criteria for the preparation and presentation of complete dossiers and of summary dossiers for the inclusion of active substances in Annex I of Directive 91/414/EEC (Article 5.3 and 8.2)* ²:-

⁷ It is not sufficient to state that a particular test or study is not required or is not relevant. An explanation must be provided as to why the particular test or study is not required or is not relevant, having regard to the requirements of Annex II and Annex III and to any relevant evaluative and decision making criteria

- Part 1 Evaluation Form 1 - for use in checking that the required supporting documentation has been provided,
- Part 2 Evaluation Form 2 - for use in checking that the required Annex II and Annex III dossier summaries and an overall assessment, have been provided,
- Part 3 Evaluation Form 3 - for use in checking that all test and study reports required in accordance with Annex II have been provided,
- Part 4 Evaluation Form 4 - for use in checking that all test and study reports required in accordance with Annex III have been provided, and
- Part 5 Evaluation Form 5 - for use in checking that the *Tier I* quality checks for individual test and study reports conducted in accordance with test methods other than those currently specified, are themselves of acceptable quality.

2.2.8 Supporting documentation to facilitate the checking of individual *Tier I* quality checks, are also provided in Appendix 11 to those Guidelines:-

- Part 6 Listing of the test guidelines specified and the requirements relating to compliance with GLP and GEP for individual Annex IIA tests and studies, and
- Part 7 Listing of the test guidelines specified and the requirements relating to compliance with GLP and GEP for individual Annex IIIA tests and studies.

3 OVERALL STRUCTURE AND CONTENT OF MONOGRAPHS

3.1 Monographs should be sufficiently comprehensive to permit decisions to be made without the need for further reference to individual study reports and supporting documentation. Each monograph should include a concise assessment, prepared by the Rapporteur Member State, of the data and information evaluated, in the light of relevant evaluative and decision making criteria. Each such concise assessment prepared should be accompanied by a detailed summary consisting of formatted tables with supporting explanatory text, of all relevant data and information considered in evaluating applications submitted. A full and reasoned statement should be included, to explain the basis for and to support the conclusions reached and proposals made, for the decisions to be taken.

3.2 The main elements to be included in monographs, which are represented graphically in Figure 1, include:-

Level 1 a statement of the subject matter and purpose for which the monograph was written;

Level 2 a reasoned statement of the conclusions drawn;

Level 3 the proposed decision with respect to the application for inclusion of the active substance in Annex I and proposals for the conditions and restrictions to be associated with any such inclusion;

Level 4 where relevant, a statement of the further studies and information necessary to permit a decision to be made as to whether or not the active substance concerned can be included in Annex I, or a statement of the studies and information necessary for consideration of the removal of conditions or restrictions associated with the proposed inclusion of the active substance in Annex I;

Annex A the list of the tests and studies (Annex II and Annex III) submitted;

Annex B a summary, evaluation and assessment of the data base considered in preparing the monograph, providing the scientific background to the conclusions reached and proposals made at levels 2 to 4, together with a list of the tests and studies relied upon for the conclusions reached; and

Annex C confidential information and, for existing active substances for which there was more than one notifier, an assessment as to whether or not all reasonable steps were taken to collectively submit the complete dossier.


3.3 Those parts of the monograph comprising levels 1 to 4, form the report of the Rapporteur Member State to the Commission, with respect to the proposed inclusion of the active substance concerned in Annex I of the Directive. Annex A to the monograph should consist of an annotated list of the Annex II and Annex III test and study reports submitted for consideration, including any other relevant information taken into account. Annex B to the monograph should contain a supporting text providing the scientific background to the conclusions reached and to the proposals made, with a listing of the tests and studies relied upon for the conclusions reached at the end of each section, while Annex C should contain that information which is not to be included in any version of the monograph subsequently published, or otherwise made available to interested parties, on the basis that it should be treated as confidential information.


3 Overall Structure and Content of Monographs

3.4 The four levels and three annexes comprising monographs should consist of:-

Level 1 (i) a statement of the subject matter of and the purpose for which the monograph was written, prepared on the basis of Documents A, C to E, J and the relevant parts of documents K and M of the complete dossier submitted by the applicant (further details are provided in paragraphs 4.1.1 through 4.1.4);


Level 2 (ii) a reasoned statement of the overall conclusions which the Rapporteur Member State believes should be reached on the basis of -


 the data and information provided by the applicant, taking account of the applicants own assessment of the data submitted (Document N), and where relevant, in the case of formulants (ingredients other than active substances), information concerning their use in food, animal feeding stuffs, medicines or cosmetics in accordance with Community legislation as well as relevant safety data sheets and, where available, other relevant toxicological information (Documents G, H and I), and

 data and information otherwise available to the Rapporteur Member State,

in the light of the relevant evaluative and decision making criteria (further details are provided in paragraphs 4.2.1 through 4.2.5);

Level 3 (iii) a proposal for the decision which the Rapporteur Member State believes should be made with respect to the application for inclusion of the active substance in Annex I, on the basis of -

 the data and information provided by the applicant, taking account of the applicants own overall assessment of the data submitted (Document N), and

 data and information otherwise available to the Rapporteur Member State,






as well as, where relevant, proposals for the conditions and restrictions, if any, which the Rapporteur Member State believes should be associated with any inclusion of the active substance in Annex I, together with a detailed explanation of the rationale for any such proposals, taking account of relevant evaluative and decision making criteria (further details are provided in paragraphs 4.3.1 through 4.3.5);

Level 4 (iv) where relevant, a statement of the further Annex II and Annex III studies, data and information not provided and without which a proposal for the inclusion of the active substance in Annex I cannot be made (further details are provided in paragraphs 4.4.1 and 4.4.3);

(v) where relevant, a statement of the Annex II and Annex III studies and information necessary for the removal of any conditions or restrictions associated with the proposed inclusion of the active substance in Annex I, taking account of Documents G, H, I and M of the complete dossier as submitted by the applicant (further details are provided in paragraphs 4.4.2 and 4.4.3);

Annex A (vi) a list of the tests and studies (Annex II and Annex III) submitted for consideration, prepared on the basis of Documents J and L and where relevant I of the



complete dossier submitted by the applicant, taking into account, documentation and information provided by other interested parties, as well as other relevant available information which was taken into account, annotated to indicate for each individual test and study report -

-  the organization or person that provided the test or study,
-  compliance, or not, with the principles of GLP, where relevant,
-  compliance, or not, with the requirements of points 2.2 and 2.3 of the introduction to Annex II to Directive 93/71/EEC⁸, where appropriate,
-  whether or not, in accordance with Article 13 (3) (d) of Directive 91/414/EEC, data protection is claimed, and
-  whether or not it is published,

(further details are provided in paragraphs 4.5.1 through 4.5.3);

Annex B

(vii) the Rapporteur Member State's summary, evaluation and assessment of -

-  the data and information submitted by the applicant, in particular Documents C to E, G to M,
-  as well as other available data and information,



in the light of relevant evaluative and decision making criteria, incorporating a detailed description of each critical point in so far as decision making is concerned, providing in 9 chapters, the scientific background to the conclusions reached and to the proposals made in Levels 2 to 4 (further details are provided in paragraphs 4.6.1 through 4.6.7 and 4.6.10);

(viii) the list of tests and studies relied upon for the conclusions reached by the Rapporteur Member State (further details are provided in paragraphs 4.6.8 and 4.6.9);

(ix) an indication of the test and study reports for which protection was claimed in accordance with Article 13 (3) (d) of Directive 91/414/EEC, and to the extent feasible an assessment of those claims, for each relevant test and study report (further details are provided in paragraph 4.6.9 and 4.6.10); and

Annex C

(x) information which is not to be included in any version of the monograph subsequently published or otherwise made available to interested parties -

-  information involving industrial and commercial secrets which the applicant wishes to be treated as confidential - as specified in Document J - and which, in accordance with the provisions of Article 14 of the Directive, the Rapporteur Member State believes should be treated as confidential,
-  an assessment as to whether or not all reasonable steps were taken to collectively submit the complete dossier - for existing active substances for which there was more than one notifier (Document B),

(further details are provided in paragraphs 4.7.1 through 4.7.4).

3.5

It is envisaged that the documentation submitted in support of an application for the inclusion of an active substances in Annex I, subject to its being deemed to be complete, will serve as basis for preparing the various levels of the monograph, as follows -

⁸ OJ No L221, 31. 8. 1993, p 27

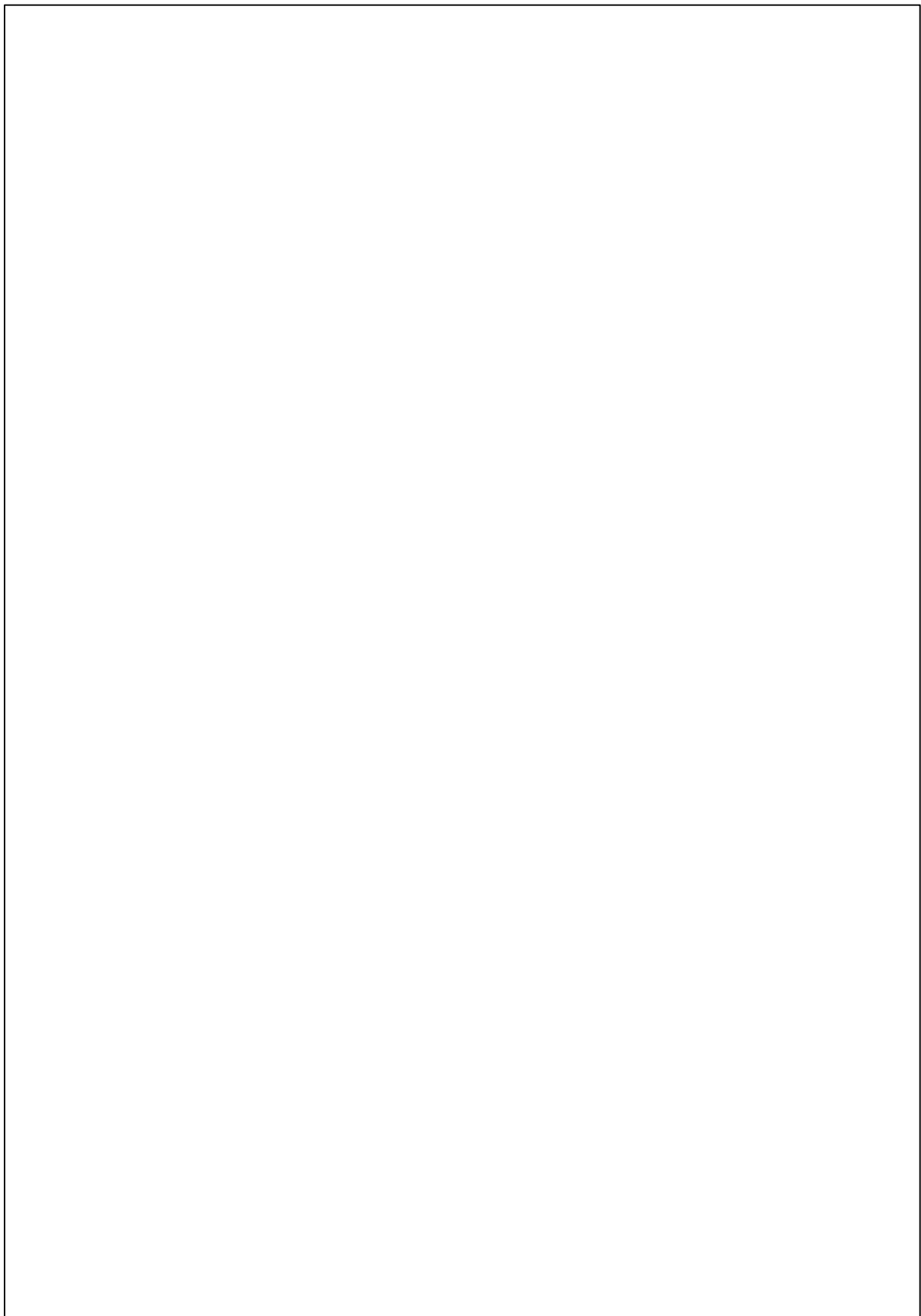
	Monograph	Dossier
Level 1	Purpose and context Statement of subject matter	Dossier Document A Test and study reports and <i>Tier II</i> summary and evaluation: Annex II, Point 1 (Dossier Documents J, K-II, and M-II), Annex III, Point 1 and 3, (Dossier Documents J, K-III, and M-III), and Dossier Documents A and C to E
Level 2	Overall conclusions	Overall assessment and conclusions (Dossier Documents N and Dossier Documents G, H and I)
Level 3	Proposed decision	Overall assessment and conclusions (Dossier Document N)
Level 4	Data requirements to permit a decision to be made or for reconsideration of proposed conditions and restrictions	Annex II and Annex III <i>Tier II</i> summary and evaluation (Dossier Documents M-II and M-III) and Dossier Documents G, H and I
Annex A	Listing of data and information submitted	The final part of Annex II and Annex III, <i>Tier I</i> , (Dossier Documents L reference lists), and Dossier Documents I and J
Annex B	Summary, evaluation and assessment of the data, List of tests and studies relied upon	Annex II and Annex III test and study reports and <i>Tier II</i> summaries (Dossier Documents J, K-II, K-III, L-II, L-III, M-II, M-III and Dossier Documents C, D, E, G, H and I)
Annex C	Confidential information Collective submission of dossiers - reasonable steps	Dossier Document J Dossier Document B

3.6

The four levels and three annexes comprising monographs provide a tiered structure which is intended to facilitate the examination and consideration of draft monographs and proposed decisions with respect to the inclusion of active substances in Annex I, by the relevant Commission Working Groups and by the Standing Committee on Plant Health. It is envisaged that at Community level, in the normal course of events, the working documents and background

or reference documents for the various Working Groups, for the Scientific Committee on Plants and for the Standing Committee on Plant Health, will be those indicated here under -

	Working Documents	Background/Reference Documents
<i>ad hoc</i> Working Groups (peer review)	Monograph levels Dossier 1 to 4 and Annex A to C and comments from Member States and the Notifier	Study Reports, Dossier Summaries <i>Tiers I - III</i> and Supporting Documentation
Tripartite Meeting (Commission, Rapporteur Member State & Notifier) (where necessary only)	Reports of <i>ad hoc</i> Working Groups and comments from Member States and the Notifier	Monograph Levels 1 to 4 and Annex A to C
Working Group "Pesticides" Evaluations (all Member States)	Draft Commission Proposal, Draft Review Report and Evaluation Table, Report of Tripartite Meeting	Monograph levels 1 to 4 and Annex A to C (...) Reports of <i>ad hoc</i> Working Groups and comments from Member States and the Notifier
Scientific Committee for Plants	Draft Commission Proposal, Monograph Levels 1 to 4 and Annex A to C, Reports of the <i>ad hoc</i> Working Groups, Draft Review Report and Evaluation Table	Dossier Study Reports, Dossier Summaries <i>Tiers I - III</i> and Supporting Documentation Documents and Comments received after the peer review
Working Group "Pesticides" Legislation (all Member States)	Draft Commission Proposal, Final Review Report and Evaluation Table, Report of Evaluation Group, Opinion of the Scientific Committee on Plants	Monograph levels 3 and 4
Standing Committee on Plant Health	Commission Proposal, Final Review Report, Report of Working Group "Pesticides" Legislation	Monograph levels 3 and 4



4 DETAILED CRITERIA AND GUIDELINES FOR THE PREPARATION OF MONOGRAPHS

Monographs should be compiled such that they contain the detailed information specified in paragraphs 4.1 through 4.7, in the order specified in Appendix 4.

4.1 Level 1 Statement of the subject matter of and the purpose for which the monograph was prepared

4.1.1 A statement of the purpose for which, or context in which, the application was submitted, prepared on the basis of document A of the summary dossier submitted by the applicant:-

- (i) first inclusion of a new active substance in Annex I;
- (ii) first inclusion of an existing active substance in Annex I;
- (iii) modification or removal of conditions or restrictions associated with the inclusion of an active substance already included in Annex I;
- (iv) special review of the inclusion of an active substance in Annex I, where indications exist suggesting that the conditions of inclusion are no longer satisfied; or
- (v) routine review anticipating expiry of the period for which the active substance was included in Annex I.

4.1.2 Information to identify the active substance for which application is made, prepared on the basis of documents J, K-II and M-II of the complete dossier submitted by the applicant:-

- (i) ISO common name, or proposed ISO common name and where relevant, other proposed or accepted common names (synonyms), including the name (title) of the nomenclature authority concerned;
- (ii) the chemical name, in accordance with both IUPAC and CA nomenclature;
- (iii) code numbers used to identify the active substance, and formulations containing the active substance, during development work. For each code number reported, the material to which it relates, the period for which it was used, and the Member States or other countries in which it was used and is being used;
- (iv) Chemical Abstracts (CAS), EEC (EINECS or ELINCS), CIPAC numbers where they exist and other existing identifying numbers (*e.g.* CODEX Alimentarius);
- (v) the empirical formula, molecular mass and structural formula of the active substance, and where relevant, the structural formula of each stereo and optical isomer present in the active substance;
- (vi) the manufacturer or manufacturers (name and address), and if different the applicant⁹;

⁹ In certain circumstances, the information concerned should be treated as confidential in accordance with the provisions of Article 14 of the Directive and therefore should be included in Annex C, rather than in Level 1 - see paragraph 4.7

4.1 Detailed Criteria and Guidelines for the Preparation of Monographs - Level 1

- (vii) the specification of purity of the active substance (minimum content in g/kg, excluding inactive isomers);
- (viii) the impurity profile of the active substance (identity and content in g/kg of isomers, impurities and additives) ¹⁰;
- (ix) the results of batch analysis reported for the active substance ¹⁰; and
- (x) the method of manufacture, in terms of the identity of the starting materials, the chemical pathways involved, and the identity of by-products and impurities present in the final product, for each manufacturing plant ¹⁰.

4.1.3 Information to identify each preparation containing the active substance for which an Annex III dossier is submitted in support of the application, prepared on the basis of documents J, K-III and M-III of the complete dossier submitted by the applicant:-

- (i) all former trade names, proposed trade names, current trade names and development code numbers of the preparation, for each Member State;
- (ii) the name and address of the manufacturer of the preparation ⁹;
- (iii) the type of preparation, using the relevant two letter code (see Appendix 2); and
- (iv) detailed quantitative and qualitative information on its composition *e.g.* active substance(s), impurities, formulants, inert components ¹⁰.

4.1.4 Information to identify the uses and authorizations for each preparation containing the active substance for which an Annex III dossier is submitted in support of the application, prepared on the basis of documents C, D and E of the complete dossier submitted by the applicant:-

- (i) use category *e.g.* herbicide, insecticide;
- (ii) field of use *e.g.* agriculture, horticulture, food or feed storage, *etc.*;
- (iii) effects on harmful organisms *e.g.* contact, inhalation or stomach poison, fungitoxic or fungistatic, systemic or not in plants;
- (iv) a concise summary of all intended uses reported ¹¹, using forms as set out in Appendix 5; and

¹⁰ The information concerned should be included in Annex C, rather than in Level 1, if it is to be treated as confidential in accordance with the provisions of Article 14 of the Directive - see paragraph 4.7

4.1 Detailed Criteria and Guidelines for the Preparation of Monographs - Level 1

- (v) a summary of authorizations (registrations, approvals or clearances) granted in EU Member States.

¹¹ intended uses consist of those existing uses and proposed uses which are supported by the applicant for which data have been provided or for which data are to be provided by a specified date

4.2 Detailed Criteria and Guidelines for the Preparation of Monographs - Level 2

4.2 Level 2 **Reasoned statement of the overall conclusions which the Rapporteur Member State believes should be reached on the basis of the data and information provided, or available, taking account of relevant evaluative and decision making criteria**

4.2.1 The statement of the conclusions which the Rapporteur Member State believes should be drawn, should reflect application of a sensitivity analysis to take account of potential uncertainties in the critical data and must highlight the levels and duration of exposure likely to occur under practical conditions of use - normal and realistic worst case - and the nature and significance of the effects anticipated, on the basis of the data and information evaluated, having regard to:

- (i) the weight of the evidence available - extent, quality and consistency of the data concerned;
- (ii) the criteria specified in Article 5 of Directive 91/414/EEC;
- (iii) the criteria and guidelines for evaluation and decision making with respect to the inclusion of active substances in Annex I, where available; and
- (iv) to the extent that they are relevant, the evaluative and decision making criteria specified in Annex VI of Directive 91/414/EEC.

4.2.2 The statement of the conclusions reached by the Rapporteur Member State should be structured as indicated in Appendix 4. It should be prepared on the basis of:

- (i) the data and information provided by the applicant, taking account of the applicants own assessment of the data submitted (Document N), and where relevant, in the case of formulants (ingredients other than active substances), information concerning their use in food, animal feeding stuffs, medicines or cosmetics in accordance with Community legislation as well as relevant safety data sheets and, where available, other relevant toxicological information (Documents G, H and I); and
- (ii) data and information otherwise available to the Rapporteur Member State.

4.2.3 The statement of the conclusions reached by the Rapporteur Member State, should not include details of the risk assessments carried out - such detailed information should be included in Annex B of the Monograph. The information included in Level 2 should only include information relevant to those issues which are important in the context of the overall conclusions reached, taking account of relevant evaluative and decision making criteria. It should include, where relevant, a diagrammatic representation of the metabolic pathway(s) for the active substance in animals, plants, soil and water. The molecular structure of the active substance and its metabolites, degradation and reaction products should be shown. Major pathways should be distinguishable from minor pathways, which in turn should be distinguishable from possible or suspected pathways.

4.2.4 The lists of standard terms, special terms and abbreviations used in the Monograph should be appended to Level 2 of the Monograph. Those lists should form Appendices 1 and 2 to Level 2 of the Monograph:-

- (i) Appendix 1 standard terms and abbreviations (to be drawn from Appendix 1 and Appendix 2 to these Guidelines); and

4.2 Detailed Criteria and Guidelines for the Preparation of Monographs - Level 2

4.3 Detailed Criteria and Guidelines for the Preparation of Monographs - Level 3

- (ii) Appendix 2 - specific terms and abbreviations (to be a listing of those additional terms and abbreviations used in the Monograph but not included in Appendix 1).

4.2.5 In addition, a listing of all end points which are used in or are relevant to the conclusions reached and to the proposed decision, should be appended to Level 2 - to form Appendix 3. The format to be followed in listing end points is provided in Appendix 6. The listing of end points is intended to provide an overview of the properties and characteristics of the active substance and should reflect the considered opinion of the specialist evaluators that examined the data, taking account of the weight of the evidence provided by the data evaluated (its extent, quality and consistency).

4.3 **Level 3 Proposed decision with respect to the application for inclusion of the active substance in Annex I, the proposed conditions and restrictions to be associated with any inclusion of the active substance in Annex I, together with a reasoned statement as to the reasons therefor, taking account of relevant evaluative and decision making criteria**

4.3.1 The Rapporteur Member State's proposed decision with respect to the possible inclusion of the active substance in Annex I, which should be structured as indicated in Appendix 4, should be supported with a full and reasoned statement as to the rationale used in making its proposal, in the light of:

- (i) the criteria specified in Article 5 of Directive 91/414/EEC;
- (ii) the criteria and guidelines for evaluation and decision making with respect to the inclusion of active substances in Annex I, where available; and
- (iii) to the extent that they are relevant, the evaluative and decision making criteria specified in Annex VI of Directive 91/414/EEC.

4.3.2 Where a negative decision is proposed, or where it is proposed that the decision be postponed, a full explanation of the key issues and findings which resulted in such a proposal being made, should be included.

4.3.3 A full and reasoned statement of the Rapporteur Member State's proposals for any conditions or restrictions to be associated with the inclusion of the active substance in Annex I, should be included, having particular regard to:

- (i) the criteria specified in Article 5 of Directive 91/414/EEC;
- (ii) the criteria and guidelines for evaluation and decision making with respect to the inclusion of active substances in Annex I, where available; and
- (iii) to the extent that they are relevant, the evaluative and decision making criteria specified in Annex VI of Directive 91/414/EEC.

4.3	Detailed Criteria and Guidelines for the Preparation of Monographs - Level 3
4.4	Detailed Criteria and Guidelines for the Preparation of Monographs - Level 4

- 4.3.4 Conditions to be associated with an inclusion of an active substance in Annex I may be of two types:-
- (i) specified test and study reports to be submitted by specified deadlines;
 - (ii) authorizations granted for preparations containing the active substance to respect specified restrictions.
- 4.3.5 Restrictions to be associated with an inclusion of an active substance in Annex I may be of several types, all of which limit the terms under which authorizations may be granted for preparations containing the active substance: minimum degree of purity of the active substance; nature and maximum content of certain impurities; restrictions necessary on the basis of the examination of the data considered for the proposed inclusion of the active substance in Annex I, taking account of the agricultural, plant health and environmental (including climatic) conditions in question; type of preparation; manner of use.
- 4.4 **Level 4** **Where relevant, a statement of the studies and information believed necessary to permit a decision to be made, or a statement of the studies and information necessary for the removal of any conditions or restrictions associated with the proposed inclusion of the active substance in Annex I**
- 4.4.1 Where it is proposed that a decision as to the inclusion, or not, of an active substance in Annex I be postponed pending the availability of further data and information, the monograph should contain a listing of the further Annex II and Annex III studies required together with proposals for the deadlines for their submission. Where it is considered that the results of a particular study, or group of studies, may lead to the conclusion that the active substance not be included in Annex I, the deadline for the submission of such studies, should be such that they can be evaluated prior to a decision being taken by the applicant to proceed with other required additional studies. Accordingly, a much later deadline should be specified for any such additional studies.
- 4.4.2 In each case in which proposals for conditions and/or restrictions to be associated with the inclusion of the active substance in Annex I, are made, the monograph should contain a statement, which should be structured as indicated in Appendix 4, of any additional Annex II and Annex III studies and information which, if made available, could result in the variation or removal of each such condition and restriction.
- 4.4.3 Statements relating to additional studies must provide an explanation as to the rationale for the suggestions made and must include sufficient information to indicate with clarity the key parameters to be investigated.

4.5 Detailed Criteria and Guidelines for the Preparation of Monographs - Annex A

4.5 Annex A Listing of the available data and information (Annex II and Annex III)

4.5.1 Annex A of the monograph should comprise a listing of all test and study reports, test guidelines, and published papers submitted in support of the application (Documents J, K, and L and where relevant I) and other relevant information available to, or brought to the attention of, the Rapporteur Member State. The listing should cover each of the nine chapters of Annex A separately (see Appendix 4). References which relate to more than one chapter should be listed in each relevant chapter. Where, for existing active substances, more than one dossier is submitted, the reference list should reflect all the test and study reports, test guidelines, and published papers submitted. Those references not submitted by applicants for inclusion of the active substance in Annex I, but which are available to, or are brought to the attention of the Rapporteur Member State, should also be included. Within the listing for each chapter, the references relevant to Annex II should be presented first and be followed by the references relevant to Annex III. Where more than one Annex III dossier is submitted in support of an application, care must be taken to indicate the preparation to which particular test and study reports, test guidelines, and published papers relate.

4.5.2 References should be listed alphabetically by first author. Where there is more than one reference for a particular author (first author) the references concerned should be listed in chronological order - the most recent being listed last. In cases where for a particular author, more than one reference is listed for any one year, the references should be distinguished by inserting letters after the year *i.e.* a, b, c, *etc.*, as appropriate. The authors of each test and study report, test guideline and published document, the Annex II or Annex III point to which it relates and the reference number of the report, the year of the report, its title, source (where different from the company that submitted the report), the company that submitted the report, the report number, an indication as to whether or not data protection is claimed in accordance with the provisions of Article 13 (3) (d) of Directive 91/414/EEC and the owner of the report, should be indicated. In addition, an indication should be provided as to whether it is published or unpublished and as to whether, or not, it was conducted in compliance with the principles of GLP or the requirements of points 2.2 and 2.3 of the introduction to Annex II to Directive 93/71/EEC¹², as appropriate.

¹² Commission Directive 95/35/EC of 14 July 1995 amending Council Directive 91/414/EEC concerning the placing of plant protection products on the market - OJ No L172, 22. 7. 1995, p 6 - provides for the following derogations which may, or may not, be availed of by the Member States:-

4.5 Detailed Criteria and Guidelines for the Preparation of Monographs - Annex A





4.5.3 A suggested format for the presentation of the listing of test and study reports, test guidelines, and published papers is contained in Appendix 7.

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- ✎ supervised residue trials effectively started prior to 1 January 1998, to be conducted in accordance with the requirements of points 2.2 and 2.3 of the introduction to Annex II to Directive 93/71/EEC, rather than in accordance with the principles of GLP; and
 - ✎ testing with respect to effects on honeybees and other beneficial arthropods, effectively started prior to 1 January 1999, to be conducted in accordance with the requirements of points 2.2 and 2.3 of the introduction to Annex II to Directive 93/71/EEC, rather than in accordance with the principles of GLP





4.6 Annex B Rapporteur Member States's summary, evaluation and assessment of the data and information submitted or available, in the light of relevant evaluative and decision making criteria, providing the scientific background to the conclusions reached and proposals made at levels 2 to 4, together with a list of the tests and studies relied upon for conclusions reached

4.6.1 The summary, evaluation and assessment, made on the basis of documents C, D, E and G to M, as submitted by applicants and other available information, included in monographs, should address each relevant point of Annex II and Annex III and be presented in separate chapters in the sequence specified in Appendix 4. It should be sufficiently comprehensive to permit decisions to be made without the need for further reference to individual study reports and supporting documentation. Where feasible, a tabular format for the presentation of the data and information concerned, with an accompanying supporting text, should be used to provide a comprehensive overview of the data base evaluated. The documentation prepared and constituting Annex B of monographs, should provide the scientific background to the conclusions reached and proposals made at levels 2, 3 and 4.







4.6.2 The summary, evaluation and assessment of the data and information considered should include a critical assessment as to the quality of the data base concerned. Deficiencies and inadequacies in the tests and studies conducted and in the documentation submitted, which influence the degree of confidence that can be placed on particular findings and on the conclusions reached by the Rapporteur Member State, should be highlighted. The critical assessment required should contain the following elements:

- (i) an overall statement as to the quality and completeness of the data base evaluated;
- (ii) for individual tests and studies referred to, for which the principles of GLP apply, but have not been complied with, a statement of the acceptability of the quality of the test or study, having regard to the justification provided for non-compliance with the principles of GLP¹²;
- (iii) for individual tests and studies referred to, for which the requirements of points 2.2 and 2.3 of the introduction to Annex II to Directive 93/71/EEC apply, but have not been complied with, a statement of the acceptability of the quality of the test or study, having regard to the justification provided for non-compliance with those requirements¹²;
- (iv) in instances where the choice of methodology is such that the scientific validity of the test or study is questionable, a tabular listing of the tests and studies concerned, cross-referenced to the relevant Annex II or Annex III point addressed, together with a brief comment as to the nature and extent of the inadequacy or deficiency, whether relating to -
 -  the suitability of the test method used, having regard to the justification provided for use of methods other than those specified in Annex II and Annex III,
 -  where test guidelines provide choice as to the particular method to be used, the suitability of the test method actually used, having regard to the justification provided for the choice made,
 -  where there were deviations from the test guidelines specified, or from other methods used, the suitability of the test method actually used, having regard to the justification provided for the deviations concerned, or
 -  where the identity of the test substance or material has not been adequately specified, or its stability in dosing vehicles or solvents used is questionable, the reliability or usefulness of the test or study concerned;



(v) where relevant, for individual tests and studies, a summary of the key elements of the study design, of the observations made and of the findings, accompanied by a brief statement of the acceptability or not of the test or study, together with a concise statement of the rationale used where the study is not considered acceptable - in the case of toxicological studies the following information should be included -

-  number, sex, species and strain of laboratory animals used,
-  the identity of the test material, the method of dosing and the doses administered, expressed, as appropriate, in mg/kg bw or in mg/kg bw/day,
-  effects observed and their toxicological significance, as a function of dose and derived limit doses (*e.g.* LD₅₀, NOEL)₂ and
-  a brief statement as to the acceptability of the study and in the case of it not being of acceptable quality, a concise statement of the rationale used in reaching that conclusion, having regard to both information contained in the study report and information not so included,





while in the case of tests and studies relating to fate and behaviour in the environment, the following information should be included -

-  the identity of test material, purity, position of radiolabel, amount applied (concentration), method of analysis, LOQ,
-  an outline of the test conditions, to include details of temperature and light conditions, soil and/or sediment characteristics (including % OC or OM, CEC, clay content, moisture content), study duration,
-  for column leaching studies, column length, water volume applied and leaching time,
-  for aqueous photolysis studies, details of pH, buffering and sensitizers used, and of the light conditions (intensity and wavelengths) used,
-  results obtained - *e.g.* DT₅₀, distribution and material balance, where relevant, in different compartments, soil segments and leachates, in the case of adsorption studies K_{ads}, K_{oc} or K_{om}, together with kinetic and statistical calculations, and
-  a brief statement as to the acceptability of the study and in the case of it not being of acceptable quality, a concise statement of the rationale used in reaching that conclusion, having regard to both information contained in the study report and information not so included,

and in the case of ecotoxicological studies, the following information should be included -

-  test organism(s), where relevant number, sex, species, strain, age, size, life stage and feeding regime used,
-  the identity of the test material, purity, test concentration, exposure route and time of exposure,

4.6 Detailed Criteria and Guidelines for the Preparation of Monographs - Annex B

-  effects observed as a function of dose and derived limit doses (*e.g.* EC₅₀, LC₅₀, LD₅₀, NOEL, % mortality), including sublethal effects, repellency and measured (actual) concentrations and statistical calculations, and
 -  a brief statement as to the acceptability of the study and in the case of it not being of acceptable quality, a concise statement of the rationale used in reaching that conclusion, having regard to both information contained in the study report and information not so included;
- (vi) in the case of supervised residues trials data, where relevant, a clear statement to indicate the differences, if any, in the data base included in comparison to that considered by the JMPR for the purposes of the elaboration of Codex MRLs; and
- (vii) in the case of studies concerning metabolism, distribution and expression of residues in livestock and in the case of livestock feeding studies -
-  a clear indication as to whether feed items and dose levels are expressed on a dry or on a wet weight basis - dose levels should be reported on a dry weight basis,
 -  a statement as to the fat content of meat samples (to facilitate avoiding the incorrect classifications of residues as being fat soluble or not being fat soluble).
- 4.6.3 Within each chapter, having regard to the data provided and included, it is necessary that each key point relevant to decision making be highlighted, having regard to:
- (i) the weight of the evidence available - extent, quality and consistency of the data concerned;
 - (ii) the criteria specified in Article 5 of Directive 91/414/EEC;
 - (iii) the criteria and guidelines for evaluation and decision making with respect to the inclusion of active substances in Annex I, where available; and
 - (iv) to the extent that they are relevant, the evaluative and decision making criteria specified in Annex VI of Directive 91/414/EEC.
- 4.6.4 In the interest of facilitating the reader, summary information relevant to more than one chapter should be repeated within each chapter to which it is relevant *e.g.* metabolic pathways should be reproduced in each section in which they are relevant.
- 4.6.5 In the interest of precluding the need for requiring the repetition of studies involving use of vertebrate species, or involving the deployment of scarce resources to undertake additional testing, where in accordance with paragraph 4.6.2, it is apparent that the quality and reliability of individual tests and studies is questionable, it is particularly important that for relevant groups of studies and tests relating to particular points or effects concerned, the overall weight of evidence be assessed before concluding that there is a need for the repetition of any particular test or study, or group of tests or studies.
- 4.6.6 Where appropriate, conclusions as to the relevance of particular studies conducted regionally (*e.g.* residues at harvest, rate of degradation in soils), to the agricultural, plant health and environmental (including climatic) conditions of other regions, together with the rationale for extrapolations accepted, should be included.

4.6 Detailed Criteria and Guidelines for the Preparation of Monographs - Annex B

- 4.6.7 The assessments made should be presented as a composite element of the Rapporteur Member State's summary and evaluation of the data and information considered. Those tests and studies relied on by the Rapporteur Member State in reaching its conclusions should be clearly referenced in the assessment.
- 4.6.8 Towards the end of each chapter a listing should be provided of the test and study reports relied on. References which relate to more than one chapter should be listed in each relevant chapter. A suggested format for the presentation of the listing of test and study reports relied on is contained in Appendix 8. Where a single study would suffice, but two or more acceptable studies are submitted with respect to any particular data requirement, a footnote should be included in the list of references to indicate that any one of the studies concerned can be relied on by applicants for authorization of plant protection products containing the active substance concerned. Alternatively, that information can be provided by means of a set of comments which should be included after the list of test and study reports relied on.
- 4.6.9 The list of test and study reports relied on should be listed by Annex II or Annex III point as appropriate. For each individual Annex point, references should be listed alphabetically by first author. Where there is more than one reference for a particular author (first author) the references concerned should be listed in chronological order - the most recent being listed last. In cases where for a particular author, more than one reference is listed for any one year, the references should be distinguished by inserting letters after the year *i.e.* a, b, c, *etc.*, as appropriate. The authors of each test and study report, test guideline and published document, and the reference number of the report, the year of the report, its title, source (where different from the company that submitted the report), the company that submitted the report, the report number. An indication as to whether or not data protection is claimed in accordance with the provisions of Article 13 (3) (d) of Directive 91/414/EEC and the owner of the report, should also be indicated - before decisions to include particular active substances in Annex I are made, applicants may be required, where appropriate, to certify that the studies for which they have claimed data protection, were not submitted to the designated authorities of any of the Member States (including those of Austria, Finland and Sweden) in support of an authorization decision. In addition, an indication should be provided as to whether it is published or unpublished and as to whether, or not, it was conducted in compliance with the principles of GLP or the requirements of points 2.2 and 2.3 of the introduction to Annex II to Directive 93/71/EEC¹², as appropriate.
- 4.6.10 The final part of Annex B should consist of the lists of standard terms, special terms and abbreviations used in the Monograph. Those lists are also to be appended to level 2 of the Monograph (see paragraph 4.2.4). The lists should be included as Appendices to Annex B of the Monograph:-
- (i) Appendix 1 - standard terms and abbreviations (to be drawn from Appendix 1 and Appendix 2 to these Guidelines); and
 - (ii) Appendix 2 - specific terms and abbreviations (to be a listing of those additional terms and abbreviations used in the Monograph but not included in Appendix 1).

4.6 Detailed Criteria and Guidelines for the Preparation of Monographs - Annex C

4.7 **Annex C Confidential information and, in the case of existing active substances for which there was more than one notifier, the Rapporteur Member State's assessment of the steps taken to collectively submit the complete dossier**

4.7.1 In accordance with Article 14 of Directive 91/414/EEC, application may be made to have particular information involving industrial and commercial secrets treated as confidential (Document J as submitted by applicants). Information which is likely to qualify to be treated as confidential includes that relating to the detailed specification of active substances and preparations containing them, detailed information on manufacturing processes, especially that relating to process engineering where provided, the names and addresses of manufacturing sites and of testing facilities as well as information based on individual medical records (see also paragraph 1.8). Rapporteur Member States concerned, should assess all such claims made and:

- (i) in the case of claims which it believes should be rejected, indicate the information concerned, indicate where it is included in the draft Monograph (volume and page number) and state the rationale used for rejection of the claims made; and
- (ii) in the case of claims made which it believes should be accepted, state the rationale used.

4.7.2 All information which the Rapporteur Member State believes should be treated as confidential should not be included in levels 1, 2, 3 or 4, or in Annex A or Annex B of the draft Monograph. Instead such information should be included in Annex C, in summary form. However, appropriate cross references to particular items of information contained in Annex C, should be included in other parts of the draft Monograph, as appropriate.

4.7.3 Where in the context of the Article 8 (2) of Directive 91/414/EEC and Commission Regulations made pursuant to that Article, the notifiers of particular existing active substances fail to *collectively present individual complete dossiers*, the notifiers concerned are required to provide -

- (i) details of the claims made that all reasonable steps were taken to present the dossier collectively, and
- (ii) documentation to justify the claims made.

The Rapporteur Member State should prepare a summary and assessment of the information and documentation provided (Document B as submitted by applicants). In particular, a statement should be included containing the conclusions reached with respect to whether the steps taken to collectively present the complete dossier were reasonable or not (*cf* paragraph 1.9).

4.7.4 Annex C of draft Monographs will not be included in any version of the monograph subsequently published or otherwise made available to interested parties.

APPENDIX 1

STANDARD TERMS AND ABBREVIATIONS

Part 1 Technical Terms

A	ampere
ACh	acetylcholine
AChE	acetylcholinesterase
ADI	acceptable daily intake
ADP	adenosine diphosphate
AE	acid equivalent
AFID	alkali flame-ionization detector or detection
A/G	albumin/globulin ratio
ai	active ingredient
ALD ₅₀	approximate median lethal dose, 50%
ALT	alanine aminotransferase (SGPT)
AOEL	acceptable operator exposure level
AMD	automatic multiple development
ANOVA	analysis of variance
AP	alkaline phosphatase
approx	approximate
ARC	anticipated residue contribution
ARfD	acute reference dose
as	active substance
AST	aspartate aminotransferase (SGOT)
ASV	air saturation value
ATP	adenosine triphosphate
BCF	bioconcentration factor
bfa	body fluid assay
BOD	biological oxygen demand
bp	boiling point
BSAF	biota-sediment accumulation factor
BSE	bovine spongiform encephalopathie
BSP	bromosulfophthalein
Bt	bacillus thuringiensis
Bti	bacillus thuringiensis israelensis
Btk	bacillus thuringiensis kurstaki
Btt	bacillus thuringiensis tenebrionis
BUN	blood urea nitrogen
bw	body weight
c	centi- (x 10 ⁻²)
°C	degree Celsius (centigrade)
CA	controlled atmosphere
CAD	computer aided design
CADDY	computer aided dossier and data supply (an electronic dossier interchange and archiving format)
cd	candela
CDA	controlled drop(let) application
cDNA	complementary DNA
CEC	cation exchange capacity
<i>cf</i>	confer, compare to
CFU	colony forming units

Appendix 1 Standard Terms and Abbreviations

ChE	cholinesterase
CI	confidence interval
CL	confidence limits
cm	centimetre
CNS	central nervous system
COD	chemical oxygen demand
CPK	creatinine phosphatase
cv	coefficient of variation
Cv	ceiling value
CXL	Codex Maximum Residue Limit (Codex MRL)
d	day
DES	diethylstilboestrol
DFR	dislodgeable foliar residue
DMSO	dimethylsulfoxide
DNA	deoxyribonucleic Acid
dna	designated national authority
DO	dissolved oxygen
DOC	dissolved organic carbon
dpi	days pot inoculation
DRES	dietary risk evaluation system
DT ₅₀	period required for 50 percent dissipation (define method of estimation)
DT ₉₀	period required for 90 percent dissipation (define method of estimation)
dw	dry weight
DWQG	drinking water quality guidelines
&	decadic molar extinction coefficient
EC ₅₀	median effective concentration
ECD	electron capture detector
ECU	European currency unit
ED ₅₀	median effective dose
EDI	estimated daily intake
ELISA	enzyme linked immunosorbent assay
e-mail	electronic mail
EMDI	estimated maximum daily intake
EPMA	electron probe micro analysis
ERC	environmentally relevant concentration
ERL	extraneous residue limit
F	field
F ₀	parental generation
F ₁	filial generation, first
F ₂	filial generation, second
FIA	fluorescence immuno assay
FID	flame ionization detector
FOB	functional observation battery
fp	freezing point
FPD	flame photometric detector
FPLC	fast protein liquid chromatography
g	gram
G	glasshouse
GAP	good agricultural practice
GC	gas chromatography
GC-EC	gas chromatography with electron capture detector
GC-FID	gas chromatography with flame ionization detector

Appendix 1 Standard Terms and Abbreviations

GC-MS	gas chromatography-mass spectrometry
GC-MSD	gas chromatography with mass-selective detection
GEP	good experimental practice
GFP	good field practice
GGT	gamma glutamyl transferase
GI	gastro-intestinal
GIT	gastro-intestinal tract
GL	guideline level
GLC	gas liquid chromatography
GLP	good laboratory practice
GM	geometric mean
GMO	genetically modified organism
GMM	genetically modified micro-organism
GPC	gel-permeation chromatography
GPPP	good plant protection practice
GPS	global positioning system
GSH	glutathion
GV	granulosevirus
h	hour(s)
H	Henry's Law constant (calculated as a unitless value) (see also K)
ha	hectare
Hb	haemoglobin
HCG	human chorionic gonadotropin
Hct	haematocrit
HDT	highest dose tested
hL	hectolitre
HEED	high energy electron diffraction
HID	helium ionization detector
HPAEC	high performance anion exchange chromatography
HPLC	high pressure liquid chromatography or high performance liquid chromatography
HPLC-MS	high pressure liquid chromatography - mass spectrometry
HPPLC	high pressure planar liquid chromatography
HPTLC	high performance thin layer chromatography
HRGC	high resolution gas chromatography
H _S	Shannon-Weaver index
Ht	haematocrit
I	indoor
I ₅₀	inhibitory dose, 50%
IC ₅₀	median immobilization concentration or median inhibitory concentration ¹³
ICM	integrated crop management
ID	ionization detector
IEDI	international estimated daily intake
IGR	insect growth regulator
im	intramuscular
inh	inhalation
ip	intraperitoneal
IPM	integrated pest management
IR	infrared
ISBN	international standard book number
ISSN	international standard serial number
iv	intravenous
IVF	<i>in vitro</i> fertilization

¹³ The first time the abbreviation is used in a document, it should be defined (using a footnote to do so)

Appendix 1 Standard Terms and Abbreviations

k	kilo
K	Kelvin or Henry's Law constant (in atmospheres per cubic meter per mole) (see also H) ¹³
K _{ads}	adsorption constant
K _{des}	apparent desorption coefficient
K _{oc}	organic carbon adsorption coefficient
K _{om}	organic matter adsorption coefficient
kg	kilogram
L	litre
LAN	local area network
LASER	light amplification by stimulated emission of radiation
LBC	loosely bound capacity
LC	liquid chromatography
LC-MS	liquid chromatography- mass spectrometry
LC ₅₀	lethal concentration, median
LCA	life cycle analysis
LC _{Lo}	lethal concentration low
LC-MS-MS	liquid chromatography with tandem mass spectrometry
LD ₅₀	lethal dose, median; dosis letalis media
LD _{Lo}	lethal dose low
LDH	lactate dehydrogenase
LOAEC	lowest observable adverse effect concentration
LOAEL	lowest observable adverse effect level
LOD	limit of detection
LOEC	lowest observable effect concentration
LOEL	lowest observable effect level
LOQ	limit of quantification (determination)
LPLC	low pressure liquid chromatography
LSC	liquid scintillation counting or counter
LSD	least squared denominator multiple range test
LSS	liquid scintillation spectrometry
LT	lethal threshold
m	metre
M	molar
μm	micrometer (micron)
MC	moisture content
MCH	mean corpuscular haemoglobin
MCHC	mean corpuscular haemoglobin concentration
MCV	mean corpuscular volume
MDL	method detection limit
MFO	mixed function oxidase
μg	microgram
mg	milligram
MHC	moisture holding capacity
min	minute(s)
mL	millilitre
MLT	median lethal time
MLD	minimum lethal dose
mm	millimetre
mo	month(s)
mol	Mole(s)
MOS	margin of safety
mp	melting point
MRE	maximum residue expected
MRL	maximum residue level or limit

Appendix 1 Standard Terms and Abbreviations

mRNA	messenger ribonucleic acid
MS	mass spectrometry
MSDS	material safety data sheet
MTD	maximum tolerated dose
n	normal (defining isomeric configuration) or number of observations ¹³
NAEL	no adverse effect level
nd	not detected
NEDI	national estimated daily intake
NEL	no effect level
NERL	no effect residue level
ng	nanogram
nm	nanometer
NMR	nuclear magnetic resonance
no	number
NOAEC	no observed adverse effect concentration
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
NOED	no observed effect dose
NOEL	no observed effect level
NOIS	notice of intent to suspend
NPD	nitrogen-phosphorus detector or detection
NPV	nuclear polyhedrosis virus
NR	not reported
NTE	neurotoxic target esterase
OC	organic carbon content
OCR	optical character recognition
ODP	ozone-depleting potential
ODS	ozone-depleting substances
OM	organic matter content
op	organophosphorous pesticide
Pa	pascal
PAD	pulsed amperometric detection
2-PAM	2-pralidoxime
pc	paper chromatography
PC	personal computer
PCV	haematocrit (packed corpuscular volume)
PEC	predicted environmental concentration
PEC _A	predicted environmental concentration in air
PEC _S	predicted environmental concentration in soil
PEC _{SW}	predicted environmental concentration in surface water
PEC _{GW}	predicted environmental concentration in ground water
PED	plasma-emissions-detector
pH	pH-value
PHED	pesticide handler's exposure data
PHI	pre-harvest interval
PIC	prior informed consent
pic	phage inhibitory capacity
PIXE	proton induced X-ray emission
pKa	negative logarithm (to the base 10) of the dissociation constant)
PNEC	predicted no effect concentration
po	by mouth
P _{OW}	partition coefficient between n-octanol and water
POP	persistent organic pollutants

Appendix 1 Standard Terms and Abbreviations

ppb	parts per billion (10^{-9})
PPE	personal protective equipment
ppm	parts per million (10^{-6})
ppp	plant protection product
ppq	parts per quadrillion (10^{-24})
ppt	parts per trillion (10^{-12})
PSP	phenolsulfophthalein
PrT	prothrombin time
PRL	practical residue limit
PT	prothrombin time
PTDI	provisional tolerable daily intake
PTT	partial thromboplastin time
QSAR	quantitative structure-activity relationship
r	correlation coefficient
r^2	coefficient of determination
RBC	red blood cell
REI	restricted entry interval
Rf	retardation factor
RfD	reference dose
RH	relative humidity
RL ₅₀	median residual lifetime
RNA	ribonucleic acid
RP	reversed phase
rpm	rotations per minute
rRNA	ribosomal ribonucleic acid
RRT	relative retention time
RSD	relative standard deviation
s	second
SAC	strong adsorption capacity
SAP	serum alkaline phosphatase
SAR	structure/activity relationship
SBLC	shallow bed liquid chromatography
sc	subcutaneous
sce	sister chromatid exchange
SD	standard deviation
se	standard error
SEM	standard error of the mean
SEP	standard evaluation procedure
SF	safety factor
SFC	supercritical fluid chromatography
SFE	supercritical fluid extraction
SIMS	secondary ion mass spectroscopy
SOP	standard operating procedures
sp	species (only after a generic name)
SPE	solid phase extraction
SPF	specific pathogen free
spp	subspecies
sq	square
SSD	sulphur specific detector
SSMS	spark source mass spectrometry
STEL	short term exposure limit
STMR	supervised trials median residue

Appendix 1 Standard Terms and Abbreviations

t	tonne (metric ton)
t _{1/2}	half-life (define method of estimation)
T ₃	tri-iodothyroxine
T ₄	thyroxine
TADI	temporary acceptable daily intake
TBC	tightly bound capacity
TCD	thermal conductivity detector
TC _{Lo}	toxic concentration, low
TID	thermionic detector, alkali flame detector
TD _{Lo}	toxic dose low
TDR	time domain reflectometry
TER	toxicity exposure ration
TER _I	toxicity exposure ration for initial exposure
TER _{ST}	toxicity exposure ration following repeated exposure
TER _{LT}	toxicity exposure ration following chronic exposure
tert	tertiary (in a chemical name)
TEP	typical end-use product
TGGE	temperature gradient gel electrophoresis
TIFF	tag image file format
TLC	thin layer chromatography
T _m	median tolerance limit
TLV	threshold limit value
TMDI	theoretical maximum daily intake
TMRC	theoretical maximum residue contribution
TMRL	temporary maximum residue limit
TOC	total organic carbon
Tremcard	Transport emergency card
tRNA	transfer ribonucleic acid
TSH	thyroid stimulating hormone (thyrotropin)
TWA	time weighted average
UDS	unscheduled DNA synthesis
UF	uncertainty factor (safety factor)
ULV	ultra low volume
UV	ultraviolet
v/v	volume ratio (volume per volume)
WBC	white blood cell
wk	week
wt	weight
w/v	weight per volume
ww	wet weight
w/w	weight per weight
XRFA	X-ray fluorescence analysis
yr	year
<	less than
≤	less than or equal to
>	greater than
≥	greater than or equal to

Part 2 Organisations and Publications

ACPA	American Crop Protection Association
ASTM	American Society for Testing and Materials
BA	Biological Abstracts (Philadelphia)
BART	Beneficial Arthropod Registration Testing Group
CA	Chemical Abstracts
CAB	Centre for Agriculture and Biosciences International
CAC	Codex Alimentarius Commission
CAS	Chemical Abstracts Service
CCFAC	Codex Committee on Food Additives and Contaminants
CCGP	Codex Committee on General Principles
CCPR	Codex Committee on Pesticide Residues
CCRVDF	Codex Committee on Residues of Veterinary Drugs in Food
CE	Council of Europe
CIPAC	Collaborative International Pesticides Analytical Council Ltd
COREPER	Comite des Representants Permanents
EC	European Commission
ECB	European Chemical Bureau
ECCA	European Crop Care Association
ECDIN	Environmental Chemicals Data and Information Network of the European Communities
ECDIS	European Environmental Chemicals Data and Information System
ECE	Economic Commission for Europe
ECETOC	European Chemical Industry Ecology and Toxicology Centre
ECLO	Emergency Centre for Locust Operations
ECMWF	European Centre for Medium Range Weather Forecasting
ECPA	European Crop Protection Association
EDEXIM	European Database on Export and Import of Dangerous Chemicals
EHC (number)	Environmental Health Criteria (number)
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of New Chemical Substances
EMIC	Environmental Mutagens Information Centre
EPA	Environmental Protection Agency
EPO	European Patent Office
EPPO	European and Mediterranean Plant Protection Organization
ESCORT	European Standard Characteristics of Beneficials Regulatory Testing
EU	European Union
EUPHIDS	European Pesticide Hazard Information and Decision Support System
EUROPOEM	European Predictive Operator Exposure Model
FAO	Food and Agriculture Organization of the UN
FOCUS	Forum for the Co-ordination of Pesticide Fate Models and their Use
FRAC	Fungicide Resistance Action Committee
GATT	General Agreement on Tariffs and Trade
GAW	Global Atmosphere Watch
GIFAP	Groupement International des Associations Nationales de Fabricants de Produits Agrochimiques (now known as GCPF)
GCOS	Global Climate Observing System
GCPF	Global Crop Protection Federation (formerly known as GIFAP)
GEDD	Global Environmental Data Directory

Appendix 1 Standard Terms and Abbreviations

GEMS	Global Environmental Monitoring System
GIEWS	Global Information and Early Warning System for Food and Agriculture
GRIN	Germplasm Resources Information Network
HRAC	Herbicide Resistance Action Committee
IARC	International Agency for Research on Cancer
IATS	International Academy of Toxicological Science
IBT	Industrial Bio-Test Laboratories
ICBB	International Commission of Bee Botany
ICBP	International Council for Bird Preservation
ICES	International Council for the Exploration of the Seas
ICPBR	International Commission for Plant-Bee Relationships
ILO	International Labour Organization
IMO	International Maritime Organisation
IOBC	International Organization for Biological Control of Noxious Animals and Plants
IPCS	International Programme on Chemical Safety
IRAC	Insecticide Resistance Action Committee
IRC	International Rice Commission
ISCO	International Soil Conservation Organization
ISO	International Organization for Standardization
IUPAC	International Union of Pure and Applied Chemistry
JECFA	FAO/WHO Joint Expert Committee on Food Additives
JFCMP	Joint FAO/WHO Food and Animal Feed Contamination Monitoring Programme
JMP	Joint Meeting on Pesticides (WHO/FAO)
JMPR	Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues (Joint Meeting on Pesticide Residues)
NATO	North Atlantic Treaty Organisation
NAFTA	North American Free Trade Agreement
NCI	National Cancer Institute (USA)
NCTR	National Centre for Toxicological Research (USA)
NGO	non-governmental organization
NTP	National Toxicology Programme (USA)
OECD	Organization for Economic Co-operation and Development
OLIS	On-line Information Service of OECD
PAN	Pesticide Action Network
RNN	Re-registration Notification Network
RTECS	Registry of Toxic Effects of Chemical Substances (USA)
SCPH	Standing Committee on Plant Health
SETAC	Society of Environmental Toxicology and Chemistry
SI	Système International d'Unités
SITC	Standard International Trade Classification
TOXLINE	Toxicology Information On-line
UN	United Nations
UNEP	United Nations Environment Programme
WCDP	World Climate Data Programme
WCP	World Climate Programme
WCRP	World Climate Research Programme

Appendix 1 Standard Terms and Abbreviations

WFP	World Food Programme
WHO	World Health Organization
WTO	World Trade Organization
WWF	World Wildlife Fund

APPENDIX 2

PREPARATION (FORMULATION) TYPES AND CODES*

Code	Description	Definition
AB	Grain bait	Special forms of bait.
AE	Aerosol dispenser	A container-held preparation which is dispersed generally by a propellant as fine droplets/particles upon actuation of a valve.
AL	Other liquids to be applied undiluted	Self defining.
BB	Block baits	Special forms of bait.
BR	Briquette	Solid block designed for controlled release of active ingredient into water.
CB	Bait concentrate	A solid or liquid intended for dilution before use as a bait.
CG	Encapsulated granule	A granule with a protective or release controlling coating.
CS	Capsule suspension	A stable suspension of capsules in a fluid normally intended for dilution with water before use.
DC	Dispersible concentrate	A liquid homogeneous preparation to be applied as a solid dispersion after dilution in water.
DP	Dustable powder	A free-flowing powder suitable for dusting.
DS	Powder for dry seed treatment	A powder for application in the dry state directly to seed.
EC	Emulsifiable concentrate	A liquid, homogenous preparation to be applied as an emulsion after dilution in water.
ED	Electrochargeable liquid	Special liquid preparation for electrostatic (electrodynamic) spraying.
EO	Emulsion, water in oil	A fluid, heterogeneous preparation consisting of a dispersion of fine globules of pesticide in water in a continuous organic liquid phase.
ES	Emulsion for seed treatment	A stable emulsion for application to the seed either directly or after dilution.
EW	Emulsion, oil in water	A fluid, heterogeneous preparation consisting of a dispersion of fine globules of pesticide in an organic liquid in a continuous water phase.
FD	Smoke tin	Special form of smoke generator.

Appendix 2 Preparation (Formulation) Types and Codes*

Code	Description	Definition
FG	Fine granule	A granule in the particle size range from 300 to 2500 μ .
FK	Smoke candle	A smoke generator in the form of a candle.
FP	Smoke cartridge	Special form of smoke generator.
FR	Smoke rodlet	Special form of smoke generator.
FS	Flowable concentrate for seed treatment	A stable suspension for application to the seed either directly or after dilution.
FT	Smoke tablet	Special form of smoke generator.
FU	Smoke generator	A combustible preparation generally solid, which upon ignition releases the active substances in the form of a smoke.
FW	Smoke pellet	Special form of smoke generator.
GA	Gas	A gas packed in pressure bottle or pressure tank.
GB	Granular bait	Special forms of bait.
GE	Gas generating product	A preparation which generates a gas by chemical reaction.
GG	Macrogranule	A granule in the particle size range from 2000 to 6000 μ .
GP	Flo-dust	Very fine dustable powder for pneumatic application in glass-houses.
GR	Granule	A free-flowing solid preparation of a defined granule size range ready for use.
GS	Grease	Very viscous preparation based on oil or fat.
HN	Hot fogging concentrate	A preparation suitable for application by fogging equipment either directly or after dilution.
KN	Cold fogging concentrate	A preparation suitable for application by cold fogging equipment, either directly or after dilution.
LA	Lacquer	A solvent based film-forming preparation.
LS	Solution for seed treatment	A solution for application to the seed either directly or after dilution.
MG	Microgranule	A granule in the particle size range from 100 to 600 μ .
OF	Oil miscible flowable (=oil active substances in a miscible suspension)	A stable suspension of concentrate fluid intended for dilution in an organic liquid before use.
OL	Oil miscible liquid	A liquid, homogenous preparation to be applied as a homogenous liquid after dilution in an organic liquid.

Appendix 2 Preparation (Formulation) Types and Codes*

Code	Description	Definition
OP	Oil dispersible powder	A powder preparation to be applied as a suspension after dispersion in an organic liquid.
PA	Paste	A water based film forming preparation.
PB	Plate bait	Special forms of bait.
PC	Gel or paste concentrate	A solid preparation to be applied as a gel or a paste after dilution with water.
PR	Plant rodlet	A small rodlet, usually a few centimetres in length and a few millimetres in diameter containing active substance.
PS	Seed coated with a pesticide	Self defining.
RB	Bait (ready for use)	A preparation designed to attract and be eaten by the target species.
SB	Scrap bait	Special forms of bait.
SC	Suspension concentrate (= flowable concentrate)	A stable suspension of active substance(s) in a fluid intended for dilution with water before use.
SE	Suspo-emulsion	A fluid, heterogeneous preparation consisting of a stable dispersion of active substance(s) in the form of solid particles and of fine globules in a continuous water phase.
SG	Water soluble granules	A preparation consisting of granules to be applied as a true solution of active substance after dissolution in water but may contain insoluble inert ingredients.
SL	Soluble concentrate	A liquid homogenous preparation to be applied as a true solution of the active substance after dilution with water.
SO	Spreading oil	A preparation designed to form a surface layer on application to water.
SP	Water soluble powder	A powder preparation to be applied as a true solution of the active substance after solution in water but which may contain insoluble inert ingredients.
SS	Water soluble powder for seed treatment	A powder to be dissolved in water before application to the seed.
SU	Ultra low volume (ULV) suspension	A suspension ready for use through ULV equipment.
TB	Tablet	Solid preparation in the form of small, flat plates for dissolution in water.
TP	Tracking powder	A rodenticidal contact preparation in powder form.

Appendix 2 **Preparation (Formulation) Types and Codes***

Code Description		Definition
UL	Ultra low volume (ULV) liquid	A homogenous liquid ready for use through ULV equipment.
VP	Vapour releasing product	A preparation containing one or more volatile ingredients, the vapours of which are released into the air. Evaporation rate normally is controlled by using suitable preparations and/or dispensers.
WG	Water dispersible	A preparation granule consisting of granules to be applied after disintegration and dispersion in water.
WP	Wettable powder	A powder preparation to be applied as a suspension after dispersion in water.
WS	Water dispersible powder for slurry seed treatment	A powder to be dispersed at high concentration in water before application as a slurry to the seed.
XX	Others	

*based upon the catalogue of Pesticide Formulation types and International Coding Systems, developed by GIFAP in co-operation with the German working group on documentation questions. (Arbeitsgruppe EDV Pflanzenschutz Versuchswesen). GIFAP Technical Monograph No 2. 1989.

APPENDIX 3

GUIDANCE WITH RESPECT TO PAGINATION, LAY-OUT, TABLES AND REFERENCES

1 General

- 1.1 Documents should be produced using a standard word-processing programme, preferably using a Windows[®] environment.
- 1.2 Both disk and hard copies versions of documents should be submitted.
- 1.3 One copy of the monograph should be produced with text on one side of pages only, with line spacing of 1½ - or doubled spacing, to facilitate editing. In all copies, tables can be single spaced.
- 1.4 All programme codes for pagination, font, page numbering, *etc.* should be at the start of the document. If possible, such codes should not be repeated in the text unless a temporary change is unavoidable. Codes scattered throughout the body of the text can make editing difficult.

2 Format

- 2.1 As the text of the monograph is likely to be printed using a 10 point font, such a font, if available on the system used, should be used.
- 2.2 Left/right margins should be 2.5 cm and top/bottom margins 12.5 mm. Lines should be fully justified, with widow/orphan protection.
- 2.3 Tabs for general text should be set at 12.5 mm intervals. If tabs are needed in tables they should be re-set so that a single tab, not a series of tabs, separates sections.
- 2.4 A page header should be introduced on the top left of each page of the document to show the title of the document, the level and where relevant the chapter.

3 Page numbering

Page numbering should be set to "Top centre".

4 Tables

- 4.1 Tables should be inserted in their intended positions in the text or thereabouts, not at the end of the monograph, where it is feasible to do so. Although it is customary to insert tables at the end of articles for publication in journals, different considerations apply to the production of camera-ready copy. It facilitates editing if tables are in their correct places from the outset.
- 4.2 Where possible, a spreadsheet program *e.g.* Lotus 123[®] or Excel[®], should be used in compiling tables as it facilitates editing.
- 4.3 As a general rule, separate items of information should be recorded in separate cells of tables.
- 4.4 Portrait (vertical) rather than landscape (horizontal) lay-out for tables should if possible be used. Wide tables can be accommodated vertically by reducing the font size. It is particularly important that standard margins are used on all pages including pages with tables. Tables which occupy the full width of a page can be very difficult to edit.

- 4.6 The caption of a table should not be included within the table itself.
- 4.7 It is generally better not to construct a table covering several pages as a series of separate single-page tables are easier to follow, even though this often results in a number of partly-filled pages.

5 **Diagrams**

These can be hand-drawn or photocopies, but where possible, a suitable graphics package should be used.

6 **References**

References to reports, journals and books, included in the text of monographs (Level 2 and Annex B) should include the first author and year of publication of the reference. Where more than one reference for a particular author is listed in any one year, letters (a, b, c, *etc.*) should follow the year of publication, to indicate the particular reference concerned. In the case of unpublished reports, the year in which the report is finalized, rather than the year of publication, should be used. Thus references included in the text of monographs should take the following form -

In the Draize intracutaneous allergy test two groups of male Pirbright White guinea-pigs received 10 injections of *active substance x* or the formulation agent on its own, followed by a further injection after a 14 days treatment-free interval. No evidence of sensitising properties was found (Mihail, 1981a).

APPENDIX 4

SUGGESTED ORDER FOR THE PREPARATION OF EACH OF THE FOUR LEVELS AND THE THREE ANNEXES OF THE MONOGRAPHS TO BE PREPARED BY RAPPORTEUR MEMBER STATES

Level 1

- 1 *Statement of subject matter and purpose for which the monograph was prepared*
- 1.1 *Purpose for which the monograph was prepared* (Dossier Document A)
- 1.2 *Summary and assessment of information relating to the collective provision of dossiers* (Dossier Document B)¹⁴
- 1.3 *Identity of the active substance* (Annex IIA 1) (Dossier Documents J, K-II and L-II)
 - 1.3.1 Name and address of applicant(s) for inclusion of the active in Annex I (Annex IIA 1.1)
 - 1.3.2 Common name and synonyms (Annex IIA 1.3)
 - 1.3.3 Chemical name (Annex IIA 1.4)
 - 1.3.4 Manufacturer's development code number (Annex IIA 1.5)
 - 1.3.5 CAS, EEC and CIPAC numbers (Annex IIA 1.6)
 - 1.3.6 Molecular and structural formulae, molecular mass (Annex IIA 1.7)
 - 1.3.7 Manufacturer or manufacturers of the active substance (Annex IIA 1.2)
 - 1.3.8 Method or methods of manufacture (Annex IIA 1.8)¹⁴
 - 1.3.9 Specification of purity of the active substance (Annex IIA 1.9)
 - 1.3.10 Identity of isomers, impurities and additives (Annex IIA 1.10)¹⁴
 - 1.3.11 Analytical profile of batches (Annex IIA 1.11)¹⁴
- 1.4 *Identity of the plant protection product* (Annex IIA 3.1; IIIA 1) (Dossier Documents J, K-II, L-II, K-III and L-III) (to be included for each preparation for which an Annex III dossier was submitted)
 - 1.4.1 Current, former and proposed trade names and development code numbers (Annex IIIA 1.3)

¹⁴ If confidentiality in accordance with Article 14 of Directive 91/414/EEC has been claimed and accepted, the information concerned should not be included. Instead a reference should be included to the relevant paragraphs of Annex C in which the information concerned is included.

Appendix 4 **Suggested Order for the Preparation of each of the Four Levels and the Three Annexes of the Monographs to be Prepared by Rapporteur Member States - Level 1 and 2**

- 1.4.2 Manufacturer or manufacturers of the plant protection product (Annex IIIA 1.2)
- 1.4.3 Type of the preparation and code (Annex IIIA 1.5)
- 1.4.4 Function (Annex IIA 3.1; Annex IIIA 1.6)
- 1.4.5 Composition of the preparation (III 1.4) ¹⁴

- 1.5 *Uses of the plant protection product* (Annex IIA 3.2 to 3.4; Annex IIIA 3.1 to 3.7, 3.9 and 12.1) (Dossier Documents C, D and E) (to be included for each preparation for which an Annex III dossier was submitted)
- 1.5.1 Field of use (Annex IIA 3.3; Annex IIIA 3.1)
- 1.5.2 Effects on harmful organisms (Annex IIA 3.2; Annex IIIA 3.2)
- 1.5.3 Summary of intended uses (Annex IIA 3.4; Annex IIIA 3.3 to 3.7, 3.9)
- 1.5.4 Information on authorizations in EU Member States (Annex IIIA 12.1)

Level 2

- 2 ***Reasoned statement of the overall conclusions drawn by the Rapporteur Member State***
- 2.1.1 *Identity*
- 2.1.2 *Physical and chemical properties*
- 2.1.3 *Details of uses and further information*
- 2.1.4 *Classification and labelling*

- 2.2 *Methods of analysis*
- 2.2.1 Analytical methods for analysis of the active substance as manufactured
- 2.2.2 Analytical methods for formulation analysis
- 2.2.3 Analytical methods for residue analysis

Appendix 4 **Suggested Order for the Preparation of each of the Four Levels and the Three Annexes of the Monographs to be Prepared by Rapporteur Member States - Level 2**

- 2.3 *Impact on human and animal health*
- 2.3.1 Effects having relevance to human and animal health arising from exposure to the active substance or to impurities contained in the active substance or to their transformation products
- 2.3.2 ADI
- 2.3.3 ARfD (acute reference dose)
- 2.3.4 AOEL
- 2.3.5 Drinking water limit
- 2.3.6 Impact on human or animal health arising from exposure to the active substance or to impurities contained in it

- 2.4 *Residues*
- 2.4.1 Definition of the residues relevant to MRLs
- 2.4.2 Residues relevant to consumer safety
- 2.4.3 Residues relevant to worker safety
- 2.4.4 Proposed EU MRLs and compliance with existing MRLs
- 2.4.5 Proposed EU import tolerances and compliance with existing MRLs
- 2.4.6 Basis for differences, if any, in conclusions reached having regard to established or proposed CAC MRLs

- 2.5 *Fate and behaviour in the environment*
- 2.5.1 Definition of the residues relevant to the environment
- 2.5.2 Fate and behaviour in soil
- 2.5.3 Fate and behaviour in water
- 2.5.4 Fate and behaviour in air

- 2.6 *Effects on non-target species*
- 2.6.1 Effects on terrestrial vertebrates

Appendix 4 Suggested Order for the Preparation of each of the Four Levels and the Three Annexes of the Monographs to be Prepared by Rapporteur Member States - Level 2 and Level 3

- 2.6.2 Effects on aquatic species
- 2.6.3 Effects on bees and other arthropod species
- 2.6.4 Effects on earthworms and other soil macro-organisms
- 2.6.5 Effects on soil micro-organisms
- 2.6.6 Effects on other non-target organisms (flora and fauna)
- 2.6.7 Effects on biological methods of sewage treatment

Overall Conclusions

- Appendix 1 Standard terms and abbreviations
- Appendix 2 Specific terms and abbreviations
- Appendix 3 Listing of end points

Level 3

- 3 ***Proposed decision with respect to the application for inclusion of the active substance in Annex I***
- 3.1 Background to the proposed decision
- 3.2 Proposed decision concerning inclusion in annex I
- 3.3 Rational for the postponement of the decision to include the active substance in Annex I, or for the conditions and restrictions to be associated with a proposed inclusion in Annex I, as appropriate

Level 4

- 4 ***Further information to permit a decision to be made, or to support a review of the conditions and restrictions associated with the proposed inclusion in Annex I***
- 4.1 Identity of the active substance
- 4.2 Physical and chemical properties of the active substance
- 4.3 Data on application and further information
- 4.4 Classification, packaging and labelling
- 4.5 Methods of analysis
- 4.6 Toxicology and metabolism
- 4.7 Residue data
- 4.8 Environmental fate and behaviour
- 4.9 Ecotoxicology

Annex A

- A ***List of the tests and studies submitted and of information available***
(Annex IIA and Annex IIIA) (Dossier Documents J, I, K-II, L-II, K-III and L-III and other information available to or brought to the attention of the Rapporteur Member State)
- A.1 *Identity* (Annex IIA 1, 3.1 to 3.4; Annex IIIA 1, 3.1 to 3.7, 3.9 and 12.1)
- A.2 *Physical and chemical properties* (Annex IIA 2; Annex IIIA 2)
- A.3 *Further information* (Annex IIA 3; Annex IIIA 3 and 4)
- A.4 *Classification, packaging and labelling* (Annex IIA 10; Annex IIIA 12.3 and 12.4)
- A.5 *Methods of analysis* (Annex IIA 4; Annex IIIA 5)
- A.6 *Toxicology and metabolism* (Annex IIA 5; Annex IIIA 7)
- A.7 *Residue data* (Annex IIA 6; Annex IIIA 8 and 12.2)
- A.8 *Environmental fate and behaviour* (Annex IIA 7; Annex IIIA 9)
- A.9 *Ecotoxicology* (Annex IIA 8; Annex IIIA 10)

Annex B

B *Rapporteur Member States summary, evaluation and assessment of the data and information*

B.1 *Identity*

B.1.1 Identity of the active substance (Annex IIA 1 and 3.1)

B.1.2 Identity of the plant protection product (annex IIIA 1)

B.1.3 References relied on

B.2 *Physical and chemical properties*

B.2.1 Physical and chemical properties of the active substance (Annex IIA 2)

B.2.2 Physical, chemical and technical properties of the plant protection products (Annex IIIA 2)

B.2.3 References relied on

B.3 *Data on application and further information*

B.3.1 Data on application relevant to the active substance (Annex IIA 3.1 to 3.6)

B.3.2 Data on application relevant to the plant protection product (Annex IIIA 3)

B.3.3 Summary of data on application

B.3.4 Further information on the active substance (Annex IIA 3.7 to 3.9)

B.3.5 Further information on the plant protection product (Annex IIIA 4)

B.3.6 References relied on

B.4 *Proposals for classification and labelling*

B.4.1 Proposals for the classification and labelling of the active substance (Annex IIA 10)

B.4.2 Proposals for the classification and labelling of preparations (Annex IIIA 12.3 and 12.4)

B.4.3 References relied on

B.5 *Methods of analysis*

B.5.1 Analytical methods for formulation analysis (Annex IIA 4.1; Annex IIIA 5.1)

B.5.2 Analytical methods (residue) for plants, plant products, foodstuffs of plant and animal origin, feedingstuffs (Annex IIA 4.2.1; Annex IIIA 5.2)

B.5.3 Analytical methods (residue) soil, water, air (Annex IIA 4.2.2 to 4.2.4; Annex IIIA 5.2)

Appendix 4 Suggested Order for the Preparation of each of the Four Levels and the Three Annexes of the Monographs to be Prepared by Rapporteur Member States - Annex B

- B.5.4 Analytical methods (residue) for body fluids and tissues (Annex IIA 4.2.5; Annex IIIA 5.2)
- B.5.5 Evaluation and assessment
- B.5.6 References relied on

- B.6 *Toxicology and metabolism*
- B.6.1 Absorption, distribution, excretion and metabolism (toxicokinetics) (Annex IIA 5.1)
- B.6.2 Acute toxicity including irritancy and skin sensitization (Annex IIA 5.2)
- B.6.3 Short-term toxicity (Annex IIA 5.3)
- B.6.4 Genotoxicity (Annex IIA 5.4)
- B.6.5 Long-term toxicity and carcinogenicity (Annex IIA 5.5)
- B.6.6 Reproductive toxicity (Annex IIA 5.6)
- B.6.7 Delayed neurotoxicity (Annex IIA 5.7)
- B.6.8 Further toxicological studies (Annex IIA 5.8)
- B.6.9 Medical data and information (Annex IIA 5.9)
- B.6.10 Summary of mammalian toxicology and proposed ADI, AOEL, ARfD and drinking water limit (Annex IIA 5.10)
- B.6.11 Acute toxicity including irritancy and skin sensitization of preparations (Annex IIIA 7.1)
- B.6.12 Dermal absorption (Annex IIIA 7.3)
- B.6.13 Toxicological data on non active substances (Annex IIIA 7.4 and point 4 of the introduction)
- B.6.14 Exposure data (Annex IIIA 7.2)
- B.6.15 References relied on

- B.7 *Residue data*
- B.7.1 Metabolism, distribution and expression of residues in plants (Annex IIA 6.1 and Annex IIIA 8.1)
- B.7.2 Metabolism, distribution and expression of residues in livestock (Annex IIA 6.2 and Annex IIIA 8.1)
- B.7.3 Definition of the residue (Annex IIA 6.7; Annex IIIA 8.6)
- B.7.4 Use pattern
- B.7.5 Identification of critical GAPS
- B.7.6 Residues resulting from supervised trials (Annex IIA 6.3; Annex IIIA 8.2)

Appendix 4 **Suggested Order for the Preparation of each of the Four Levels and the Three Annexes of the Monographs to be Prepared by Rapporteur Member States - Annex B**

- B.7.7 Effects of industrial processing and/or household preparation (Annex IIA 6.5; Annex IIIA 8.4)
- B.7.8 Livestock feeding studies (Annex IIA 6.4; Annex IIIA 8.3)
- B.7.9 Residues in succeeding or rotational crops (Annex IIA 6.6; Annex III 8.5)
- B.7.10 Proposed pre-harvest intervals for envisaged uses, or withholding periods, in the case of post-harvest uses (Annex IIA 6.8; Annex IIIA 8.7)
- B.7.11 Community MRLs and MRLs in EU Member States (Annex IIIA 12.2)
- B.7.12 Proposed EU MRLs and justification for the acceptability of those MRLs (Annex IIA 6.7; Annex IIIA 8.6)
- B.7.13 Proposed EU Import tolerances and justification for the acceptability of those residues
- B.7.14 Basis for differences, if any, in conclusions reached having regard to established or proposed CAC MRLs
- B.7.15 Estimates of potential and actual dietary exposure through diet and other means (Annex IIA 6.9; Annex IIIA 8.8)
- B.7.16 Summary and evaluation of residue behaviour (Annex IIA 6.10; Annex IIIA 8.9)
- B.7.17 References relied on

- B.8 *Environmental fate and behaviour*
- B.8.1 Route and rate of degradation in soil (Annex IIA 7.1.1; Annex IIIA 9.1.1)
- B.8.2 Adsorption, desorption and mobility in soil (Annex IIA 7.1.2 and 7.1.3; Annex IIIA 9.1.2)
- B.8.3 Predicted environmental concentrations in soil (PEC_s) (Annex IIIA 9.1.3)
- B.8.4 Fate and behaviour in water (Annex IIA 7.2.1; Annex IIIA 9.2.1, 9.2.3)
- B.8.5 Impact on water treatment procedures (Annex IIIA 9.2.2)
- B.8.6 Predicted environmental concentrations in surface water and in ground water (PEC_{sw}, PEC_{gw}) (Annex IIIA 9.2.1, 9.2.3)
- B.8.7 Fate and behaviour in air (Annex IIA 7.2.2; Annex IIIA 9.3)
- B.8.8 Predicted environmental concentrations in air (PEC_a) (Annex IIIA 9.3)
- B.8.9 Definition of the residue (Annex IIA 7.3)
- B.8.10 References relied on

- B.9 *Ecotoxicology*
- B.9.1 Effects on birds (Annex IIA 8.1; Annex IIIA 10.1)
- B.9.2 Effects on aquatic organisms (Annex IIA 8.2; Annex IIIA 10.2)

Appendix 4 Suggested Order for the Preparation of each of the Four Levels and the Three Annexes of the Monographs to be Prepared by Rapporteur Member States - Annex B

- B.9.3 Effects on other terrestrial vertebrates (Annex IIIA 10.3)
- B.9.4 Effects on bees (Annex IIA 8.3.1; Annex IIIA 10.4)
- B.9.5 Effects on other arthropod species (Annex IIA 8.3.2; Annex IIIA 10.5)
- B.9.6 Effects on earthworms (Annex IIA 8.4; Annex IIIA 10.6.1)
- B.9.7 Effects on other soil non-target macro-organisms (Annex IIIA 10.6.2)
- B.9.8 Effects on soil non-target micro-organisms (Annex IIA 8.5; Annex IIIA 10.7)
- B.9.9 Effects on other non-target organisms (flora and fauna) believed to be at risk (Annex IIA 8.6)
- B.9.10 Effects on biological methods of sewage treatment (Annex IIA 8.7)
- B.9.11 References relied on

Appendix 1 Standard terms and abbreviations

Appendix 2 Specific terms and abbreviations

Annex C

C *Confidential information and summary and assessment of information relating to the collective submission of dossiers*

C.1 *Confidential information*

C.1.1 Detailed information on the manufacturing process or processes for the active substance

C.1.2 Detailed specification of the active substance

C.1.3 Detailed specification of the preparations

C.1.4 Other confidential information

C.2 *Summary and assessment of information relating to collective submission of dossiers*

C.2.1 Summary of the information and documentation provided (Dossier Document B)

C.2.2 Assessment of the information and documentation provided

C.2.3 Conclusion as to whether the steps taken by notifiers were reasonable or not

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		

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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

FORM FOR USE IN REPORTING DETAILS OF INTENDED USES (GAP INFORMATION)

APPENDIX 5

APPENDIX 6

FORMAT FOR THE LISTING OF END POINTS TO BE INCLUDED IN THE REASONED STATEMENT OF THE OVERALL CONCLUSIONS DRAWN BY THE RAPPORTEUR MEMBER STATE (LEVEL 2)¹⁵

Chapter 2.1: Identity, Physical and Chemical Properties, Details of Uses, Further Information, and Proposed Classification and Labelling

Active substance (ISO Common Name)	
Function (<i>e.g.</i> fungicide)	
Rapporteur Member State	

Identity (Annex IIA, point 1)

Chemical name (IUPAC)	
Chemical name (CA)	
CIPAC No	
CAS No	
EEC No (EINECS or ELINCS)	
FAO Specification (including year of publication)	
Minimum purity of the active substance as manufactured (g/kg)	
Identity of relevant impurities (of toxicological, environmental and/or other significance) in the active substance as manufactured (g/kg)	
Molecular formula	
Molecular mass	
Structural formula	

¹⁵ Other end points will be relevant in particular cases - decisions as to the additional end points to be included can only be made on a case by case basis.

Rapporteur Member State	Month and year	Active Substance (Name)	page of
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Physical-chemical properties (Annex IIA, point 2)

Melting point (state purity)	
Boiling point (state purity)	
Temperature of decomposition	
Appearance (state purity)	
Relative density (state purity)	
Surface tension	
Vapour pressure (in Pa, state temperature)	
Henry's law constant (Pa m ³ mol ⁻¹)	
Solubility in water (g/l or mg/l, state temperature)	pH_____:
	pH_____:
	pH_____:
Solubility in organic solvents (in g/l or mg/l, state temperature)	

Partition co-efficient (log P _{OW}) (state pH and temperature)	pH_____:
	pH_____:
	pH_____:
Hydrolytic stability (DT ₅₀) (state pH and temperature)	pH_____:
	pH_____:
	pH_____:
Dissociation constant	
UV/VIS absorption (max.) (if absorption > 290 nm state ε at wavelength)	
Photostability (DT ₅₀) (aqueous, sunlight, state pH)	
Quantum yield of direct phototransformation in water at Σ > 290 nm	
Flammability	
Explosive properties	

Appendix 6 **Format for the Listing of End Points to be Included in the Reasoned Statement of the Overall Conclusions Drawn by the Rapporteur Member State (Level 2)**

Rapporteur Member State	Month and year	Active Substance (Name)	page of
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Classification and proposed labelling (Annex IIA, point 10)

with regard to physical/chemical data	
with regard to toxicological data	
with regard to fate and behaviour data	
with regard to ecotoxicological data	

Chapter 2.2: Methods of Analysis

Analytical methods for the active substance (Annex IIA, point 4.1)

Technical as (principle of method)	
Impurities in technical as (principle of method)	
Plant protection product (principle of method)	

Analytical methods for residues (Annex IIA, point 4.2)

Food/feed of plant origin (principle of method and LOQ for methods for monitoring purposes)	
Food/feed of animal origin (principle of method and LOQ for methods for monitoring purposes)	
Soil (principle of method and LOQ)	
Water (principle of method and LOQ)	
Air (principle of method and LOQ)	
Body fluids and tissues (principle of method and LOQ)	

Rapporteur Member State	Month and year	Active Substance (Name)	page of
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Chapter 2.3: Impact on Human and Animal Health

Absorption, distribution, excretion and metabolism in mammals (Annex IIA, point 5.1)

Rate and extent of absorption:	
Distribution:	
Potential for accumulation:	
Rate and extent of excretion:	
Metabolism in animals	
Toxicologically significant compounds (animals, plants and environment)	

Acute toxicity (Annex IIA, point 5.2)

Rat LD ₅₀ oral	
Rat LD ₅₀ dermal	
Rat LC ₅₀ inhalation	
Skin irritation	
Eye irritation	
Skin sensitization (test method used and result)	

Short term toxicity (Annex IIA, point 5.3)

Target / critical effect	
Lowest relevant oral NOAEL / NOEL	
Lowest relevant dermal NOAEL / NOEL	
Lowest relevant inhalation NOAEL / NOEL	

Genotoxicity (Annex IIA, point 5.4)

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Rapporteur Member State	Month and year	Active Substance (Name)	page of
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Long term toxicity and carcinogenicity (Annex IIA, point 5.5)

Target/critical effect	
Lowest relevant NOAEL / NOEL	
Carcinogenicity	

Reproductive toxicity (Annex IIA, point 5.6)

Reproduction target / critical effect	
Lowest relevant reproductive NOAEL / NOEL	
Developmental target / critical effect	
Lowest relevant developmental NOAEL / NOEL	

Neurotoxicity / Delayed neurotoxicity (Annex IIA, point 5.7)

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Other toxicological studies (Annex IIA, point 5.8)

.....	
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Medical data (Annex IIA, point 5.9)

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Summary (Annex IIA, point 5.10)

	Value	Study	Safety factor
ADI			
AOEL			
Drinking water limit			
ARfD (acute reference dose)			

Dermal absorption (Annex IIIA, point 7.3)

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Acceptable exposure scenarios (including method of calculation)

Operator	
Workers	
Bystanders	

Appendix 6 **Format for the Listing of End Points to be Included in the Reasoned Statement of the Overall Conclusions Drawn by the Rapporteur Member State (Level 2)**

Rapporteur Member State	Month and year	Active Substance (Name)	page of
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Chapter 2.4: Residues

Metabolism in plants (Annex IIA, point 6.1 and 6.7, Annex IIIA, point 8.1 and 8.6)

Plant groups covered	
Rotational crops	
Plant residue definition for monitoring	
Plant residue definition for risk assessment	
Conversion factor (monitoring to risk assessment)	

Metabolism in livestock (Annex IIA, point 6.2 and 6.7, Annex IIIA, point 8.1 and 8.6)

Animals covered	
Animal residue definition for monitoring	
Animal residue definition for risk assessment	
Conversion factor (monitoring to risk assessment)	
Metabolism in rat and ruminant similar (yes/no)	
Fat soluble residue: (yes/no)	

Residues in succeeding crops (Annex IIA, point 6.6, Annex IIIA, point 8.5)

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Stability of residues (Annex IIA, point 6 introduction, Annex IIIA, point 8 introduction)

.....	
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Residues from livestock feeding studies (Annex IIA, point 6.4, Annex IIIA, point 8.3)

Intakes by livestock ≥ 0.1 mg/kg diet/day:	Ruminant: yes/no	Poultry: yes/no	Pig: yes/no
Muscle			
Liver			
Kidney			
Fat			
Milk			
Eggs			

Appendix 6 **Format for the Listing of End Points to be Included in the Reasoned Statement of the Overall Conclusions Drawn by the Rapporteur Member State (Level 2)**

Rapporteur Member State	Month and year	Active Substance (Name)	page of
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Chapter 2.5: Fate and Behaviour in the Environment

Route of degradation (aerobic) in soil (Annex IIA, point 7.1.1.1.1)

Mineralization after 100 days	
Non-extractable residues after 100 days	
Relevant metabolites - name and/or code, % of applied (range and maximum)	

Route of degradation in soil - Supplemental studies (Annex IIA, point 7.1.1.1.2)

Anaerobic degradation	
Soil photolysis	

Rate of degradation in soil (Annex IIA, point 7.1.1.2, Annex IIIA, point 9.1.1)

Method of calculation	
Laboratory studies (range or median, with n value, with r ² value)	DT _{50lab} (20°C, aerobic):
	DT _{90lab} (20°C, aerobic):
	DT _{50lab} (10°C, aerobic):
	DT _{50lab} (20°C, anaerobic):
	degradation in the saturated zone:
Field studies (state location, range or median with n value)	DT _{50f} :
	DT _{90f} :
Soil accumulation and plateau concentration	

Soil adsorption/desorption (Annex IIA, point 7.1.2)

K _f /K _{oc}	
K _d	
pH dependence (yes / no) (if yes type of dependence)	

Mobility in soil (Annex IIA, point 7.1.3, Annex IIIA, point 9.1.2)

Column leaching	
Aged residues leaching	
Lysimeter/ field leaching studies	

Appendix 6 **Format for the Listing of End Points to be Included in the Reasoned Statement of the Overall Conclusions Drawn by the Rapporteur Member State (Level 2)**

Rapporteur Member State	Month and year	Active Substance (Name)	page of
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PEC (soil) (Annex IIIA, point 9.1.3)

Method of calculation	
Application rate	

PEC _(s)	Single application	Single application	Multiple application	Multiple application
	Actual	Time weighted average	Actual	Time weighted average
Initial				
Short term 24h				
2d				
4d				
Long term 7d				
28d				
50d				
100d				

Route and rate of degradation in water (Annex IIA, point 7.2.1)

Hydrolysis of active substance and relevant metabolites (DT ₅₀) (state pH and temperature)	pH_____:
	pH_____:
	pH_____:
Photolytic degradation of active substance and relevant metabolites	
Readily biodegradable (yes/no)	
Degradation in water/sediment	- DT ₅₀ water - DT ₉₀ water - DT ₅₀ whole system - DT ₉₀ whole system
Mineralization	
Non-extractable residues	
Distribution in water / sediment systems (active substance)	
Distribution in water / sediment systems (metabolites)	

Rapporteur Member State	Month and year	Active Substance (Name)	page of
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PEC (surface water) (Annex IIIA, point 9.2.3)

Method of calculation

Application rate

Main routes of entry

PEC _(sw)	Single application	Single application	Multiple application	Multiple application
	Actual	Time weighted average	Actual	Time weighted average
Initial				
Short term 24h 2d 4d				
Long term 7d 14d 21d 28d 42d				

PEC (sediment)

Method of calculation

Application rate

PEC _(sed)	Single application	Single application	Multiple application	Multiple application
	Actual	Time weighted average	Actual	Time weighted average
Initial				
Short term				
Long term				

PEC (ground water) (Annex IIIA, point 9.2.1)

Method of calculation and type of study (e.g. modelling, monitoring, lysimeter)

Application rate

Rapporteur Member State	Month and year	Active Substance (Name)	page of
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PEC_(gw)

Maximum concentration

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Average annual concentration

--

Fate and behaviour in air (Annex IIA, point 7.2.2, Annex III, point 9.3)

Direct photolysis in air

--

Quantum yield of direct phototransformation

--

Photochemical oxidative degradation in air

Latitude: Season: DT ₅₀
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Volatilization

from plant surfaces:

from soil:

PEC (air)

Method of calculation

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PEC_(a)

Maximum concentration

--

Definition of the Residue (Annex IIA, point 7.3)

Relevant to the environment

--

Monitoring data, if available (Annex IIA, point 7.4)

Soil (indicate location and type of study)

--

Surface water (indicate location and type of study)

--

Ground water (indicate location and type of study)

--

Air (indicate location and type of study)

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Appendix 6 **Format for the Listing of End Points to be Included in the Reasoned Statement of the Overall Conclusions Drawn by the Rapporteur Member State (Level 2)**

Rapporteur Member State	Month and year	Active Substance (Name)	page of
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Application rate (kg as/ha)	Crop	Organism	Time-scale	Distance (m)	TER	Annex VI Trigger

Bioconcentration

Bioconcentration factor (BCF)	
Annex VI Trigger for the bioconcentration factor	
Clearance time (CT ₅₀) (CT ₉₀)	
Level of residues (%) in organisms after the 14 day depuration phase	

Effects on honeybees (Annex IIA, point 8.3.1, Annex IIIA, point 10.4)

Acute oral toxicity	
Acute contact toxicity	

Hazard quotients for honey bees (Annex IIIA, point 10.4)

Application rate (kg as/ha)	Crop	Route	Hazard quotient	Annex VI Trigger
Laboratory tests				

Field or semi-field tests

Effects on other arthropod species (Annex IIA, point 8.3.2, Annex IIIA, point 10.5)

Species	Stage	Test	Dose	Endpoint	Effect	Annex VI
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Appendix 6

Format for the Listing of End Points to be Included in the Reasoned Statement of the Overall Conclusions Drawn by the Rapporteur Member State (Level 2)

Rapporteur Member State	Month and year	Active Substance (Name)	page of
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		Substance	(kg as/ha)		Trigger
Laboratory tests					

Field or semi-field tests

Effects on earthworms (Annex IIA, point 8.4, Annex IIIA, point 10.6)

Acute toxicity	
Reproductive toxicity	

Toxicity/exposure ratios for earthworms (Annex IIIA, point 10.6)

Application rate (kg as/ha)	Crop	Time-scale	TER	Annex VI Trigger

Effects on soil micro-organisms (Annex IIA, point 8.5, Annex IIIA, point 10.7)

Nitrogen mineralization	
Carbon mineralization	

APPENDIX 7

FORMAT FOR THE LISTING OF TEST AND STUDY REPORTS AND OTHER DOCUMENTATION EVALUATED

(Annex A - list of Annex II and Annex III information tests and studies evaluated)

- 1 As indicated in paragraph 4.5.1, the listing should cover each separate chapter specified for the preparation of the evaluation and assessment to be included as Annex A of the Monograph. It should include a listing of all test and study reports, test guidelines, and published papers submitted in support of the application (Documents J, K and L and where relevant I) and other relevant information available to, or brought to the attention of, the Rapporteur Member State.
- 2 Within chapters, references should be listed alphabetically by first author. Where there is more than one reference for a particular author (first author), the references concerned should be listed in chronological order - the most recent being listed last. In cases where for a particular author, more than one reference is listed for any one year, the references should be distinguished by inserting letters after the year *i.e.* a, b, c, *etc.*, as appropriate.
- 3 For each reference, the following indications should be provided -
 - (i) the Annex IIA or IIIA point to which it relates, the reference number and the year of the report or publication;
 - (ii) for each test and study report, test guidelines, and published paper, its title, source, company and report number;
 - (iii) whether it is published or unpublished;
 - (iv) whether, or not, it was conducted in compliance with the principles of GLP or the requirements of points 2.2 and 2.3 of the introduction to Annex II to Directive 93/71/EEC¹⁶, as appropriate;
 - (v) the owner of the test or study concerned - the codes contained in Annex II to Commission Regulation (EC) No 933/94¹⁷, can be used to identify the companies concerned; and
 - (vi) whether or not protection in accordance with the provisions of Article 13 (3) (d) of Directive 91/414/EEC is claimed.
- 4 References which relate to more than one chapter should be listed in each relevant chapter. Where, for existing active substances, more than one dossier is submitted, the reference list should reflect all the test and study reports, test guidelines, and published papers submitted. Those references not submitted by applicants for inclusion of the active substance in Annex I, but which are available to, or are brought to the attention of the Rapporteur Member State, should be included. Within the listing for each chapter, the references relevant to Annex II should be presented first and be followed by the references relevant to Annex III. Where more than one Annex III dossier is submitted in support of an application, care must be taken to indicate the preparation to which particular test and study reports, test guidelines, and published papers relate.
- 5 The reference lists that follow are intended to be illustrative of the required approach and relate to a fictitious compound, *active substance XXX 1111*.

¹⁶ see footnotes 8 and 12

¹⁷ OJ No L 107, 28. 4. 1994, p 8

Active Substance - XXX 1111 Name of Competent Authority Month & Year List Compiled

Section A.6, Toxicology and Metabolism (Annex IIA, Point 5, Annex IIIA, Point 7)

Author(s)	Annex point / reference number	Year	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant), Published or not	Data Protection Claimed Y/N	Owner
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Annex II Data and Information

Bomann, W.	IIA, 5.2/01	1991	XXX 1111 / study for acute oral toxicity in rats. Organics Inc Report No: 19852 GLP, Unpublished	Y ¹⁸	ORG
Casida, J.E., Gaughan, L.C, Ruzo, L.O.	IIA, 5.1/01	1979	Comparative metabolism of pyrethroids derived from 3-phenoxybenzyl and α -cyano-3-phenoxybenzyl alcohols. Advances in pesticide science, Fourth International Congress of Pesticide Chemistry, Zürich, Switzerland, July 24-38, 1978, part 2, 182-189 Not GLP, Published	N	-
Chopade, H.M., McCann, S.A., Gentile, C.C.	IIA, 5.1/02	1983	The distribution and metabolism of XXX 1111 in laying hens. Organics Inc Report No: MR86044 Not GLP, Unpublished	N	ORG
Eben, A., Fuchs, R., Kurz, J., Wunsche, C., Flucke, W.	IIA, 5.1/06	1987	Biotransformation of XXX 1111 in the chicken after oral administration of a high dose. Organics Inc Report No: 15849 GLP, Unpublished	N	ORG
Eben, A., Heimann, K.G, Machemer, L.	IIA, 5.1/04	1982a	Comparative study of rats on absorption of XXX 1111 after single oral administration in polyethylene glycol 400 or cremophor El/water as formulation vehicle. Organics Inc Report No: 10715 Not GLP, Unpublished	N	ORG
Eben, A., Machemer, L., Thyssen, J.	IIA, 5.1/05	1982b	Comparative study of inhibition of the Na ⁺ , K ⁺ and Mg ⁺⁺ -dependent ATPase from rats and chickens' brains in vitro by XXX 1722, some of its	N	ORG

¹⁸ protection for 5 years claimed from date of decision concerning listing in Annex I - the owner of the study report indicated that it had not previously been submitted to any of the Member States in support of an application for authorization

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Section A.6, Toxicology and Metabolism (Annex IIA, Point 5, Annex IIIA, Point 7)

Author(s)	Annex point / reference number	Year	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant), Published or not	Data Protection Claimed Y/N	Owner
			metabolites and further substances DDT, ouabain, some pyrethroids and phosphoric acid esters. Organics Inc Report No: 11116 Not GLP, Unpublished		
Eben, A., Thyssen, J.	IIA, 5.1./03	1981	Thiocyanate excretion in rats' urine after intraperitoneal administration of XXX 1111 and decamethrin in comparable doses and after exposure to defined XXX 1111 concentrations in the inhalation air. Organics Inc Report No: 10130 Not GLP, Unpublished	N	ORG
Ecker, W.	IIA, 5.1/07	1982	Biotransformation of [Fluorobenzene ring- U- ¹⁴ C]-XXX 1111; characterisation and provisional identification of metabolites. Organics Inc Report No: 10575 Not GLP, Unpublished	N	ORG
Ecker, W.	IIA, 5.1/08	1993	[Fluorobenzene-UL- ¹⁴ C]XXX 1111; [fluorobenzene-UL- ¹⁴ C]XXX 1111: metabolism part of the general metabolism study in the rat. Organics Inc Report No: 2059 GLP, Unpublished	N	ORG
Flucke, W., Schilde, B.	IIA, 5.3/01	1980b	XXX 1111 / subacute oral toxicity study on rats. Organics Inc Report No: 9039 Not GLP, Unpublished	N	ORG
Flucke, W., Thyssen, J.	IIA, 5.2/02	1980a	XXX 1111 / acute toxicity studies. Organics Inc Report No: 8800 Not GLP, Unpublished	N	ORG
Flucke, W., Thyssen, J.	IIA, 5.2/03	1981	XXX 1111 (cis:trans isomer ratio = 11:11) / acute toxicity studies. Organics Inc Report No: 9673 Not GLP, Unpublished	N	ORG
Heimann, K.G	IIA, 5.2/05	1982b	Determination of acute toxicity (LD ₅₀). Organics Inc Not GLP, Unpublished	N	ORG

Active Substance - XXX 1111 Name of Competent Authority Month & Year List Compiled

Section A.6, Toxicology and Metabolism (Annex IIA, Point 5, Annex IIIA, Point 7)

Author(s)	Annex point / reference number	Year	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant), Published or not	Data Protection Claimed Y/N	Owner
Heimann, K.G	IIA, 5.2/04	1982a	XXX 1111 / comparative tests for acute toxicity with various formulation aids. Organics Inc Report No: 10931 Not GLP, Unpublished	N	ORG
Heimann, K.G	IIA, 5.2/06	1984	Determination of acute toxicity (LD ₅₀). Organics Inc Not GLP, Unpublished	N	ORG
Heimann, K.G	IIA, 5.2/07	1987	XXX 1111 / study for acute oral toxicity to rats (formulation acetone and peanut oil). Organics Inc Report No: 15847 GLP, Unpublished	N	ORG
Hoffmann, K.	IIA, 5.2/08	1981a	XXX 1111 / acute toxicity for sheep after oral administration. Organics Inc Report No: 9750 Not GLP, Unpublished	N	ORG
Hoffmann, K.	IIA, 5.2/09	1981b	XXX 1111 / Akute Toxizität am Hund nach oraler Verabreichung, Organics Inc Report No: Letter Not GLP, Unpublished	N	ORG
Iyatomi, A.	IIA, 5.2/11	1982b	Report of acute toxicity - A. Nihon Tokushu Noyaku Seizo Report No: 5378 Organics Inc Report No: 10373 Not GLP, Unpublished	N	NTN
Iyatomi, A.	IIA, 5.2/12	1983	Report of acute toxicity - B. Nihon Tokushu Noyaku Seizo Report No: 59261 Organics Inc Report No: 11343 Not GLP, Unpublished	N	NTN
Iyatomi, A., Watanabe, M., Ohta, K.	IIA, 5.2/10	1982a	XXX 1111 / eye and skin irritation study on rabbits. Nihon Tokushu Noyaku Seizo Report No: 54165 Organics Inc Report No: 10365 Not GLP, Unpublished	N	NTN

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Section A.6, Toxicology and Metabolism (Annex IIA, Point 5, Annex IIIA, Point 7)

Author(s)	Annex point / reference number	Year	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant), Published or not	Data Protection Claimed Y/N	Owner
Klein, O., Weber, H., Suwelak, D.1	IIA, 5.1/09	1983	[U- ¹⁴ C]-C ([U- ¹⁴ C]XXX 1111), fluorobenzene label): biokinetic part of the general metabolism study in the rat. Organics Inc Report No: 11872 Not GLP, Unpublished	N	ORG
Löser, E., Schilde, B.	IIA, 5.3/02	1980	XXX 1111 / subchronic toxicity study on rats (three-month feeding experiment). Organics Inc Report No: 9386 Not GLP, Unpublished	N	ORG
Mihail, F.	IIA, 5.2/13	1981a	XXX 1111 / intracutaneous sensitisation test on guinea pigs (Draize-test). Organics Inc Report No: 10222 Not GLP, Unpublished	N	ORG
Mihail, F.	IIA, 5.2/14	1981b	XXX 1111 / test for sensitising effect on guinea pigs (Maximization test according to Magnusson and Klingman). Organics Inc Report No: 10267 Not GLP, Unpublished	N	ORG
Miyamoto, L., Beynon, K.I., Roberts, T.R., Hemingway, R.J., Swaine, H.	IIA, 5.1/10	1981	The chemistry, metabolism and residue analysis of synthetic pyrethroids. Pure & Appl. Chem., Vol. 53, pp. 1976-2022, 1981 Not GLP, Published	N	-
Pauluhn, J.	IIA, 5.2/17	1987	XXX 1111 / study of the acute inhalation toxicity to rats using OECD guideline No. 403. Organics Inc Report No: 15612 GLP, Unpublished	N	ORG
Pauluhn, J.	IIA, 5.2/18	1988a	XXX 1111 / study for sensory irritant potential in the rat (RD ₅₀ determination). Organics Inc Report No: 16693 GLP, Unpublished	N	ORG
Pauluhn, J.	IIA, 5.2/19	1988b	XXX 1111 / study for sensory irritant potential in the mouse (RD ₅₀ determination).	N	ORG

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Section A.6, Toxicology and Metabolism (Annex IIA, Point 5, Annex IIIA, Point 7)

Author(s)	Annex point / reference number	Year	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant), Published or not	Data Protection Claimed Y/N	Owner
			Organics Inc Report No: 16713 GLP, Unpublished		
Pauluhn, J.	IIA, 5.2/20	1988c	XXX 1111 / study of the blood gases in rats. Organics Inc Report No: 16763 GLP, Unpublished	N	ORG
Pauluhn, J.	IIA, 5.2/21	1989	XXX 1111 / studies of acute inhalation toxicity in the mouse, in accordance with OECD guideline No. 403. Organics Inc Report No: 17765 GLP, Unpublished	Y ¹⁸	ORG
Pauluhn, J., Kaliner, G.	IIA, 5.2/16	1983	XXX 1111 / study for acute and subacute inhalation toxicity on chickens. Organics Inc Report No: 11558 Not GLP, Unpublished	N	ORG
Pauluhn, J., Thyssen, J.	IIA, 5.2/15	1982	XXX 1111 / Study for acute inhalation toxicology (effect of formulation agent on inhalation). Organics Inc Report No: 10965 Not GLP, Unpublished	N	ORG
Sachsse, K.	IIA, 5.2/22	1985a	Acute oral toxicity (LD ₅₀) study with XXX 1111 (c.n. XXX 1111) vehicle: cremophor EL 2% in distilled water in the hen. Organics Inc Report No: R3621 GLP, Unpublished	N	ORG
Sachsse, K.	IIA, 5.2/23	1985b	Acute oral toxicity (LD ₅₀) study with XXX 1111 vehicle: PEG 400 in the hen. Organics Inc Report No: R3622 GLP, Unpublished	N	ORG
Shaw, H.R., Ayers, J. E., McCann, S.A.	IIA, 5.1/11	1983	Metabolism of XXX 1111 in a dairy cow. Organics Inc Report No: MR86043 Not GLP, Unpublished	N	ORG
Thyssen, J.	IIA, 5.2/25	1982	XXX 1111, formulation in water and influence on acute oral toxicity. Organics Inc Not GLP, Unpublished	N	ORG

APPENDIX 8

FORMAT FOR THE LISTING OF TEST AND STUDY REPORTS AND OTHER DOCUMENTATION RELIED ON

(Annex B - list of Annex II and Annex III information tests and studies
relied on by the Rapporteur Member State)

- 1 As indicated in paragraph 4.6.8, a listing of the studies relied on by the Rapporteur Member State should be included at the end of each chapter of the Annex B summary, evaluation and assessment of the data and information considered. The listing should include only those test and study reports, test guidelines, and published papers relied on by the Rapporteur Member State in reaching its conclusions, whether submitted in support of the application (Documents J, K and L and where relevant I) or, consisting of other relevant information available to, or brought to the attention of the Rapporteur Member State.
- 2 References which relate to more than one chapter should be listed in each relevant chapter. The listing should be arranged in the order of the relevant Annex II and Annex III points, as appropriate, with the references for Annex II preceding those for Annex III. For each separate Annex point, references should be listed alphabetically by first author. Where there is more than one reference for a particular author (first author), the references concerned should be listed in chronological order - the most recent being listed last. In cases where for a particular author, more than one reference is listed for any one year, the references should be distinguished by inserting letters after the year *i.e.* a, b, c, *etc.*, as appropriate.
- 3 In instances where a single study would suffice, but two or more acceptable studies are submitted with respect to any particular data requirement, a footnote should be included in the list of references to indicate that any one of the studies concerned can be relied on by applicants for authorization of plant protection products containing the active substance concerned.
- 4 For each reference, the following indications should be provided -
 - (i) the reference number, authors and year of the report or of publication;
 - (ii) for each test and study report, test guidelines, and published paper, its title, source, company and report number;
 - (iii) whether it is published or unpublished;
 - (iv) whether, or not, it was conducted in compliance with the principles of GLP or the requirements of points 2.2 and 2.3 of the introduction to Annex II to Directive 93/71/EEC¹⁹, as appropriate;
 - (v) the owner of the test or study concerned - the codes contained in Annex II to Commission Regulation (EC) No 933/94²⁰, can be used to identify the companies concerned.; and
 - (vi) whether or not protection in accordance with the provisions of Article 13 (3) (d) of Directive 91/414/EEC is claimed.
- 5 The reference lists that follow are intended to be illustrative of the required approach and relate to a fictitious compound, *active substance XXX 1111*.

¹⁹ see footnotes 8 and 12

²⁰ see footnote 17

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Section B.6 Toxicology and Metabolism (Annex IIA, Point 5, Annex IIA, Point 7)

Annex point / reference number	Author(s)	Year	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant), Published or not	Data Protection Claimed Y/N	Owner
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Annex II Data and Information

IIA, 5.1/01	Casida, J.E., Gaughan, L.C, Ruzo, L.O.	1979	Comparative metabolism of pyrethroids derived from 3-phenoxybenzyl and α -cyano-3-phenoxybenzyl alcohols. Advances in pesticide science, Fourth International Congress of Pesticide Chemistry, Zürich, Switzerland, July 24-38, 1978, part 2, 182-189 Not GLP, Published	N	-
IIA, 5.1/02	Chopade, H.M., McCann, S.A., Gentile, C.C.	1983	The distribution and metabolism of XXX 1111 in laying hens. Organics Inc Report No: MR86044 Not GLP, Unpublished	N	ORG
IIA, 5.1/03	Eben, A., Thyssen, J.	1981	Thiocyanate excretion in rats' urine after intraperitoneal administration of XXX 1111 and decamethrin in comparable doses and after exposure to defined XXX 1111 concentrations in the inhalation air. Organics Inc Report No: 10130 Not GLP, Unpublished	N	ORG
IIA, 5.1/04	Eben, A., Heimann, K.G, Machemer, L.	1982a	Comparative study of rats on absorption of XXX 1111 after single oral administration in polyethylene glycol 400 or cremophor EI/water as formulation vehicle. Organics Inc Report No: 10715 Not GLP, Unpublished	N	ORG
IIA, 5.1/05	Eben, A., Machemer, L., Thyssen, J.	1982b	Comparative study of inhibition of the Na ⁺ , K ⁺ and Mg ⁺⁺ -dependent ATPase from rats and chickens' brains in vitro by XXX 1722, some of its metabolites and further substances DDT, ouabain, some pyrethroids and phosphoric acid esters. Organics Inc Report No: 11116 Not GLP, Unpublished	N	ORG
IIA, 5.1/06	Eben, A.,	1987	Biotransformation of XXX 1111 in the chicken	N	ORG

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Section B.6 Toxicology and Metabolism (Annex IIA, Point 5, Annex IIA, Point 7)

Annex point / reference number	Author(s)	Year	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant), Published or not	Data Protection Claimed Y/N	Owner
	Fuchs, R., Kurz, J., Wunsche, C., Flucke, W.		after oral administration of a high dose. Organics Inc Report No: 15849 GLP, Unpublished		
IIA, 5.1/07	Ecker, W.	1982	Biotransformation of [Fluorobenzene ring- U- ¹⁴ C]-XXX 1111; characterisation and provisional identification of metabolites. Organics Inc Report No: 10575 Not GLP, Unpublished	N	ORG
IIA, 5.1/08	Ecker, W.	1993	[Fluorobenzene-UL- ¹⁴ C]XXX 1111; [fluorobenzene-UL- ¹⁴ C]XXX 1111: metabolism part of the general metabolism study in the rat. Organics Inc Report No: 2059 GLP, Unpublished	N	ORG
IIA, 5.1/09	Klein, O., Weber, H., Suwelak, D.1	1983	[U- ¹⁴ C]-C ([U- ¹⁴ C]XXX 1111), fluorobenzene label): biokinetic part of the general metabolism study in the rat. Organics Inc Report No: 11872 Not GLP, Unpublished	N	ORG
IIA, 5.1/10	Miyamoto, L., Beynon, K.I., Roberts, T.R., Hemingway, R.J., Swaine, H.	1981	The chemistry, metabolism and residue analysis of synthetic pyrethroids. Pure & Appl. Chem., Vol. 53, pp. 1976-2022, 1981 Not GLP, Published	N	-
IIA, 5.1/11	Shaw, H.R., Ayers, J. E., McCann, S.A.	1983	Metabolism of XXX 1111 in a dairy cow. Organics Inc Report No: MR86043 Not GLP, Unpublished	N	ORG
IIA, 5.1/12	Weber, H., Suwelack, D.	1983	Fluorophenyl-U- ¹⁴ C XXX 1111) biokinetic study on rats. Organics Inc Report No: PH11575(F) Not GLP, Unpublished	N	ORG
IIA, 5.2/01	Bomann, W.	1991	XXX 1111 / study for acute oral toxicity in rats.	Y ²¹	ORG

²¹ protection for 5 years claimed from date of decision concerning listing in Annex I - the owner of the study report indicated that it had not previously been submitted to any of the Member States in support of an application for authorization

Active Substance - XXX 1111 Name of the Competent Authority Month & Year List Compiled

Section B.6 Toxicology and Metabolism (Annex IIA, Point 5, Annex IIA, Point 7)

Annex point / reference number	Author(s)	Year	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant), Published or not	Data Protection Claimed Y/N	Owner
			Organics Inc Report No: 19852 GLP, Unpublished		
IIA, 5.2/02	Flucke, W., Thyssen, J.	1980a	XXX 1111 / acute toxicity studies. Organics Inc Report No: 8800 Not GLP, Unpublished	N	ORG
IIA, 5.2/03	Flucke, W., Thyssen, J.	1981	XXX 1111 (cis:trans isomer ratio = 11:11) / acute toxicity studies. Organics Inc Report No: 9673 Not GLP, Unpublished	N	ORG
IIA, 5.2/04	Heimann, K.G.	1982a	XXX 1111 / comparative tests for acute toxicity with various formulation aids. Organics Inc Report No: 10931 Not GLP, Unpublished	N	ORG
IIA, 5.2/05	Heimann, K.G.	1982b	Determination of acute toxicity (LD ₅₀). Organics Inc Not GLP, Unpublished	N	ORG
IIA, 5.2/06	Heimann, K.G.	1984	Determination of acute toxicity (LD ₅₀). Organics Inc Not GLP, Unpublished	N	ORG
IIA, 5.2/07	Heimann, K.G.	1987	XXX 1111 / study for acute oral toxicity to rats (formulation acetone and peanut oil). Organics Inc Report No: 15847 GLP, Unpublished	N	ORG
IIA, 5.2/08	Hoffmann, K.	1981a	XXX 1111 / acute toxicity for sheep after oral administration. Organics Inc Report No: 9750 Not GLP, Unpublished	N	ORG
IIA, 5.2/09	Hoffmann, K.	1981b	XXX 1111 / Akute Toxizität am Hund nach oraler Verabreichung. Organics Inc Report No: Letter Not GLP, Unpublished	N	ORG

Active Substance - XXX 1111 Name of the Competent Authority Month & Year List Compiled

Section B.6 Toxicology and Metabolism (Annex IIA, Point 5, Annex IIA, Point 7)

Annex point / reference number	Author(s)	Year	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant), Published or not	Data Protection Claimed Y/N	Owner
IIA, 5.2/10	Iyatomi, A., Watanabe, M., Ohta, K.	1982a	XXX 1111 / eye and skin irritation study on rabbits. Nihon Tokushu Noyaku Seizo Report No: 54165 Organics Inc Report No: 10365 Not GLP, Unpublished	N	NTN
IIA, 5.2/11	Iyatomi, A.	1982b	Report of acute toxicity - A. Nihon Tokushu Noyaku Seizo Report No: 5378 Organics Inc Report No: 10373 Not GLP, Unpublished	N	NTN
IIA, 5.2/12	Iyatomi, A.	1983	Report of acute toxicity - B. Nihon Tokushu Noyaku Seizo Report No: 59261 Organics Inc Report No: 11343 Not GLP, Unpublished	N	NTN
IIA, 5.2/13	Mihail, F.	1981a	XXX 1111 / intracutaneous sensitisation test on guinea pigs (Draize-test). Organics Inc Report No: 10222 Not GLP, Unpublished	N	ORG
IIA, 5.2/14	Mihail, F.	1981b	XXX 1111 / test for sensitising effect on guinea pigs (Maximization test according to Magnusson and Klingman). Organics Inc Report No: 10267 Not GLP, Unpublished	N	ORG
IIA, 5.2/15	Pauluhn, J., Thyssen, J.	1982	XXX 1111 / Study for acute inhalation toxicology (effect of formulation agent on inhalation). Organics Inc Report No: 10965 Not GLP, Unpublished	N	ORG
IIA, 5.2/16	Pauluhn, J., Kaliner, G.	1983	XXX 1111 / study for acute and subacute inhalation toxicity on chickens. Organics Inc Report No: 11558 Not GLP, Unpublished	N	ORG
IIA, 5.2/17	Pauluhn, J.	1987	XXX 1111 / study of the acute inhalation toxicity to rats using OECD guideline No. 403. Organics Inc Report No: 15612 GLP, Unpublished	N	ORG
IIA, 5.2/18	Pauluhn, J.	1988a	XXX 1111 / study for sensory irritant potential in	N	ORG

Active Substance - XXX 1111 Name of the Competent Authority Month & Year List Compiled

Section B.6 Toxicology and Metabolism (Annex IIA, Point 5, Annex IIA, Point 7)

Annex point / reference number	Author(s)	Year	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant), Published or not	Data Protection Claimed Y/N	Owner
			the rat (RD ₅₀ determination). Organics Inc Report No: 16693 GLP, Unpublished		
IIA, 5.2/19	Pauluhn, J.	1988b	XXX 1111 / study for sensory irritant potential in the mouse (RD ₅₀ determination). Organics Inc Report No: 16713 GLP, Unpublished	N	ORG
IIA, 5.2/20	Pauluhn, J.	1988c	XXX 1111 / study of the blood gases in rats. Organics Inc Report No: 16763 GLP, Unpublished	N	ORG
IIA, 5.2/21	Pauluhn, J.	1989	XXX 1111 / studies of acute inhalation toxicity in the mouse, in accordance with OECD guideline No. 403. Organics Inc Report No: 17765 GLP, Unpublished	Y ²¹	ORG
IIA, 5.2/22	Sachsse, K.	1985a	Acute oral toxicity (LD ₅₀) study with XXX 1111 (c.n. XXX 1111) vehicle: cremophor EL 2% in distilled water in the hen. Organics Inc Report No: R3621 GLP, Unpublished	N	ORG
IIA, 5.2/23	Sachsse, K.	1985b	Acute oral toxicity (LD ₅₀) study with XXX 1111 vehicle: PEG 400 in the hen. Organics Inc Report No: R3622 GLP, Unpublished	N	ORG
IIA, 5.2/24	Thyssen, J., Kaliner, G., Gröning, P.	1981	XXX 1111 / neurotoxicity studies on hens. Organics Inc Report No: 9753 Not GLP, Unpublished	N	ORG
IIA, 5.2/25	Thyssen, J.	1982	XXX 1111, formulation in water and influence on acute oral toxicity. Organics Inc Not GLP, Unpublished	N	ORG
IIA, 5.2/26	Watanabe, M., Iyatomi, A.	1984	Acute inhalation study of XXX 1111 on rats. Nihon Tokushu Noyaku Seizo Report No: 73126	N	NTN

