OECD Guidance for Country Data Review Reports on Plant Protection Products and their Active Substances

(Monograph Guidance)

Guidelines and Criteria for the Evaluation of Dossiers and for the Preparation of Reports by Regulatory Authorities in OECD Countries Relating to the Evaluation of Active Substances the Registration of Plant Protection Products and the Establishment of Maximum Residue Limits (MRLs) and Import Tolerances

- Revision 3, April 2008 -

- OECD Environment Directorate -

FOREWORD

This document is intended to provide guidance as to the format and presentation of the documentation to be prepared by the regulatory authorities, in the context of applications for the approval of particular active substances made to them, for the registration of plant protection products, for the establishment of maximum residue limits (MRLs) or for the establishment of import tolerances.

This guidance document was developed with the aim of facilitating the exchange of monographs between OECD countries with a view to achieving a sharing of the work necessary for the evaluation of plant protection products and their active substances. In order to achieve that objective, the format described in this document is designed to help countries to prepare monographs which are sufficiently detailed so that -

- the basis for all proposed decisions are clear, thereby facilitating their use for decision making purposes by other countries, and

- countries receiving monographs can perform separate and critical assessments of the study results described, in the light of the evaluative decision making criteria specified in their countries, without having to conduct separate reviews of the original study reports.

Since the preparation of monographs requires considerable resources, it is not expected that OECD countries will systematically use the recommended format for all evaluations conducted. Regulatory authorities in particular countries may use the format for the first evaluation conducted by it of an active substance. In other instances, the recommended format may be used only for certain parts of the evaluation (*i.e.* scientific disciplines). Agreement may be achieved in particular OECD bodies or other international fora as to the circumstances in which OECD countries should use the recommended format.

This guidance document is based on and is consistent with the Guidelines and criteria for the evaluation of dossiers and for the preparation of reports to the European Commission by Rapporteur Member States relating to the proposed inclusion of active substances in Annex I of Directive 91/414/EEC issued by the European Commission (Commission Document 1654/VI/94, rev 7 of 22 April 1998) and was prepared with the benefit of comments provided by the delegations of countries participating in the OECD Working Group on Pesticides and by pesticide industry representatives.

This document was first approved by the 7th Meeting of the Working Group on Pesticides that took place in February 1998 at the Château de la Muette, Paris, and was endorsed by the Joint Meeting of the Chemicals Group and Management Committee of the Special Programme on the Control of Chemicals in June 1998. New and revised parts, prepared to ensure its consistency with the revised Dossier Guidance document and dated March 2001, were approved by the 11th Meeting of the Working Group that took place in November 2000, while those dated May 2005 were approved by the 17th Meeting of the Working Group that took place in November 2004. The latest revision, which requires the inclusion of specific text in government monographs concerning the correct use of summary information, was endorsed by the Working Group on Pesticides, on 4 April, 2008.

Note:
This document will be periodically revised, as some sections will be added or updated. Please consult the OECD Pesticide Web site at http://www.oecd.org/ehs/pesticid.htm or contact the OECD Secretariat to make sure that you have the latest version.

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1 GENERAL INTRODUCTION

1.1 In the interest of avoiding wastage of scarce and expensive evaluative resources, dossiers (data submissions provided by industry) 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 plant protection products and their active substances in support of regulatory decisions in OECD countries,* require that applicants complete and submit a set of forms designed to facilitate the checking of dossiers for completeness, by the regulatory authority to which application is made.

1.2 Evaluations and assessments of dossiers prepared by the regulatory authorities, are to be used as a basis for decision making with respect to the approval of individual active substances, the registration of plant protection products, the establishment of a maximum residue limit (MRL) or limits, or the establishment of an import tolerance or tolerances, as appropriate. It is envisaged that the guidance contained in this document will be used by regulatory authorities, where the evaluation of extensive data submissions is necessary. In the case of the evaluation of less comprehensive data submissions, reliance on the approach recommended in this guidance document may be neither necessary nor appropriate.

1.3 In the interest of ensuring efficiency and economy in the use of the resources necessary for the use of monographs by the regulatory authorities of other countries, 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 regulatory authorities nevertheless are required to use expert judgement in preparing the documentation concerned. It is especially important that regulatory authorities treat the guidance contained in this document as providing a degree of flexibility. Guidance notes for the analysis and evaluation of particular types of studies developed by OECD are referenced in Appendix 9. It is envisaged that future versions of this guidance document will contain information in relation to guidance notes for the preparation of summaries and assessments of other tests and studies and that the various guidance notes prepared will form modules which will be appended to this document.

1.4 For each active substance and/or plant protection product, the documentation to be prepared by the regulatory authority to which application is made 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 details of the decision proposed. Those elements of each monograph form the report of the regulatory authority. 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. With a view to reducing the extent of the difficulties that can arise as a result of language barriers, a tabular approach should be used in the presentation of data and information included, in so far as is it is practical to do so.

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 regulatory authority. The evaluations and assessments contained in monographs should reflect the evaluative and decision making criteria which apply in the country to which application is made and in which the monograph is prepared.

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

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

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 the development of burden sharing arrangements by regulatory authorities, thereby further increasing efficiency and economy in the use of evaluative resources:-

(i) by the regulatory authority to which application is made and in which the monograph is prepared; and

(ii) by the regulatory authorities of other countries that are provided with copies of monographs and which may use them as a basis for decision making, thereby precluding the need for duplicative evaluation of the test and study reports submitted.

1.8 Each monograph of necessity will contain certain information provided in confidence in accordance with the legislative provisions of the country to which application is made. Where in accordance with those provisions, 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, data submitted in support of an application is submitted by a task force formed by a number of applicants, relevant details of the task force should be included:-

(i) the membership of the task force and a contact point for the task force (name, address, telephone and telefax numbers and e-mail address);

(ii) a contact point for each member of the task force (name, address, telephone and telefax numbers and e-mail address); and

(iii) the list of test and study reports which were generated by or on behalf of the task force - where some members of the task force share ownership of, or have access to, some but not all of the test and study reports, a clear indication should be provided as to the ownership of, and rights of access to, the individual test and study reports listed.

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 parentheses [1];

(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.

1.11 Where requested to do so, regulatory authorities that have prepared monographs on particular active substances or particular plant protection products, should make them available to the regulatory authorities of other OECD countries, in both hard copy and electronic format. 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, when published or otherwise made available to interested parties, will ensure transparency with respect to the basis for decisions made for each individual active substance and plant protection product.

[1] 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. If non metric units are used, metric equivalents or conversion factors to metric units must be provided.

2 CHECKING DOSSIERS FOR COMPLETENESS

2.1 Introduction

2.1.1 The guidance provided herewith, is for use by the regulatory authorities of OECD countries in checking dossiers for completeness, regardless of whether such dossiers have been submitted in support of applications for the approval of an active substance, the registration of a plant protection product, for the variation of the conditions of any such registration or approval, for the establishment of an MRL(s), or for the establishment of an import tolerance or tolerances, and regardless of whether the dossiers have been submitted in the context of the review or renewal of any such approval, registration, MRL or import tolerance.

2.1.2 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 3 of Appendix 11 to the *Guidelines and criteria for the industry for the preparation and presentation of complete dossiers and of summary dossiers for plant protection products and their active substances in support of regulatory decisions in OECD countries*; and

(iii) assessment of the extent and significance of any deficiencies noted in dossiers, as reflected in the completed or corrected forms, as appropriate.

2.2 Suggested approach

2.2.1 The nature and extent of the check for completeness to be conducted by the regulatory authorities of OECD countries 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 guidance document),
- all test and study reports for the active substance and for plant protection product(s) containing it required in accordance with the relevant regulatory requirements 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 data and information for the active substance and for plant protection product(s) containing it, and an overall assessment and conclusions, as specified in the relevant guidance document, have been provided;

(iv) it includes checks to ensure that the requirements of the relevant guidance document, 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 separate sections of dossiers (data submission provided by industry) 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, 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. Similarly, in the case of testing with respect to the efficacy of plant protection products (where such testing must be reported), *Tier I* checks as to quality are not required. In all such cases, 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 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 [2]. 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 sections of dossiers (data submission provided by industry), should be examined using Evaluation Form 5 as set out in Part 3 of Appendix 11 to the *Guidelines and criteria for the industry for the preparation and presentation of complete dossiers and of summary dossiers for plant protection products and their active substances in support of regulatory decisions in OECD countries*. 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 the 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 (data submission provided by industry) for a new active substance or for a plant protection product containing 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, the applicant should be informed of the deficiencies and be given an opportunity to complete the dossier. The detailed evaluation of the dossier by specialists need not be undertaken until the dossier is complete.

2.2.6 In the case of reviews of existing approvals, registrations, MRLs or import tolerances, 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 renewal of an approval, registration, MRL or import tolerance, has not been substantiated.

[2] 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 data requirements of the country to which application is made and to any relevant evaluative and decision making criteria.

2.2.7 Three of the forms to be completed by applicants and to be used by regulatory authorities in checking dossiers for completeness are provided in Appendix 11 to the *Guidelines and criteria for industry for the preparation and presentation of complete dossiers and of summary dossiers for plant protection products and their active substances in support of regulatory decisions in OECD countries.* Since the data to be submitted in support of applications for the approval of active substances, for the registration of plant protection products, for the establishment of MRLs and for the establishment or import tolerances are different in individual OECD countries, it is not possible to develop standardized forms for use in checking that all relevant and required tests and studies have been included in dossiers submitted. The forms required for that purpose must be designed by each individual regulatory authority. Such forms have been developed for use in EU Member States. The particular forms required for checking dossiers for completeness therefore are as follows:-

Evaluation Form 1	for use in checking that the required supporting documentation has been provided	Appendix 11, Part 1
Evaluation Form 2	for use in checking that the required active substance and formulated product dossier summaries and an overall assessment, have been provided	Appendix 11, Part 2
Evaluation Form 3	for use in checking that all test and study reports relating to the active substance which are required, have been provided	Form developed by the regulatory authorities of individual countries
Evaluation Form 4	for use in checking that all test and study reports relating to the formulated product which are required, have been provided	Form developed by the regulatory authorities of individual countries
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.	Appendix 11, Part 3

2.2.8 Supporting documentation to facilitate the checking of individual *Tier I* quality checks, may also be available:-

Supporting document	Listing of the test guidelines specified and the requirements relating to compliance with GLP and GEP for individual tests and studies relating to the active substance	Form developed by the regulatory authorities of individual countries
Supporting document	Listing of the test guidelines specified and the requirements relating to compliance with GLP and GEP for individual tests and studies relating to the formulated product	Form developed by the regulatory authorities of individual countries

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 regulatory authority, 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 the decisions proposed.

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 to be taken with respect to the application and the proposed conditions and restrictions to be associated with any approval or registration granted;

Level 4 where relevant, a statement of the further studies and information necessary to permit a decision to be made, or a statement of the studies and information necessary for consideration of the removal of conditions or restrictions associated with any approval or registration granted;

Annex A the list of the tests and studies (active substance and formulation) 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 decisions proposed (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, where relevant for existing active substances, details of any task force formed, its membership and information concerning ownership of and access to test and study reports generated by or on behalf of the task force.

3.3 Those parts of the monograph comprising levels 1 to 4, form the report of the regulatory authority, with respect to the proposed approval of an individual active substance, the registration of a plant protection product, the establishment of a maximum residue limit (MRL) or limits, or the establishment of an import tolerance or tolerances, as appropriate. Annex A to the monograph should consist of an annotated list of the test and study reports relating both to the active substance and to the formulation 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 the decision proposed, 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.

3.4 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 regulatory authority 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 the legislative provisions of the country to which application is made, 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 regulatory authority

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) the proposed decision to be taken with respect to the application, 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 regulatory authority,

as well as, where relevant, the conditions and restrictions, if any, which the regulatory authority proposes be associated with any approval or registration to be granted, together with a detailed explanation of the rationale for the imposition of any such conditions and restrictions, 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 studies, data and information relating to both the active substance and the formulation which were not provided and without which a decision cannot be made (further details are provided in paragraphs 4.4.1 and 4.4.3);

(v) where relevant, a statement of the studies and information relating to both the active substance and the formulation necessary for the removal of any conditions or restrictions associated with any proposed approval or registration, 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 (active substance and formulation) 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 principles of GEP, where appropriate,
- whether or not, in accordance with the relevant rules or provisions in place in the country to which application is made, data protection is claimed and, where relevant, the period for which it is claimed, and a concise explanation of the basis upon which it is claimed, and
- whether or not it is published,

(further details are provided in paragraphs 4.5.1 through 4.5.4);

Annex B (vii) the regulatory authority'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 (10 chapters if it is appropriate that a chapter on efficacy be included), 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 4.6.8 and 4.6.12);

(viii) the list of tests and studies relied upon for the conclusions reached by the regulatory authority (further details are provided in paragraphs 4.6.9 through 4.6.11);

(ix) an indication of the test and study reports for which protection was claimed in accordance with the relevant rules or provisions in place in the country to which application is made and to the extent feasible an assessment of those claims, for each relevant test and study report (further details are provided in paragraphs 4.6.10 and 4.6.11); 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 legislative provisions of the country to which application is made, the regulatory authority believes should be treated as confidential, and
- where relevant for existing active substances, details of any task force formed, its membership and information concerning ownership of and access to test and study reports generated by or on behalf of the task force (Document B)

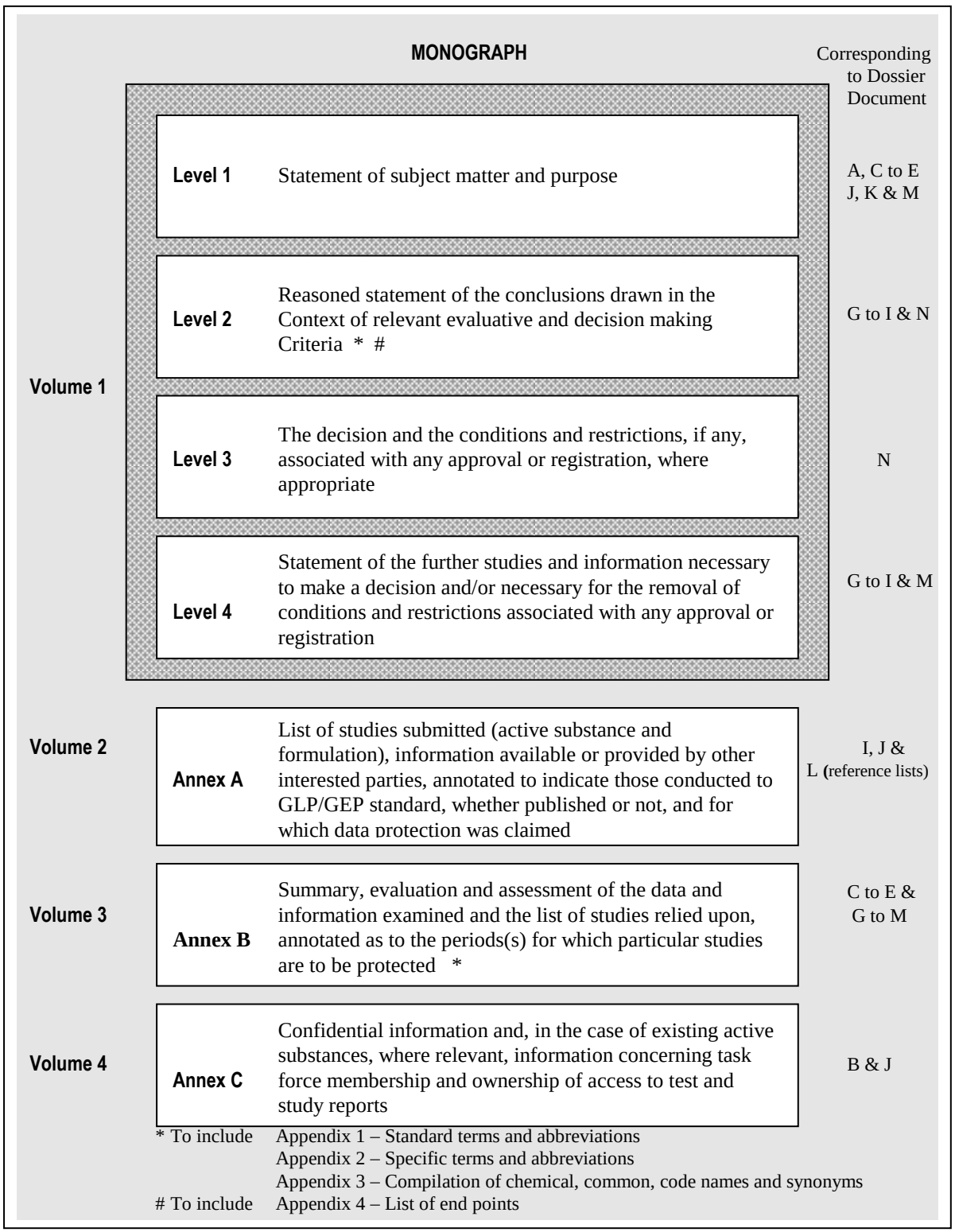
(further details are provided in paragraphs 4.7.1 through 4.7.4).

3.5 It is envisaged that the documentation submitted in support of an application for the approval of an active substance, the registration of a plant protection product, the establishment of a maximum residue limit (MRL) or limits, or the establishment of an import tolerance or tolerances, as appropriate, subject to its being deemed to be complete, will serve as basis for preparing the various levels of the monograph, as follows -

	Monograph	**Dossier**
Level 1	Purpose and Context	Dossier Document A
	Statement of Subject Matter	Test and study reports, *Tier II* summaries and evaluations and Confidential information (Dossier Documents K-active substance, M-active substance, K-formulation, M-formulation and J), 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 removal of conditions and restrictions	Active substance and formulation *Tier II* summaries and evaluations (Dossier Documents M-active substance and M-formulation) and Dossier Documents G, H and I
Annex A	Listing of Data and Information Submitted	Active substance and formulation *Tier I* reference lists (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	Active substance and formulation test and study reports and *Tier II* summaries (Dossier Documents K-active substance, K-formulation, L-active substance, L-formulation, M-active substance, M- formulation and Dossier Documents C, D, E and G to J
Annex C	Confidential Information and Task Force Information	Dossier Document J Dossier Document B

Figure 1

MONOGRAPH STRUCTURE AND CONTENT



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 caveat specifying that Regulatory Authorities should not use the contents of Monographs as a basis for their regulatory decisions unless the data package upon which a particular Monograph was based has been provided to the Regulatory Authority concerned or the owner of the data package has granted permission for use of the summary evaluation in a Monograph in *lieu* of the data. The following text should form the first element of Level 1 of each Monograph prepared:-

' The summaries and evaluations contained in this monograph or review report may be based on unpublished proprietary data submitted for the purpose of the assessment undertaken by the regulatory authority that prepared it. Other registration authorities should not grant, extend, or renew a registration on the basis of the summaries and evaluation of unpublished proprietary data contained in this Monograph or review report unless they have received the data on which the summaries and evaluation are based, either from -

- *the owner of the data, or*
- *a second party that has obtained permission from the owner of the data for this purpose,*

or alternatively -

- *the applicant has received permission from the data owner that the summary and evaluation contained in this Monograph or review report may be used in lieu of the data, or,*
- *following expiry of any period of exclusive use, mandatory compensation, where required, has been offered unless the period of protection for the proprietary data concerned has expired.*

Applicants wishing to avail of information in this Monograph or review report should seek advice from the regulatory authority to which application is made concerning the requirements in their country.'

4.1.2 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) approval of a new active substance;

(ii) approval of an existing active substance;

(iii) registration of a plant protection product containing a new active substance;

(iv) registration of a plant protection product containing an existing active substance;

(v) modification or removal of conditions or restrictions associated with the registration of a plant protection product;

(vi) special review of the registration of a plant protection product, where indications exist suggesting that the conditions of registration are no longer satisfied; or

(vii) routine review of the registration of a plant protection product, anticipating expiry of the period for which registered;

(viii) establishment of an MRL or of an import tolerance; or

(ix) renewal of an MRL or of an import tolerance.

4.1.3 Information to identify the active substance for which application is made, prepared on the basis of documents J, K-active substance and M-active substance of the complete dossier (data submission provided by industry) 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 applicant [3];

(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) [4];

(ix) the results of batch analysis reported for the active substance [4]; 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 [4].

[3] In certain circumstances, the information concerned should be treated as confidential in accordance with the legislative provisions of the country to which application is made and therefore should be included in Annex C, rather than in Level 1 - see paragraph 4.7

[4] 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 legislative provisions of the country to which application is made - see paragraph 4.7

4.1.4 Information to identify each preparation containing the active substance for which documentation is submitted in support of the application, prepared on the basis of documents J, K-formulation and M-formulation of the complete dossier (data submission provided by industry) submitted by the applicant:-

(i) all former trade names, proposed trade names, current trade names and development code numbers of the preparation, for each OECD country;

(ii) the name and address of the manufacturer of the preparation [3];

(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 [4].

4.1.5 Information to identify the uses and registrations for each preparation containing the active substance for which documentation is submitted in support of the application, prepared on the basis of documents C, D and E of the complete dossier (data submission provided by industry) 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 [5], using forms as set out in Appendix 5; and

(v) a summary of authorizations, registrations, approvals or clearances granted in OECD countries.

[5] 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 **Level 2** **Reasoned statement of the overall conclusions which the regulatory authority 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 regulatory authority reached 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; and

(ii) the criteria and guidelines for evaluation and decision making currently used in the country to which application is made.

4.2.2 The statement of the conclusions reached by the regulatory authority 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 the legislative provisions of the country to which application is made 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 regulatory authority to which application is made.

4.2.3 The statement of the conclusions reached by the regulatory authority, 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, as should a list of all the chemical names, common names, synonyms and code names, used for the active substance and its metabolites and for formulations containing the active substance. Those lists should form Appendices 1, 2 and 3 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);

(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); and

(iii) Appendix 3 chemical names, common names, synonyms and code names, used for the active substance and its metabolites and for formulations containing the active substance (the format suggested is illustrated in Part 3 of Appendix 1 of this guidance document).

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 decision proposed, should be appended to Level 2 - to form Appendix 4. 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 approval of an active substance, the registration of a plant protection product, the establishment of an MRL or of an import tolerance, the conditions and restrictions associated with any proposed approval or registration, together with a reasoned statement as to the reasons therefore, taking account of relevant evaluative and decision making criteria**

4.3.1 The regulatory authority's proposed decision with respect to the approval of an active substance, the registration of a plant protection product, the establishment of an MRL or MRLs or the establishment of an import tolerance or tolerances, as appropriate, or with respect to the review or renewal of any such approval, registration, MRL or import tolerance, which should be structured as indicated in Appendix 4, should be supported with a full and reasoned statement as to the rationale used in elaborating its proposed decision, in the light of the criteria and guidelines for evaluation and decision making currently used in the country to which application is made.

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

4.3.3 A full and reasoned statement of the regulatory authority's proposed decisions with respect to any conditions or restrictions to be associated with the approval of an active substance or the registration of a plant protection product, should be included, having particular regard to the criteria and guidelines for evaluation and decision making currently used in the country to which application is made.

4.3.4 Conditions to be associated with a proposed approval of an active substance or the proposed registration of a plant protection product, may be of two types: specified test and study reports to be submitted by specified deadlines; registrations granted to respect specified restrictions.

4.3.5 Restrictions to be associated with a proposed approval of an active substance or the proposed registration of a plant protection product may be of several types, all of which limit the terms under which registrations may be granted: 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 approval of the active substance, 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 any approval or registration**

4.4.1 Where a decision as to whether or not to issue an approval for an active substance, to register a plant protection product, to establish an MRL or MRLs or to establish an import tolerance or tolerances, as appropriate, or as to whether or not to renew any such approval, registration, MRL or import tolerance, is postponed pending the availability of further data and information, the monograph should contain a listing of the further studies required (active substance and formulation) 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 an approval or registration may be refused or be revoked, or that an MRL or import tolerance may not be established or that an existing MRL or import tolerance may be revoked, 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 conditions and/or restrictions associated with any approval or registration, are specified, the monograph should contain a statement, which should be structured as indicated in Appendix 4, of any additional studies and information required (active substance and formulation) 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 **Annex A Listing of the available data and information (active substance and formulation)**

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 regulatory authority. The listing should cover each of the nine chapters of Annex A (10 chapters if it is appropriate that a chapter on efficacy be included) separately (see Appendix 4). References which relate to more than one chapter should be listed in each relevant chapter. Where, for existing active substances, documentation is submitted by more than one company, the reference list should reflect all the test and study reports, test guidelines, and published papers submitted. Those references not submitted by applicants, but which are available to, or are brought to the attention of the regulatory authority, should also be included. Within the listing for each chapter, the references relevant to the active substance should be presented first and be followed by the references relevant to the formulation. Where documentation relating to more than one formulation 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 number of the data point addressed, 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 rules or provisions in place in the country to which application is made 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 principles of GEP, as appropriate.

4.5.3 The numbering systems used in the various OECD countries for the data and information which must be submitted, differ. In order to facilitate work sharing arrangements, the OECD numbering system which may be found in Parts 4 and 5 of Appendix 6 to the *Guidelines and criteria for industry for the preparation and presentation of complete dossiers and of summary dossiers for plant protection products and their active substances in support of regulatory decisions in OECD countries* should be used for the purposes of compiling the reference list which comprises Annex A. A compilation of the numbering systems used in some OECD countries is also included with the OECD numbering system.

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

4.6 **Annex B Regulatory authority'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 decisions proposed 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 active substance and formulation data point which in accordance with the current legal provisions must be addressed and be presented in separate chapters in the sequence specified in Appendix 4. It should be sufficiently comprehensive to permit decisions to be proposed 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 the decisions proposed as reflected in levels 2, 3 and 4.

4.6.2 Guidance notes for the analysis and evaluation of particular types of studies developed by OECD are referenced in Appendix 9. Additional guidance notes are in preparation (*e.g.* chronic toxicity and carcinogenicity studies). It is envisaged that guidance notes relating to other specific types of tests and studies will be developed in due course. The guidance notes are intended to illustrate the approach required and the structure recommended for the preparation of summaries and assessments for individual tests and study types.

4.6.3 Pending the availability of detailed guidance notes for the various types of tests and studies involved, it is recommended that the following general guidance be followed. 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 regulatory authority, 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 GLP;

(iii) for individual tests and studies referred to, for which the principles of GEP 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 requirements;

(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 active substance or formulation data 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 currently specified,
- 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.* LD_{50}, NOEL), 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.* DT_{50}, 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,
- effects observed as a function of dose and derived limit doses (*e.g.* EC_{50}, LC_{50}, LD_{50}, 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, and

(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.

(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), and
- a description of observed effects, if any, on animal health.

4.6.4 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 and guidelines for evaluation and decision making currently used in the country to which application is made.

4.6.5 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.

4.6.6 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 paragraphs 4.6.2 and 4.6.3, 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.

4.6.7 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.

4.6.8 The assessments made should be presented as a composite element of the regulatory authority's summary and evaluation of the data and information considered. Those tests and studies relied on by the regulatory authority in reaching its conclusions should be clearly referenced in the assessment.

4.6.9 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 the registration 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.

4.6.10 The list of test and study reports relied on should be listed by active substance or formulation data point as appropriate. For each individual data 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 rules or provisions in place in the country to which application is made and the owner of the report, should be indicated - applicants should be required, where appropriate, to certify that the studies for which they have claimed data protection, were not previously submitted in support of an application, or if previously submitted, they should be required to report the period of protection, if any, remaining. In addition, an indication should be provided systematically as to whether individual test and study reports have been published or not and as to whether, or not, it was conducted in compliance with the principles of GLP or the principles of GEP, as appropriate.

4.6.11 The reference list should also include the regulatory authority's assessment of the claims made for the protection of particular tests and study reports in accordance with the relevant rules or provisions in place in the country to which application is made.

4.6.12 The final part of Annex B should consist of the list of standard terms and abbreviations, the list of special terms and the list of all chemical names, common names, synonyms and code names, used for the active substance and its metabolites and for formulations containing the active substance, 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 this guidance document);

(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).

(iii) Appendix 3 - chemical names, common names, synonyms and code names, used for the active substance and its metabolites and for formulations containing the active substance (the format suggested is illustrated in Part 3 of Appendix 1 to this guidance document).

4.7 **Annex C Confidential information and, where relevant, details of any task force formed for the purposes of generating tests and studies submitted**

4.7.1 In accordance with the legislative provisions of the country to which application is made, 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). The regulatory authority 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 regulatory authority 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 In each instance that, data submitted in support of an application is submitted by a task force formed by a number of applicants, a summary of relevant details of the task force should be included:-

(i) the membership of the task force and a contact point for the task force (name, address, telephone and telefax numbers and e-mail address);

(ii) a contact point for each member of the task force (name, address, telephone and telefax numbers and e-mail address); and

(iii) the list of test and study reports which were generated by or on behalf of the task force - where some members of the task force share ownership of, or have access to, some but not all of the test and study reports, a clear indication should be provided as to the ownership of, and rights of access to, the individual test and study reports listed.

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.