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Guidance Document on the Planning and Implementation of Joint Reviews of Pesticides

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OECD Environment, Health and Safety Publications
Series on Pesticides

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Guidance Document on the Planning and Implementation of Joint Review of Pesticides

IOMC

INTER-ORGANIZATION PROGRAMME FOR THE SOUND MANAGEMENT OF CHEMICALS

A cooperative agreement among FAO, ILO, UNEP, UNIDO, UNITAR, WHO, World Bank and OECD

Environment Directorate

ORGANISATION FOR ECONOMIC COOPERATION AND DEVELOPMENT

Paris 2011

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No. 59 *Report of the OECD Seminar on Risk Reduction through Prevention, Detection and Control of the Illegal International Trade in Agricultural Pesticides* (2011)

Published separately

OECD Guidance for Country Data Review Reports on Plant Protection Products and their Active Substances-Monograph Guidance (1998, revised 2001, 2005, 2006)

OECD Guidance for Industry Data Submissions on Plant Protection Products and their Active Substances-Dossier Guidance (1998, revised 2001, 2005)

Report of the Pesticide Aquatic Risk Indicators Expert Group (2000)

Report of the OECD Workshop on the Economics of Pesticide Risk Reduction (2001)

Report of the OECD-FAO-UNEP Workshop on Obsolete Pesticides (2000)

Report of the OECD Pesticide Aquatic Risk Indicators Expert Group (2000)

Report of the 2nd OECD Workshop on Pesticide Risk Indicators (1999)

Guidelines for the Collection of Pesticide Usage Statistics Within Agriculture and Horticulture (1999)

Report of the [1st] OECD Workshop on Pesticide Risk Indicators (1997)

Report of the OECD/FAO Workshop on Pesticide Risk Reduction (1995)

About the OECD

The Organisation for Economic Co-operation and Development (OECD) is an intergovernmental organisation in which representatives of 34 industrialised countries in North and South America, Europe and the Asia and Pacific region, as well as the European Commission, meet to co-ordinate and harmonise policies, discuss issues of mutual concern, and work together to respond to international problems. Most of the OECD's work is carried out by more than 200 specialised committees and working groups composed of member country delegates. Observers from several countries with special status at the OECD, and from interested international organisations, attend many of the OECD's workshops and other meetings. Committees and working groups are served by the OECD Secretariat, located in Paris, France, which is organised into directorates and divisions.

The Environment, Health and Safety Division publishes free-of-charge documents in ten different series: **Testing and Assessment**; **Good Laboratory Practice and Compliance Monitoring**; **Pesticides and Biocides**; **Risk Management**; **Harmonisation of Regulatory Oversight in Biotechnology**; **Safety of Novel Foods and Feeds; Chemical Accidents; Pollutant Release and Transfer Registers; Emission Scenario Documents;** and **Safety of Manufactured Nanomaterials.** More information about the Environment, Health and Safety Programme and EHS publications is available on the OECD's World Wide Web site (www.oecd.org/ehs/).

This publication was developed in the IOMC context. The contents do not necessarily reflect the views or stated policies of individual IOMC Participating Organizations.

The Inter-Organisation Programme for the Sound Management of Chemicals (IOMC) was established in 1995 following recommendations made by the 1992 UN Conference on Environment and Development to strengthen co-operation and increase international co-ordination in the field of chemical safety. The Participating Organisations are FAO, ILO, UNEP, UNIDO, UNITAR, WHO, World Bank and OECD. UNDP is an observer. The purpose of the IOMC is to promote co-ordination of the policies and activities pursued by the Participating Organisations, jointly or separately, to achieve the sound management of chemicals in relation to human health and the environment.

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FOREWORD

A *joint review* is an evaluation of a pesticide dossier through work-sharing between two or more countries. The participating regulatory authorities review the work of the primary reviewers for each particular science discipline, and the end product (ideally a complete monograph or key components of the monograph) is used by all participating countries (and others) as the basis for regulatory decisions.

As a formal process, joint reviews require i) a dossier to be submitted to all participating regulatory authorities simultaneously; ii) a timeline and work allocation to be negotiated in advance; iii) data reviews and peer-reviews; and iv) an agreement on both the documentation to be produced and the decision-making target date.

In conjunction with the requirements, this guidance document was prepared to support joint reviews in order to maximize opportunities of work-sharing arrangements between regulatory authorities in OECD countries. This guidance document includes two main phases of a joint review, planning and implementation phases, with a view to helping industries and regulatory authorities conduct the joint review process.

Further to the recommendations from the *OECD Workshop on Lessons Learned with Planning and Implementation of Joint Reviews of Pesticides Dossiers*, which was held on December 2008 in Bonn, Germany, this guidance document was developed in the Registration Steering Group of the Working Group on Pesticides; its documentation was led by Canada; and finally this draft was approved by the Working Group on Pesticides by written procedure which was finished in January 2011.

This document is being published under the responsibility of the Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology, which has agreed that it be unclassified and made available to the public.

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SECTION 1 – BACKGROUND AND OVERVIEW OF THE JOINT REVIEW PROCESS

1.1 Introduction

1. The Organization for Economic Co-operation and Development (OECD) vision is that, by the end of 2014, data submissions (dossiers) for chemical agricultural pesticides[1] will be prepared globally whenever possible, and dossiers in the OECD format[2] will be accepted in all member countries (notwithstanding supplementary data requirements to address unique local/national issues).

2. As this effort should maximize opportunities for cooperation between OECD countries, joint review projects between the various regulatory authorities should be a matter of routine. In addition, the pesticide regulatory system will be harmonized, to the extent that country data reviews (monographs) prepared in the OECD format will support independent risk assessments and regulatory decisions made in other regions or countries.

3. Ultimately, a single monograph for each active ingredient should become commonplace and serve the needs of regulatory authorities in all OECD countries, notwithstanding the need for separate, independent risk assessments and regulatory decisions in each jurisdiction.

4. Joint reviews provide valuable test cases for existing OECD guidelines and guidance documents. They also identify areas where more guidance is needed to increase harmonization. Furthermore, countries will ensure that the efficiencies and experience gained by the OECD Working Group on Pesticides are reflected in other relevant international for a (e.g. FAO/WHO Joint Meeting on Pesticide Residues (JMPR) and Codex Committee on Pesticide Residues (CCPR)), thereby helping developing countries manage their pesticide regulatory systems.

5. A number of joint reviews involving several OECD countries have been completed or are underway, while others are being planned. This document draws on these experiences to provide guidance in a format that will help industry and regulatory authorities conduct successful joint reviews in future.

6. Although developed under the OECD Pesticide Programme, the joint review projects are not managed by the OECD Secretariat or any official OECD body. Rather, they are coordinated by various groups of countries (which may or may not all be OECD members) and pesticide companies.

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1 Does not include antimicrobial pesticides.

2 Information on the OECD format for dossiers and OECD templates is available on the OECD Web site, at http://www.oecd.org/department/0,3355,en_2649_34383_1_1_1_1_1,00.html.

1.2 Definition of "Joint Review"

"Joint review" may be defined as follows:

- The evaluation of a pesticide dossier is shared by two or more countries. The participating regulatory authorities review the work of the primary reviewers for each particular science discipline, and the end product (ideally a complete monograph or key components of the monograph) is used by all participating countries (and others) as the basis for regulatory decisions. This type of work sharing is the focus of this guidance document.

7. A joint review requires that the dossier be submitted to all participating regulatory authorities simultaneously. This is a formal process in which timelines and work allocation are negotiated in advance. Data reviews are exchanged and peer reviewed, and there is agreement on both the documentation to be produced and the decision-making target date, i.e. the date on which the decision (which may be a proposed decision) is communicated to the applicant. This type of work sharing is the focus of this guidance document.

1.3 Essential Stages and Key Outputs of a Typical Joint Review

8. The main phases of a joint review (e.g. for a new active ingredient) are summarised below. Figure 1 shows the broad stages of the project, which is described in greater detail ***in sections 2 and 3.***

Planning Phase

- Proposal of candidate active ingredients and end-use products by the applicant(s);
- Agreement by regulatory authorities that a candidate active ingredient and/or end-use product meet(s) the criteria for joint review;
- Agreement on which regulatory authorities will participate, allocation of responsibilities and designation of one regulatory authority as project lead, to manage the joint review through the planning and implementation (dossier review) phases; and
- Agreement on the project scope, duration and key timelines/milestones and on whether a complete monograph will be produced; specific requirements for dossier format and monograph format; ensuring that all participating countries have the required resources available at the right time; establishing primary and secondary project contacts in each country/organization; and setting deadlines for achieving intermediate milestones or goals, as well as setting dates for meetings and telephone conferences. If a required output from the joint review is the accelerated establishment of Codex MRLs, then the secretariats of the Codex Committee on Pesticide Residues (CCPR) and the FAO/WHO Joint Meeting on Pesticide Residues (JMPR) should be consulted on the available options.[3]

[3] The SPS Agreement of WTO specifically states that, in the area of food safety, including MRLs for pesticides, the Codex Alimentarius Commission is the international standard-setting body. The Codex Alimentarius Commission Procedural Manual (17th Edition, 2007) stipulates that, for MRLs for pesticides, the recommendations of the JMPR for maximum limits are distributed to Codex members for comment. The CCPR itself does not review scientific data, but Codex members can check the JMPR monographs and appraisals as necessary for discussion of draft MRLs at the CCPR. The relationship between the

Implementation Phase (Dossier Review)

- Dossier submitted electronically in OECD format;
- Dossier receipt and completeness check (to confirm that the dossier is ready for evaluation);
- Participating countries must be satisfied the dossier contains all required information;
- This work should be organized to avoid duplication of effort. The output of this stage is the project lead's compilation of the data-related deficiencies and communication of these to the applicant/company in writing on behalf of all participating regulatory authorities. Document O of the dossier should form the basis of this report (modifications may be made on a case-by-case basis);
- Primary review of studies and derivation of proposed common endpoints for use in country-specific risk assessments;
- The main output from the primary review stage is the draft evaluation document(s), ideally, a complete monograph or Volume 3 of the monograph (refer to Appendix 6) which summarizes each study submitted, presents a clear overview of the key findings in each section and presents a table of the key proposed endpoints or reference values (e.g. ADI) (which regulatory authorities can use following the secondary review of the information when conducting risk assessments);
- Secondary review of the draft evaluation document(s) and agreement on endpoints for use in risk assessment;
- Additional planning points for secondary review participants; and
- One of two approaches must be selected early in the process: (a) a secondary review by project participants, i.e. by the regulatory authorities participating in the joint review,
- or (b) an "open" secondary review by the project participants and all EU member states (MSs) and the European Food Safety Authority (EFSA), to facilitate the EU processes for evaluating pesticide active ingredients and regulatory decision making. For option (b) to be viable, all relevant sections of the monograph must be prepared on time in the agreed format. Where option (b) is chosen, the EU rapporteur member state (RMS) is responsible for coordinating the input (e.g. initiating the peer review process) from EU member states and the EFSA as required. The preferred approach should be determined at the planning stage of the project.

CCPR and JMPR in the area of MRL setting and risk analysis is also described in the Procedural Manual.

While joint reviews can provide information valuable to the work of Codex, it is not mandatory for the CCPR or JMPR, which must retain their independence and neutrality, to get directly involved in joint reviews. Nevertheless, the CCPR should be advised of proposed and on-going joint reviews, as this useful information could facilitate JMPR reviews. It is noted that the OECD is not open to all Codex members, or FAO or WHO members.

The CCPR is currently reviewing some of its working procedures (e.g. on the criteria for the nomination of active ingredients). Therefore, it might be premature to propose concrete actions. During the planning phase, the manufacturer, together with joint review governments, could consider whether notification of the CCPR was appropriate. Existing monographs should be sent to the JMPR. Whether the JMPR wants to get involved in the peer review stage of the project is a matter of general principle for the JMPR. Again, it might be too early to address this matter in this document.

9. Where an EU member state is one of the project participants (i.e., the application has also been made in the EU), option (a) or option (b) could be used as input to be considered by EFSA when drafting its conclusion. However, they cannot replace the commenting to be organised by EFSA and they do not preclude EFSA from organising, where appropriate, a further expert consultation.

10. Whether (and to what extent) the applicant will take part in the secondary review stage of the project should be discussed during the project planning phase.

11. The main outputs from the secondary review stage (to be posted on CIRCA, see section 3.1.7 for information on CIRCA) are:

- Reporting table to summarize comments by secondary reviewers on the primary study reviews, capture the responses of the primary reviewers to the secondary reviewers comments, and indicate the outcome of the exchange;

- Evaluation table (if needed), to identify points of disagreement and outstanding data requirements;

- Final evaluation documents or monograph including:

  – agreed list of endpoints/reference values for risk assessment (including indication of where agreement on an endpoint was not possible to achieve); and

  – discussion and agreement, if possible, on common critical issues to consider in country/region -specific risk assessments.

- Development of country/region-specific risk assessments using the results and analysis of the agreed endpoints and evaluation documents:

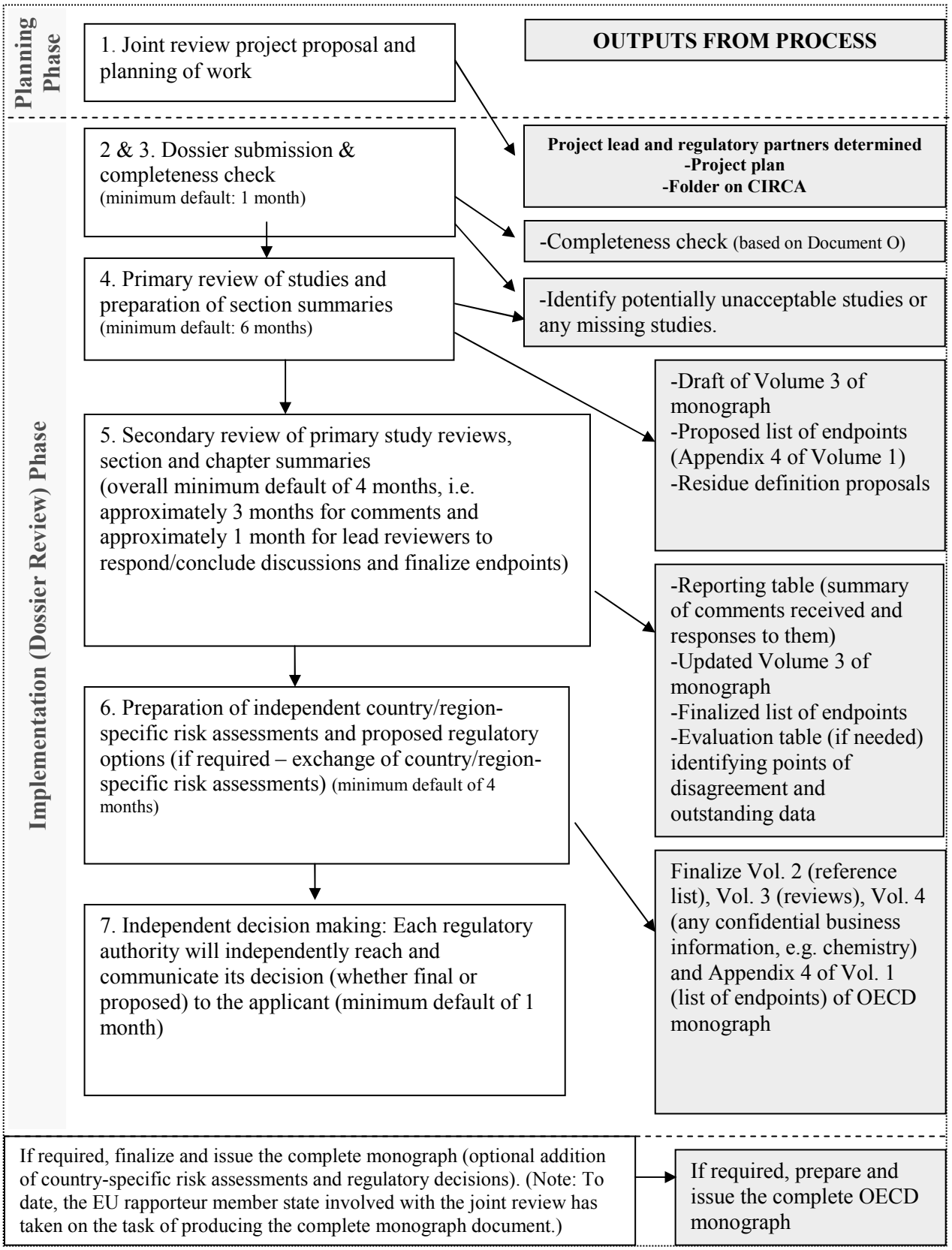
  – Participating countries (and others) conduct appropriate country/region-specific risk assessments by calculating exposure estimates using the appropriate models for their country or region, and using the evaluation documents and the list of endpoints produced at the data review stages.

  NOTE: While participating regulatory authorities work independently on their risk assessments, there should be back-and-forth discussions on whether there are opportunities to harmonize maximum residue limits (MRLs).

- Sharing of risk assessments and proposed regulatory decisions, and development of labelling and regulatory documentation among participating regulatory jurisdictions.[4]

[4] The risk assessment stage is typically outside the work-sharing/collaborative portion of the OECD joint review. However, if participating countries/regions wish, country-specific risk assessments may be exchanged for information and/or appended to the monograph.

Figure 1. Project Outline for a Joint Review (e.g. New Active Ingredient)



SECTION 2 – GUIDANCE FOR APPLICANTS

2.1 Project Proposal and Planning

2.1.1 Type of Submission

An applicant may seek a joint review for any of the following:

- The active ingredient dossier alone, with end-use product dossiers reviewed individually at the national level;
- Both the active ingredient and end-use product dossiers submitted together; and
- An additional use for an existing active or end-use product (i.e. "second-entry"), preferably for an active ingredient already approved through the joint review process.

NOTE: The amount of work that participating regulatory authorities will need to do to assess the submission may vary significantly, depending on the submission type.

2.1.2 Criteria

2.1.2.1 Criteria for Proposing a New Active Ingredient and Associated End-Use Product(s) for Joint Review

12. An applicant may request a joint review for a new active ingredient and associated end-use product(s).

13. The criteria for determining whether the active ingredient and end-use product(s) are candidates for joint review are as follows:

- For new active ingredients, the active ingredient must not be registered in any of the participating jurisdictions;
- The source(s) of the technical active ingredient should be the same in all participating jurisdictions;
- The active ingredient and associated end-use product(s) would be marketed in a significant number of countries or regions, or the produce treated with the active ingredient would be exported widely;
- The timeline for dossier submission to all participating regulatory authorities is the same (i.e. it must be done within days);
- Marketing of the active ingredient and/or end-use product in the participating countries/regions is similar;

- The proposed uses are applicable in the countries/regions intended for marketing;

- At least one end-use product (i.e. with the same formulation) should be common to all countries participating in the review; and

- If the end-use product is a co-formulation with other active ingredients, the other active ingredients must be registered in the participating jurisdictions and should have the same use pattern in each jurisdiction. If this is not the case, whether such end-use products can be part of the joint review project proposal would be considered on a case-by-case basis, taking into consideration potential impact on the joint review timelines.

2.1.2.2 Criteria for Proposing a Second-Entry Joint Review

14. A second-entry joint review is the assessment of an application for a product (new or amended) which contains active ingredients registered in the participating countries**.** At this time, for second-entry joint reviews, primarily the following types of applications which involve data review shall be considered:

- new source of active ingredient;

- use expansions for existing products, including new uses, application rates, number of applications, etc.;

- new formulations of existing products;

- new combination of active ingredients; and

- new products with new uses and/or new formulations.

15. The following criteria must be met:

a. The active ingredient(s) must be registered in all participating countries, preferably through the joint review process;

b. There must be a complete, modern database on file for the active ingredient(s) with each of the proposed regulatory authorities;

c. Proposed new uses (that are applicable in all countries) and new formulations must be new to all participating countries, i.e. they cannot have some uses or formulations already registered in one country and not the others;

d. Formulations should be the same for all countries;

e. The timeline for dossier submission to regulatory authorities is the same (i.e. it must be done within days);

f. For applications involving formulation changes, corresponding label uses should be the same in all participating countries; and

g. For new sources of registered active ingredients, the new source(s) of the active ingredient must be new to all countries and must be the same.

General Considerations:

16. To determine if a joint review is possible, the data requirements, submission timelines and data protection requirements in each country shall be considered. If data requirements and submission timelines differ significantly, a joint review might not be feasible. In addition, where precedent products are cited to support registration of some or all uses of a proposed product, differences in the data protection/compensation provisions in the participating countries may impede a joint review. (NOTE: If an EU member state is involved, the above amendments might make it necessary to amend the active ingredient approval at the EU level. That possibility should be considered in setting the timelines for the process during the project planning phase.)

2.1.3 How to Request a Joint Review

17. If an applicant believes it is has a suitable candidate for joint review, it should approach the relevant regulatory authorities. For a new active ingredient, the applicant should start this consultation process at least two years before the target date for submitting the dossier. Ideally, for a second-entry joint review (e.g. for use expansion), the applicant should start this consultation process at least 6 months before the target date for dossier submission.

Part of this consultation should look at:

a. why the candidate product(s) is (are) suitable for joint review (i.e. meeting the above criteria);

b. the perceived benefits of a joint review of the active ingredient and/or end-use product(s);

c. the anticipated date of dossier submission for the joint review; and

d. the proposed regulatory participants for the joint review.

18. The feasibility of a joint review can be discussed by the applicant and all interested regulatory authorities.

2.1.4 Joint Review Planning and Technical Pre-Submission Consultation Meetings

19. Joint review planning and technical pre-submission consultation meetings are mandatory for potential joint reviews. Applicants who believe a joint review is appropriate for a proposed new active ingredient and/or end-use product should present the idea to the regulatory authorities of their choice. Currently, these presentations are done at the government/industry meetings held the same week as the OECD pesticide meetings (e.g. those of the Working Group on Pesticides (WGP) and Registration Steering Group (RSG)). Applicants are encouraged to consider and discuss possible/likely minor uses in this pre-submission phase.

Joint Review Planning Meetings

20. The purpose of joint review planning meetings, where presentations are made by applicants to regulatory authorities, would be to introduce their new active ingredient/products and to discuss whether their proposed active ingredient/products are good candidates for the joint review program. This type of meeting is of a scoping/administrative nature, and it is important that regulatory authorities follow up with discussions on the suitability of a particular product for joint review, the regulatory participants who could

be involved, and whether they have a common understanding of the issues. For second-entry joint reviews, depending on their complexity, a presentation at the government/industry meetings held the same week as the OECD pesticide meetings (e.g. those of the WGP and RSG) may be advisable. The applicant should designate primary and secondary contacts for the proposed dossier at this phase.

Technical Pre-Submission Consultation Meetings

21. Technical pre-submission consultations are requested during the dossier development stage, to help ensure that a complete, high quality dossier is prepared and to address specific technical or process-related issues for all jurisdictions. Pre-submission consultations can confirm and clarify data requirements and product testing (e.g. the number and location of study trials), address submission formatting issues, and provide feedback from regulatory authorities on study protocols proposed by applicants.

22. Wherever possible, applicants are encouraged to have technical pre-submission consultations with all potential regulatory authorities, although some consultations may involve only one specific country or region if the questions are specific to that jurisdiction. It is recommended that the applicant record the draft minutes or notes and provide them in a timely manner to meeting participants for comment, clarification, and correction. After receiving the consolidated comments from all participating regulatory authorities regarding the draft minutes or notes, the applicant finalizes the minutes or notes and distributes them to all participating authorities for approval, so that the appropriate regulatory authority can post the approved minutes or notes on CIRCA. To arrange a technical pre-submission consultation, applicants must complete a pre-submission consultation request (see Appendix 1) and submit it via email to the appropriate regulatory authority. A completed pre-submission consultation request should provide basic information on the proposed product and indicate the science disciplines with regard to which the applicant wishes to consult (e.g. toxicology, food residue and efficacy), as well as any specific issues/questions to be addressed by regulators. In addition to the pre-submission consultation request, applicants should provide as much detail as possible on the product specifications (i.e. the identity and concentration of the active ingredient(s) and formulant(s), as well as product use information (i.e. sites, pests, rate and timing of application). If possible, a draft label outlining the proposed use pattern should be provided.

In some cases, a written response from the participating regulatory authorities to the consultation request may suffice. However, if necessary, meetings or teleconferences with the applicant and appropriate regulators may be arranged. Before meeting with the applicant, regulatory authorities may wish to discuss potential issues up front. The regulatory authority coordinating the meeting (e.g. the project lead) should ensure all participants have appropriate advance notice. Applicants should provide presentation materials and specific technical questions at least one week in advance.

NOTE: A list of studies (i.e. data matrix) must be submitted by the applicant in advance of the anticipated dossier submission date, in order that the regulatory authorities may use this information as required (e.g. to refine the work allocation among regulatory participants). The applicant should clearly indicate in the list of studies which studies are of regional interest and to which country.

2.1.5 Acceptance into the Joint Review Process

23. The fact that a candidate active ingredient/product meets the criteria for joint review does not necessarily mean that the regulatory authorities will proceed with the project, or that the joint review will be completed within a timeframe acceptable to the applicant.

24. Several factors must be considered before accepting a candidate active ingredient/product for a joint review. These include:

- the number of joint reviews currently underway;
- the resources required; and
- competing priorities of the regulatory authorities proposed for working on the joint review.

25. In general, requests for joint reviews shall be considered in chronological order of receipt. Applicants must accept that countries may, in accordance with their national regulations, require country-specific application fees.

Communication

26. Good communication is critical throughout the process, not only among regulatory authorities, but also among the applicant's international branches, to ensure a common understanding of project goals, potential issues and solutions.

2.2 Joint Review Project Implementation (Dossier Review)

2.2.1 Submission of a Complete Dossier

27. The dossier must be provided to each participating regulatory authority by an agreed date, and it should be complete at the time of submission. It must include all studies to be reviewed, unless the regulatory authorities agree to accept certain studies at a later date. Studies with only regional relevance should be identified and included as part of the dossier delivered to all regulatory authorities. A list of study reports submitted must be included at the end of each section of the dossier. The list must indicate whether:

- the study complies with the principles of GLP or GEP, as appropriate;
- the study has been published; and
- data protection is claimed for the study.

28. The dossier to be submitted must include summaries of every study in the agreed format.

29. In general, although summaries in PDF are acceptable, they should also be made available in a format such as MS Word. In advance of dossier submission, the applicant should confirm with each participating regulatory authority what it prefers (e.g. both PDF and Word format, or just Word).

30. In addition to the individual study reports, the dossier must include the overall summaries (in OECD templates format, also known as "Tier II"(i.e. Document M) of the data submitted as separate documents. 'Tier I' study summaries (Document L) are not normally required (this should be confirmed during the project planning phase when determining document expectations), although the reference lists (that also form part of Document L) should continue to be submitted. Jurisdictions may also require that

the dossier include the applicant's proposal for the endpoints to be used in the risk assessment, as well as risk assessments conducted in accordance with the methodology applied in that jurisdiction. For this reason, if required, each jurisdiction must provide appropriate guidance on how this information is to be presented in advance of dossier submission.

31. The dossier to be submitted must include the Document O completeness check forms (available on the OECD Web site). Applicants must confirm the following in Document O: that each data point has been addressed by a study; and that robust justification for non-submission of particular data has been provided, or that a commitment to submit outstanding information, test and study reports by specified date has been made.

32. If required, applicants must help participating regulatory authorities conduct completeness checks by making knowledgeable personnel available to answer questions.

2.2.2 Interaction with Regulatory Authorities during Dossier Evaluation

33. Detailed rules for interaction between applicants and regulatory authorities may be established on a project-by-project basis and set out in the project plan. At the end of the dossier evaluation stage, if one or more regulatory authorities wish to share the draft evaluation with the applicant to identify typographical or other errors, this must be discussed in advance among the regulatory partners.

2.2.3 Interaction with Regulatory Authorities during the Secondary Review Stage

34. Detailed rules for interactions between the applicant/company and the regulatory authorities may be established on a project-by-project basis and set out in the project plan.

2.2.4 Interaction with Regulatory Authorities during Finalization of the Project

35. Detailed rules for interactions between the applicant and the regulatory authorities may be established on a project-by-project basis and set out in the project plan.

SECTION 3 – GUIDANCE FOR REGULATORY AUTHORITIES

36. This section outlines the procedure for planning and conducting a joint review. The basis for the review is the dossier submitted by the applicant. The successful completion of a high quality/timely joint review depends in large part on effective communication among team members. Managing a joint review is a complex task. The project lead, working with the primary project contacts (i.e. country leads) and the primary reviewers for each science discipline shall ensure that, as far as possible, each stage of the project is completed on schedule and that the time period between acknowledgement of the dossier as complete and the project conclusion reflects the agreed project plan.

3.1 Planning Joint Reviews

3.1.1 Identification and Agreement of Joint Review Partners

37. Where two or more countries agree that an active ingredient is suitable for joint review, the optimum number of countries to take part in the project should be considered. It is recommended that the countries involved appoint the project lead as soon as possible (e.g. a year in advance), and determine the role of each participating regulatory authority (e.g., reviewer, observer). The project lead is responsible for preparing the project plan, establishing a folder on CIRCA, and coordinating the joint review planning phase as required. At the same time, a tentative work allocation (work split) among regulatory partners should be established, and primary and secondary project contacts (i.e. country leads) designated for each of the participating regulatory authorities.

3.1.2 Agreement on the Scope and Objectives of a Project

38. At the outset, before the dossier is received, it is important to agree on the project scope and primary objectives. The duration of the joint review, the key timelines (milestones) and the requirements for dossier and monograph format should be discussed and reflected in the project plan. The project planning team, in consultation with the applicant, needs to consider a range of issues, including:

- Which end-use product(s) will be included in the scope of the joint review, e.g. submissions going to all participating regulatory authorities vs. those only going to a subset of regulatory partners? As a general rule, joint review projects should be kept simple and should not involve too many end-use products. In addition, at least one end-use product (i.e. with the same formulation) should be common to all countries involved in the joint review. NOTE: The complexity of a joint review (e.g. number of end-use products/co-formulations) may affect the timeline;

- Will a complete monograph be produced? Or will volumes 2, 3 and 4 and a list of endpoints (Appendix 4 of Vol. 1) of the OECD monograph be sufficient? (NOTE: At this time, if a complete monograph is to be produced and an EU RMS has been involved in the joint review project, it has been the EU RMS which has compiled the complete monograph and issued as required.);

- If a complete monograph is to be produced, the following must be considered:

- Which end-use product(s) will be included in the monograph? (It is suggested that no more than two end-use products be included.)

- Will all studies be evaluated and reported in the monograph, including those of regional significance only?

- Inclusion of risk assessments or identification of issues that countries need to consider when conducting risk assessments.

- Should all regionally specific residue field studies be included in the monograph?

- Should regionally specific efficacy be included in the monograph?

- Depending on which approach has been taken for the secondary review (see section 1.3), the responsibilities of the EU RMS with regard to the EU process needs to be defined;

- The format of the dossier must be discussed and accepted early in the process;

- Objectives regarding the early elaboration of MRLs and/or import tolerances should be discussed. (Define how regionally specific residue field studies are to be reviewed and reported.) If an EU RMS is involved, it is their responsibility to involve EFSA, EU Member States and Commission as required to have the required maximum residue limits (MRLs) and import tolerances established in the European Union;

- Is the monograph (or are parts of it) to be used as a basis for a JMPR monograph?; and

- Will the joint review include an evaluation of efficacy data?

39. In addition, regulatory authorities should respect certain general project principles:

a. Resolve difficulties encountered on an ad hoc basis. However, if authorities have to "agree to disagree," justify clearly why this is;

b. Each jurisdiction is to prepare its own country-specific risk assessments and regulatory decision; and

c. Each country is to inform partners when regulatory decisions are made.

NOTE: The Registration Steering Group (RSG) of the OECD is not formally involved in the operational planning and implementation of joint reviews, as this is the role of regulatory authorities participating in the government/industry meetings on joint reviews. However, participating regulatory authorities may wish to inform the RSG of any issues/experiences that could impact future joint review projects for further consideration.

3.1.3 Designation of Project Lead, Primary/Secondary Project Contacts and Primary/Secondary Reviewers

Project Lead

40. A project lead (overall administrative lead) should be identified as soon as possible by the potential regulatory partners (once the tentative regulatory partners have been proposed), to coordinate the project planning. Responsibilities include setting up a folder on CIRCA and drafting a project plan in advance of the anticipated date for dossier submission.

41. When drafting the project plan, the project lead must ensure that timelines for each stage are discussed and accepted by all participating regulatory authorities in advance of dossier receipt. The same regulatory authority shall continue as project lead (though the person designated as project lead may change), ensuring that, as much as possible, the joint review is completed in accordance with the project plan. This includes ensuring that the primary reviews are delivered as scheduled and that the secondary reviews are completed on time. A project plan template is provided in Appendix 3.

42. Note: When choosing the project lead, participants should consider whether there are other joint review applications outside the scope of the global joint review project (e.g. NAFTA Joint Review applications) that will also require a project lead.

Project Contacts (Primary and Secondary)

43. For each of the participating regulatory authorities, primary contacts (country leads) as well as secondary project contacts need to be designated (and documented) as soon as possible during the joint review planning phase, to ensure effective coordination and communication regarding the development/management of the joint review project. The applicant/company also needs to designate primary and secondary project contacts for the same purpose.

Primary Reviewer and Secondary Reviewers

44. For each science discipline, each regulatory authority shall nominate an evaluator or evaluators for that particular work area. If a particular jurisdiction is responsible for the primary review of a particular science discipline, the nominated evaluator shall serve as the primary reviewer for that science discipline, and shall be responsible for ensuring that primary reviews (study evaluations) are delivered on schedule to the primary project contact representing their jurisdiction/regulatory authority.

45. The nominated evaluators from the other participating regulatory authorities shall serve as secondary reviewers of the primary reviews. NOTE: The primary reviewer also has personal responsibility for ensuring that the secondary reviews are delivered on schedule to the primary project contact representing their jurisdiction.

3.1.4 Allocation of Work (Work Split)

46. When regulatory authorities decide which country will evaluate which elements of the dossier, efforts should be made to ensure that all participating regulatory authorities will have the required resources available at the right time. In addition, the regulatory authorities should agree on realistic

deadlines for achieving intermediate milestones, based on the complexity of the dossier. The final division of responsibilities can be shared with the applicant.

47. While one regulatory authority shall have overall responsibility for review in each science discipline, including responsibility for conducting the primary review of all studies within that discipline, other regulatory authorities may volunteer to conduct a part of the assessment on the basis of resource availability and skill mix. (Alternatively, guidance/guidelines may be provided by another country's regulatory authority to allow the primary reviewer for a particular section to complete the evaluation.) If possible, before the project starts, the regulatory authorities responsible for evaluating each section of the dossier should make it clear if there are any studies within that section that they will not evaluate. (If such studies are not identified before dossier receipt, they may also be identified after dossier submission, during the completeness check stage.) The other countries should then agree on which regulatory authority will evaluate the studies in question.

3.1.5 Technical Pre-Submission Consultation Meetings between Applicants and Regulatory Authorities (see also Section 2.1.4)

48. Primarily, these meetings should be used to clarify the scope of the submission and to discuss any technical issues arising from the studies conducted. In particular, regulatory authorities need to be informed on issues that might complicate or delay dossier evaluation. Although these meetings can take place with individual regulatory authorities if the topics to be discussed are specific to the work of that regulatory authority, decisions which could have implications for other regulatory participants may not be made without consulting and involving all the participating regulatory authorities.

49. It is important that pre-submission discussions be recorded appropriately. Minutes or notes capturing the key issues discussed during the pre-submission consultation meetings should be shared with all participants involved in a particular project. It is common practice that the applicants record the draft minutes or notes and provide them in a timely manner to meeting participants for comment, clarification and correction. Consolidated comments from all the participating regulatory authorities regarding the draft minutes shall be sent to the applicant, in order that the applicant may finalize the minutes. The approved minutes should be posted on CIRCA by the appropriate regulatory authority.

3.1.6 Drafting the Project Plan

50. Once the scope and objectives of a project have been established by the participating regulatory authorities, the project lead (representing one of the regulatory authorities) shall prepare a draft of the project plan to share with the other regulatory authorities. See Appendix 3 for the template for a joint review project plan.

51. Each regulatory authority must provide realistic estimates of the work and time required. The project lead, in consultation with the other regulatory participants, may use these estimates to set deadlines for achieving the intermediate and final project milestones.

52. In addition to designating the primary and secondary project contacts, each participating regulatory authority must nominate, for each science discipline for which it is responsible for the primary review, the lead reviewer who shall have responsibility for ensuring that the primary reviews (study evaluations) and secondary reviews are delivered on schedule to the primary and secondary project contacts nominated for its regulatory authority. A template for capturing the detailed contact information for the evaluators (both primary and secondary reviewers) in each science discipline is in Appendix 4.

53. The project plan shall establish timeframes for regular conference calls (or video conferences) involving the project lead, the primary project contacts, as well as the evaluators as required, in order to:

- review the progress to date in each science discipline (i.e. in work assigned to each participating regulatory authority);

- identify aspects on which progress is behind schedule and decide on the action to be taken to ensure that the agreed timelines are observed; and

- flag science issues that are causing concern and decide on the action to be taken to resolve those issues.

54. All decisions made in planning and progress meetings and in telephone or video conferences shall be recorded and shared with all participating countries.

3.1.7 Sharing Project Information and Documents

55. There should be a central electronic repository for project-related documents (e.g. project plans, meeting minutes or notes) to which all participating regulatory authorities have access. The Communication and Information Resource Centre Administrator (CIRCA) is the main tool for sharing such documents. CIRCA is an Internet-based groupware application developed by the European Commission under the *Interchange of Data between Administrations* (IDA) Programme. It is a Web-based software framework providing a secure, common virtual space for the sharing of resources and documents by work groups. It is offered as a common tool to public administrations. Although access to CIRCA is available via the "sign-up" procedure on the CIRCA homepage http://circa.europa.eu/Public/irc/sanco/Home/main, the Interest Group (IG) "Worksharing Pesticides" is accessible only to a closed user group (i.e., those involved with the joint review of pesticides). Users can apply for access to this IG by submitting applications to the CIRCA administrator for their jurisdiction or, if a CIRCA administrator for their jurisdiction does not exist, submit applications to another regulatory authority with leadership privileges for this IG (e.g., the regulatory authority assigned as Project Lead for the joint review project in question). Note: All jurisdictions routinely participating in joint review projects should consider appointing their own CIRCA administrator.

56. The project lead representing the regulatory authorities shall be responsible for setting up the necessary folders on CIRCA to service the project. General guidance on how to set up the folders and sub-folders is provided in Appendix 2 (Checklist for Joint Review Planning - Stage 1d).

NOTE: the first three sections of the final project plan (see Appendix 3), i.e. Overall Summary of Joint Review Project Timelines, Summary of Work Allocation among Participating Regulatory Authorities, and Primary and Secondary Project Contact Authorities, should be shared with the applicant after the dossier is received.

3.2 Joint Review Implementation (Dossier Review)

3.2.1 Communication

57. Timely and effective communication at all stages of a joint review is imperative. When the dossier is received, the primary and secondary project contacts from each participating regulatory authority and the applicant must be confirmed. The primary reviewer must also be confirmed for each work area.

58. In most cases, key communications between the applicant and regulatory authorities are through the project lead. All contact (telephone, email, correspondence) involving one or more of the participating regulatory authorities and the applicant must be carried out as follows:

1. All communication must be clear, open and transparent, whether it is between joint review team members or regulatory authorities and the applicant;

2. All communication (correspondence, emails and summaries of telephone calls) must be copied to the project lead and primary project contacts;

3. During the completeness check and study evaluation, queries (correspondence, emails, summaries of telephone calls) on the information, tests and studies submitted must be sent to the applicant's primary project contact, either by the project lead or the primary contact of the regulatory authority responsible for that section of the dossier (with a copy to the project lead). Regulatory authorities should consider capturing this information on CIRCA if appropriate; and

4. During the secondary review stage, queries (correspondence, emails, summaries of telephone calls) on the information, tests and studies submitted and their interpretation must:

   - be sent to the applicant's primary project contact (if addressed to the applicant) by either the project lead or by the primary contact of the regulatory authority responsible for the dossier section concerned, and copied to the project lead; and

   - be sent to the appropriate contacts (if addressed to participating and other regulatory authorities) by the evaluator involved, with a copy to the project lead.

3.2.2 Adherence to the Project Plan

59. The project lead (i.e. overall administrative lead), working with the primary and secondary project contacts from each participating regulatory jurisdiction, as well as the primary and secondary reviewers for each science discipline, shall ensure that, as far as possible, each stage of the project is completed on schedule and that the time between acknowledgement of the dossier as complete and the project conclusion respects the agreed project plan timeline.

60. Any partner encountering a problem that could derail or delay the project shall immediately flag the problem to the project lead. While local initiatives to resolve difficulties may be the best option, the first step must be to report the situation to the project lead.

61. Regular conference calls (or video conferences) involving the project lead and primary contacts from each participating regulatory authority shall be convened to:

- review progress to date in each science discipline (i.e. in work assigned to each participating regulatory authority);

- identify aspects on which progress is behind schedule and decide on action to be taken to ensure that timelines are observed; and

- flag science issues that are causing concern and decide on action to be taken to resolve those issues.

62. Issues that arise during the secondary review of evaluations and that cannot be resolved through discussions among evaluators and project contacts must be raised with senior managers, in order that a decision may be made on the approach needed to finalize the required documentation. If deemed appropriate by the participating regulatory authorities, the project lead should keep the applicant apprised.

63. Where, owing to unforeseen circumstances, it is not possible to observe the project plan timelines, the project partners should negotiate a revised schedule. Significant changes to timelines must be approved by the appropriate senior managers from each of the participating regulatory authorities. The project lead must amend the project plan accordingly, share the updated plan with all project partners (i.e. upload the latest plan on CIRCA), and inform the applicant of the new target date for decision making, along with (including) the rationale.

3.2.3 Dossier Completeness Check/Administrative and Scientific Screening

64. This section describes the completeness check, which determines whether the submission is complete, and the steps to be taken to inform the applicant if it is not.

65. Completeness checks (initial administrative and/or scientific screening) shall be conducted on receipt of the dossier. While separate completeness checks may be conducted by each regulatory authority, it is the responsibility of the project lead to compile all the scientific screening-related deficiencies and communicate them to the applicant in writing on behalf of all participating regulatory authorities. Given the nature of this check, it is suggested that regulatory authorities be able to exchange reports on the checks within 30 days of dossier submission. If a longer period is required, this should be accounted for in the project plan.

66. Applicants shall facilitate the conducting of completeness checks by participating regulatory authorities by making the appropriate informed personnel available (in person or by telephone or email) if required.

67. The regulatory authorities shall not accept the dossier submitted as being complete until any deficiencies identified are corrected. However, under some circumstances, countries may all agree to accept the delayed submission of particular studies, provided this will not disrupt later stages of the project. If this is the case, details, including submission dates, shall be specified in the project plan.

68. The completeness check should include checking, for each study submitted, whether:

- the study complies with the principles of GLP or GEP, as appropriate;
- the study has been published; and
- data protection is claimed for the study.

69. If gaps in test or study data are identified, or if additional information or clarification is needed, the request for more information/clarification must be discussed with the other participating regulatory authorities, and then communicated to the applicant. Discussions to resolve disagreements on a study's acceptability (or a reasoned case for waiving a study) should take place at the earliest opportunity and not delay the joint review. Participating regulatory authorities may wish to inform the RSG of any issues/experiences that could impact future joint review projects for further consideration.

70. During the completeness check, each participating regulatory authority shall review the index of all studies submitted and determine whether all required studies were submitted in the agreed format. It is

the responsibility of the project lead to compile all scientific screening-related deficiencies and communicate them to the applicant in writing on behalf of all participating regulatory authorities. It should be noted that there may be legal provisions in participating countries which limit the submission of additional studies.

71. Primary (lead) reviewers shall ensure that the following documents, if required, are included in the dossier and prepared in the agreed format:

- Appendix 1 – Standard terms and abbreviations;
- Appendix 2 – Specific terms and abbreviations; and
- Appendix 3 – Compilation of chemical, common and code names, synonyms and occurrences for the active ingredient and its metabolites and degradation products.

72. Primary reviewers may also identify supplemental files (for example, Excel files containing raw data or the statistical analysis of the raw data) that they would like to have to facilitate their assessment.

73. The clock for subsequent stages shall start once all participating regulatory authorities have confirmed the dossier is complete. The regulatory authorities reserve the right to extend the period to complete a joint review project where:

- a deferred submission date is agreed on for the submission of certain studies; or
- the applicant requires more time to address deficiencies in the dossier identified by the completeness check.

74. All participating regulatory authorities shall evaluate the project plan to determine whether adjustments are required on the basis of the completeness check. If adjustments are required, an updated project plan must be uploaded onto CIRCA and all regulatory partners, including science area leads, must be informed. NOTE: Any recommendations for significant adjustments to key milestone dates must be approved by appropriate senior managers from each of the participating regulatory authorities.

75. After the completeness check, the evaluators must confirm whether the lead regulatory authority responsible for the primary review of that science discipline will be reviewing all the submitted supporting studies. In general, the regulatory authority with overall responsibility for the review of a section of a dossier (chemistry, toxicology, residues, environmental fate and behaviour, and ecotoxicology) shall review all studies submitted for its section. However, if one or more studies are specific to the needs of another country, and the regulatory authority to which the primary review of that discipline is assigned cannot evaluate them for any reason, the responsible primary reviewer must ensure that the other participating regulatory authorities are aware of the situation and that alternative arrangements have been made for evaluation of the studies as required.

76. While one regulatory authority shall have overall responsibility for the review of the individual plant metabolism and individual residues studies, as well as for preparation of the residues section, other regulatory authorities may provide the assessments of supervised residues trials conducted in other regions. This arrangement and the deadline for delivery of the assessments should be set out in the project plan.

3.2.4 Primary Review (Study Evaluation) of Individual Studies and Preparation of Section Summaries (e.g. Acute Toxicity and Short-Term Toxicity) by Primary Reviewers

77. This section describes how to organize the review of study reports and other information provided in the dossier.

78. The evaluation of individual studies may be based on the study summaries submitted by the applicant. However, if the evaluator decides to use these evaluations as his or her starting point, the evaluator shall cut and paste from the applicant-submitted summaries and modify/revise/supplement as required, to create his or her own primary reviews of the submitted data and ensure that they reflect his or her own conclusions. It is suggested that the evaluator use the word or pdf "highlight" tool to clearly identify modified sections of the original study summary.

79. At the outset of a project, joint review partners should agree on how technical issues will be communicated when they arise. Some issues that arise in the course of study review may be easily resolved through early communication among team members in a subject area. Team members should establish a communication network (for example, an email group for the subject area team), which the evaluators can use to informally raise questions as they arise in the course of study review, provided that the project lead is copied on these communications as appropriate.

80. Regulatory partners in each science area may wish to discuss the order in which the lead for that area will review studies to maximize efficiency. For example, it may be decided that studies most critical to the risk assessment will be evaluated early in the review process. The global partners should identify a check-in point to evaluate the project plan and determine if adjustments to the project plan are required. An updated project plan should be loaded onto CIRCA for access by all joint review partners.

81. The evaluation documents must take into account all studies designated for evaluation by the primary reviewer. Participating regulatory authorities shall ensure that:

- Evaluation documents are robust and of the highest quality;
- Evaluation documents are in the agreed format and agreed order (e.g. OECD numbering and Word format);
- The review of confidential information is segregated and presented in a separate volume (Volume 4, Annex C) and in the agreed format;
- Section summaries must be prepared in the agreed format (using the agreed templates if available), setting out the overall conclusions that can be drawn from the studies included in each section (e.g. acute toxicity and short-term toxicity);
- Primary reviewers must propose a list of endpoints (reference values) for use by regulatory authorities for the purposes of risk assessment. (Refer to the OECD end-point table template.);
- Primary reviewers should identify issues that are likely to be critical and will need to be taken into account in country or regional risk assessments;
- The primary reviewer of the residues data, in consultation with the primary reviewer of the toxicology data, shall provide a proposal for one or more residue definition(s) to be used for establishing MRLs and import tolerances and for consumer risk assessment purposes by an agreed date stipulated in the project plan;

- The primary reviewer for the data on environmental fate and behaviour shall identify soil, surface water and groundwater degradation products (metabolites) which may be of significance for the environmental risk assessment. This must be done by an agreed date stipulated in the project plan; and

- All evaluation documents are to be shared with the other participating countries for secondary review. This can be achieved by uploading them onto the CIRCA Web site in the appropriate folder for the project. Note: At this time, confidential business information (CBI) and chemistry reviews are not to be uploaded onto CIRCA, but may be sent either by facsimile or by courier to the other regulatory participants.

82. There shall be discussion in advance as to whether evaluators will use the following approach (accepted OECD classification) to rate the reliability of studies:

Fully reliable: GLP-compliant and fully compliant with the test guideline specified.

Reliable with restrictions:	GLP-compliant, but not fully compliant with the test guideline specified, but nevertheless judged to provide a reliable basis for regulatory decision making. An asterisk is to be added to identify studies that are not standard and that are judged to be reliable for the purpose (e.g. mechanistic studies).
Not reliable:	Not GLP-compliant and/or not compliant with the test guideline specified, and judged not to provide a reliable basis for regulatory decision making.
Not assignable:	Insufficient information (e.g. published literature) provided for the reliability of the test or study report to be assessed.

83. Primary reviewers shall ensure that the list of studies relied on for the proposed decision is prepared in the agreed format and appended at the end of each section summary. Such lists must indicate:

- whether the study complies with the principles of GLP or GEP, as appropriate;

- whether the study has been published; and

- whether data protection is claimed for the study.

84. If necessary for monograph preparation, the project lead shall coordinate as required to ensure that the following documents are prepared in the format specified in the Monograph Guidance Document, and that they are appended to the documentation provided and to be included in Volume 1 (Annex B) of the draft monograph (see appendices 1 and 2 of the Monograph Guidance Document):

- Appendix 1 – Standard terms and abbreviations;

- Appendix 2 – Specific terms and abbreviations; and

- Appendix 3 – Compilation of chemical, common and code names, synonyms and occurrences for the active ingredient and its metabolites and degradation products.

3.2.5 Secondary Review of Primary Reviews of Individual Tests and Studies, Section and Chapter Summaries, and Proposed Endpoints for Risk Assessment Purposes

85. This section describes how the detailed study evaluations prepared by primary reviewers are reviewed by the joint review partners and other stakeholders as appropriate. It is important that, during the project planning phase, the joint review partners agree on whether additional regulatory authorities (i.e. other than those already formally identified in the project plan) should be invited to join in at the secondary review stage. In addition, agreement must be reached on whether the applicant will participate at this stage and, if so, in what way. Although some regulatory authorities see advantages in sharing draft evaluations with the applicant at a relatively early stage for the purposes of identifying errors that could impact on later stages of evaluation and risk assessment, this should be discussed and agreed to in advance by all participating regulatory authorities and be identified in the project plan.

86. For the secondary review to work efficiently, it is vital that all primary reviews be completed by the agreed deadline. Delays in the availability of any section will result in a staggered secondary review and further delays in later stages of the project. This prevents the joint review partners from making the most efficient and effective use of their resources.

87. In addition to the participating regulatory authorities, other interested regulatory authorities and, if applicable, the applicant, may be invited to peer review the primary reviews. A deadline shall be set for submission of comments by the applicant. Comments received from the applicant after the deadline need not be accepted.

88. Comments provided by secondary reviewers on the science must only be submitted electronically using a reporting table format. (Note: For each section of the monograph, there is a corresponding section in the reporting table. Comments submitted using the reporting table should focus on points that are most likely to make a material difference to the outcome of the evaluation). Regarding editorial comments (e.g. grammatical and spelling errors), there is the option of either tracking changes in Word (editorial comments are to be kept to a minimum) or recording them in a separate table specifically designed to capture non-scientific commentary. (In the completeness check call, the team should discuss and agree on the preferred method for dealing with editorial changes.)

89. The primary reviewer shall address the scientific and editorial comments and edit the primary review (i.e. study evaluation) as required.

90. For ease of handling, each section of the reporting table (e.g. that on toxicology) shall be prepared as a separate document. The annex point and/or page reference for each comment shall be entered in Column 1 of the table, and the secondary review comments in Column 2. Comments and corrections submitted by regulatory authorities should be uploaded into the appropriate folder on CIRCA. Clear instructions for naming files must be provided to avoid confusion of files and to facilitate version control with all documents, including the reporting table. If comments from the applicant are requested, this should be coordinated through the project lead.

91. Primary reviewers shall combine the comments received on their section into a single reporting table and enter their responses to comments received in Column 3 of the resulting document. In his or her responses, the primary reviewer must state whether he or she agrees with the comment, give the reasons why he or she disagrees, and record whether the evaluation has been amended to take the comment into account and whether the point is closed. Unresolved points, disagreements and data requirements are to be summarized in Column 4 of the reporting table. The updated reporting table must be uploaded onto CIRCA with the correct filename by the deadline for the completion of the secondary review stage as set out in the project plan.

92. Where necessary, primary reviewers must amend their study evaluations, section summaries and the list of endpoints to reflect comments received. Amended primary review documents must be uploaded onto CIRCA with the correct filename. This work is to be completed by the deadline set in the project plan. The goal is to resolve and close the issue by consensus of the subject area team. (It should be kept in mind that, even if the joint review partners consider a point closed, other regulatory authorities that make use of the evaluation at a later date may come to a different conclusion. Primary reviewers responsible for evaluation of particular sections of the dossier shall ensure that the secondary review of the study evaluations prepared by other regulatory authorities includes consideration of all issues raised during the commenting period provided. The primary reviewer is responsible for working through all issues. Important issues should be flagged to the project lead and the primary project contacts for each regulatory jurisdiction. Any issues that could potentially constrain future joint reviews should be referred to the RSG for further consideration. (Although the RSG is not officially involved in managing joint reviews, regulatory authorities may wish to bring to the RSG's attention any issues/resolutions which could benefit from further discussion among regulatory partners.)

93. The primary and secondary reviewers shall review all sections of the reporting table and identify all points of disagreement or other issues, such as data gaps, that need to be addressed. The project lead shall then request that the primary and secondary reviewers for each subject area consult together on whether and how the remaining points can be resolved. This part of the secondary review process can involve exchanges using email, teleconferences and meetings, as appropriate. Any issues that cannot be resolved within the joint review teams shall be transferred by the project lead to an evaluation table.

94. The project lead shall be responsible for monitoring that the reporting table is completed within the prescribed timeframe, and for creating the evaluation table if required. The project lead shall consult the primary reviewers about the most appropriate means for reaching a conclusion on unresolved issues. The steps to be taken must include checking whether any disagreements are a consequence of differences in the regulatory requirements of participating countries or in scientific interpretation or judgement.

95. The main purpose of the evaluation table is to record issues that remain open points, i.e. points on which there is no agreement. If participating countries "agree to disagree", this should be captured in the reporting table (part of Column 4) rather than in the evaluation table. In these circumstances, the relevant study evaluation or section summary must also record this position. New unresolved issues may need to be recorded for future discussion.

96. At the end of the secondary review stage, and by the deadline set in the project plan, the following documents should be available:

- a consolidated reporting table tracking the exchange of key comments and discussions;
- a consolidated evaluation table (if needed) tracking any further exchanges on unresolved or hard-to-resolve issues;
- updated study evaluations;
- updated section summaries;
- a consolidated and updated list of endpoints for use in risk assessment; and
- a consolidated and updated list of studies evaluated by the joint review partners.

3.2.6 Completing the Joint Review Project

97. This section describes how a joint review might be concluded. The exact procedure shall be determined by the scope and objectives of the project, as agreed on by the joint review partners and presented in the project plan. To date, if it has been decided that the conclusion of the project is the issuance of a complete monograph documenting the dossier evaluation, endpoints and reference values for risk assessment, the EU RMS (if involved with the joint review) has taken on the task of producing the complete monograph document. The following is a suggested approach to assembling the monograph:

a. The consolidated and updated list of studies evaluated in the joint review is presented as Volume 2 (Annex A) of the monograph;

b. The updated study evaluations and section summaries collated and presented in the order given in Appendix 6 of this guidance document form Volume 3 (Annex B) of the monograph. If any participating country has completed its national or regional risk assessments, these may be added to the relevant section summaries which comprise Volume 3 or as an appendix to Volume 3;

c. The updated evaluation of studies presenting confidential business information and the associated section summary form Volume 4 (Annex C) of the monograph;

d. The section summaries from Volume 3 are used as the basis for levels 1 and 2 of Volume 1. Taking into account the project objectives, the project lead adds the statement of purpose to Level 1 of Volume 1;

e. The consolidated and updated list of endpoints forms Appendix 4 to Volume 1;

f. If required, a high level (Level 3.1) summary of Volume 1 shall be prepared. This summary sets out important background information on the hazard assessment for the active ingredient and the designated end-use formulation(s) to be used when considering regulatory decisions. If any participating country has completed its national or regional risk assessments, the key conclusions of the risk assessments may be included in Level 3.1;

g. If any of the participating countries has made its regulatory decision, this may be recorded in Level 3.2;

h. If any country concludes that there are major data gaps in the dossier or other issues that must be addressed before any country may take a regulatory decision, these may be set out in Level 4.1. However, should this situation arise, the joint review partners may wish to discuss the available options with the applicant before deciding how to proceed; and

i. If any country has made a positive regulatory decision, but all countries agree that certain studies might be required at the country level to address more local issues or confirm that possible risks are within acceptable limits, these may be listed in Level 4.2. All primary contact points and all relevant reviewers should be consulted on whether such data requirements are appropriate.

98. It is recommended that, in addition to the issuing of the monograph, the consolidated reporting table and evaluation table (if prepared) be made available on request to other regulatory authorities or bodies such as the JMPR.

APPENDIX 1: TEMPLATE FOR JOINT REVIEW TECHNICAL PRE-SUBMISSION CONSULTATION REQUEST FORM

A proposed product label and a statement of product specifications must accompany each request for a pre-submission consultation. In some cases, a detailed description of the proposed use(s) and product formulation may be acceptable.

APPLICANT: Company name:

PARTICIPANTS: Identify all participants (incl. titles and affiliations)

PRODUCT INFORMATION: Active ingredient(s):
End-use product name(s):
Registration number(s), if a product amendment:
Proposed use site category (USC):
proposed uses (crop, use rate, application frequency and timing)
Product type:

Anticipated dossier submission date:

Anticipated Regulatory Participants:

Purpose and goals of consultation:

REGULATORY EXPERTISE REQUESTED:[ii]

Area of Expertise	Requested (T)	List Specific Questions or Issues
Administrative process, data requirements, submission organization, formulants		**NOTE TO APPLICANT:** ***A request should be made by the applicant for a pre-submission consultation to discuss:*** ***-formatting/cross-referencing of data for TGAI/EPs BEFORE the process is initiated by the applicant to assemble the data package for submission; and*** ***-the proposed product specification forms for each product (e.g. to review formulant information in advance of dossier receipt).***
Value (efficacy/crop		

Area of Expertise	Requested (T)	List Specific Questions or Issues
tolerance, sustainability)		
Environmental fate & ecotoxicology		
Food residue, plant/livestock metabolism		
Occupational/residential exposure		
Toxicology		
Product chemistry/compliance		
Other (e.g. re-evaluation)		

Please note that a written response shall be provided, unless the review team or applicant determines that a teleconference or meeting is required.

APPENDIX 2: CHECKLIST FOR JOINT REVIEW PLANNING (I.E. PRIOR TO DOSSIER RECEIPT) (E.G. NEW ACTIVE INGREDIENT)

Joint Review Planning Project Stage	Description of Joint Review Planning Project Stage	Key Activities/Deliverables	Time Allocation/ Deadline
Stage 1a: JR project objectives	**Agree on project objectives/outputs**	Agree on whether the proposed Joint Review candidate is eligible for joint review. Agree on key documentation outputs Note: The EU RMS will involve the EFSA, EU member states and the European Commission as required	Stage 1a*: (Target date: minimum of 1 year before anticipated dossier receipt.)*
Stage 1b: Regulatory partners and project lead	**Identify participating regulatory authorities and project lead**		Stage 1b*: (Target date: minimum 6 months – 1 year before anticipated dossier receipt)*
Stage 1c: Primary and secondary project contacts	**-Identify the names of the primary and secondary project contacts for each participating regulatory authority as well as for the applicant. (NOTE: It should be indicated whether any of the project contacts will change after dossier receipt)**		Stage 1c: *(Target date should ideally be a minimum of 6 months before anticipated dossier receipt)*
Stage 1d: CIRCA Folder	**Establishment of CIRCA folder by the Project Lead**	**CIRCA FOLDER and SUB-FOLDER FORMAT guidance:** **1) Primary folder: Active Name** **2) Secondary folders:** ***a) Project Planning (indicate whether primary or second entry dossier)*** ***b) Dossier Review (indicate whether primary or second entry dossier)***	Stage 1d: *(Target date should ideally be a minimum of 6 months before anticipated dossier receipt)*

Joint Review Planning Project Stage	Description of Joint Review Planning Project Stage	Key Activities/Deliverables	Time Allocation/ Deadline
		3) Tertiary folders: **<u>a) under Project Planning folder</u>:** ***-Project Plan*** ***-Teleconferences/Meetings (Planning)*** ***-Teleconferences/Meetings (Technical)*** ***-List of Studies (Data Matrix)*** **<u>b) under Dossier Review folder</u>:** ***-Project Plan and Associated Documents (including detailed evaluator contact information)*** ***-Points 1-4: Product Chemistry (Identity, Phys.-Chem. Properties, Analytical Methods)*** ***-Point 5: Toxicology*** ***-Point 6: Plant/Livestock Metabolism and Residues*** ***-Point 7: Fate and Behaviour in the Environment*** ***-Point 8: Ecotoxicology*** ***-Occupational and Residential Exposure Studies*** ***-Efficacy/Value*** ***-reporting table*** ***-Monograph***	
Stage 1e **List of Studies**	**Request list of the studies from applicant**	**List of studies anticipated for JR dossier to be requested from the applicant by the Project Lead and posted on CIRCA for discussion as required by participating regulatory authorities**	Stage 1e: (*Target date should ideally be a minimum of 6 months before anticipated dossier receipt)*

Joint Review Planning Project Stage	Description of Joint Review Planning Project Stage	Key Activities/Deliverables	Time Allocation/ Deadline
Stage 1f: Work allocation	**-Allocate primary review work among the participating regulatory authorities**		Stage 1f: *(Target date should ideally be a minimum of 6 months before anticipated dossier receipt)*
Stage 1g : Project Scope	**Determine the scope of the joint review project in terms of which products are to be included in the joint review (i.e., if applicable, which end-use products are to be included as part of the part of the global joint review vs. a NAFTA joint review or other bilateral agreement)**		Stage 1g: *(Target date should ideally be a minimum of 6 months before anticipated dossier receipt)*

Joint Review Planning Project Stage	Description of Joint Review Planning Project Stage	Key Activities/Deliverables	Time Allocation/ Deadline
Stage 1h: Project plan	**-Drafting of the project plan by the Project Lead**	-First draft of the project plan to be prepared by the project lead and distributed to the participating regulatory partners for comment (ideally by posting on CIRCA) -Project plan to be revised as required throughout the planning process and distributed to regulatory partners, as required (ideally by posting on CIRCA)	-Distribution of the draft project plan by project lead for review: *(Target date should ideally be a minimum of 2 months in advance of anticipated dossier receipt).* -Receipt of the comments on the draft project plan: *(Target date should ideally be a minimum of 1 month in advance of anticipated dossier receipt)* -Finalization and distribution of the project plan: *(Target date should ideally be a minimum of 2 weeks before anticipated dossier receipt)*

APPENDIX 3: TEMPLATE FOR A JOINT REVIEW PROJECT PLAN (4 PARTS)

Joint review project plan: (Insert active ingredient name/trade name)
Applicant: (Insert applicant name)
Regulatory Participants: (Insert as required)
Project lead: (Insert name of appropriate regulatory authority)

Date Created:
Date Last Modified:

Part 1/4 Overall Summary of Joint Review Project Timelines

Project Stage	Start Date (Starting at Dossier Receipt Stage)	Completion Date (Ending at Decision-Making Stage)
OVERALL (Dossier Receipt to Decision Making) (x months)		
Stage 1: Joint review planning **-Agree on project objectives, project leads, work allocation and timelines** **-Project plan to be drafted by regulatory project lead** **-Establish file on Circa** **-Submission of list of studies by company**		**All planning aspects to be completed at least one month before anticipated dossier receipt**
Stage 2: Dossier receipt		
Stage 3: Completeness check/screening • Teleconference recommended at end of completeness check to discuss deficiencies and project deliverables		
Stage 4: Primary review (study evaluation) *Propose residue definition (dietary and environment) *Selection of preliminary endpoints *Efficacy/ biology review to provide maximal seasonal rates *Incorporate scheduling of jurisdictional committee reviews into project milestones (e.g. CARC)		

Project Stage		**Start Date (Starting at Dossier Receipt Stage)**	**Completion Date (Ending at Decision-Making Stage)**
Stage 5: Secondary review *Document secondary review using the reporting table. *Confirm residue definition (dietary and environment) *Confirm endpoints * If required, open points to be captured in evaluation table.	Secondary reviewers to provide comments		
	Primary reviewers to respond to secondary reviewers comments		
Stage 6: Preparation of independent country/region-specific risk assessments and proposed regulatory options (if required – exchange of country specific risk assessments) *As required, discussion of harmonization of MRLs			
Stage 7: Independent Decision making *(Note: may be a proposed regulatory decision)* *** Communication of decisions among regulatory authorities.*			
Post-project: Monograph preparation as required			

Part 2/4: Summary of Work Allocation to Participating Regulatory Authorities

Note: An additional work allocation table may be required if not all end-use products are part of a joint review (e.g. a separate work allocation table for end-use products to be reviewed under a bilateral or NAFTA joint review arrangement). If there are associated joint review applications that are determined to fall outside the scope of the joint review project, clarification will be needed as to who the project lead will be in terms of managing these particular applications.

Science Discipline (Work Area)		*Lead Regulatory Authority for the Primary Review*
Product chemistry *Includes:* *-Identity of the technical grade active ingredient and end-use product* *-Physical and chemical properties (NOTE: The primary reviewer for product chemistry (if not an EU member state) may not necessarily review all the chemical and physical properties that are required by the EU. This should be established in advance.)* *-Analytical methods for the active ingredient and impurities in the technical grade active ingredient and enforcement analytical method for the end-use product (i.e. for product analysis)* *-Analytical methods (residue) for environmental samples (sediment, soil, water, biota)* ***(Note: The review of the analytical methods for environment may be reviewed by the chemistry evaluators in some jurisdictions and by the environmental evaluators in others. The regulatory authority responsible for the primary review in this discipline needs to coordinate within its organization as necessary.)***		
Toxicology **Includes occupational and residential exposure studies (i.e. non-dietary)** ***(Note: The review of the dermal absorption studies may be reviewed by the toxicology evaluators in some jurisdictions and by the occupational exposure evaluators in others. The regulatory authority responsible for the primary review of this discipline needs to coordinate within its organization as necessary.)***	**Acute** *Includes:* *Acute toxicology for the active ingredient and end-use product*	
	Chronic *Includes:* *-toxicokinetics (i.e. adsorption, distribution, metabolism, excretion).* *-Sub-chronic, chronic and oncogenicity studies* *- reproductive and developmental studies* *-genotoxicity studies* *- neurotoxicity studies* *- immunotoxicity studies* *- special/other studies (e.g. mode of action)*	
	Occupational and residential exposure studies *Includes:* *-Dermal absorption (in vivo and/or in vitro)* *Dislodgeable foliar residue studies* *-Passive dosimetry and/or biological monitoring studies*	

Plant/livestock metabolism and core residue studies *Includes: metabolism in crops, metabolism in rotational crops, metabolism in livestock, residues in rotational crops (limited field studies), residues in livestock, stability of residues in stored commodities, magnitude of residues in processed commodities, analytical methods (residue) for data collection and enforcement for foodstuffs of plant and animal origin and feeding stuffs and multiresidue method testing.*	
Residues based on regional GAP (Good Agricultural Practices) *(crop field trial studies conducted according to proposed label directions)*	
Environmental fate *Includes: field dissipation (NOTE: The review of terrestrial field dissipation studies that are not relevant to all partners should be established in advance.)*	
Eco-toxicology *Includes:* *- e-toxicology on beneficial organisms, i.e. earthworms, honeybees and predatory and parasitic insects* *- fish BCF (bio-concentration factor)*	
Efficacy/crop tolerance *Includes:* *-efficacy trials conducted according to the proposed use pattern that demonstrate that the product performs according to the proposed label claims* *-information on crop tolerance and other types of non-safety adverse effects* *-scientific rationales for extrapolation of use claims, where appropriate*	

Part 3/4: Primary and Secondary Project Contacts

Regulatory Authority/Applicant ***(Insert relevant participants)***	**Name and Contact Details**	
Regulatory authority X	Before dossier receipt (planning):	Primary (country lead): Secondary:
	After dossier receipt (review):	Primary (country lead): Secondary:
Regulatory authority Y	Before dossier receipt (planning):	Primary (country lead): Secondary:
	After dossier receipt (review):	Primary (country lead): Secondary:
Regulatory authority Z	Before dossier receipt (planning):	Primary (country lead): Secondary:
	After dossier receipt (review):	Primary (country lead): Secondary:
Applicant (Insert company name)	Before dossier receipt (planning):	Primary (company lead): Secondary:
	After dossier receipt (review):	

Part 4/4: Scope of Joint Review Project (Summary List of End-Use Products (EUPs) Being Submitted as Part of the JR dossier)

Formulation/EUP Being Submitted as Part of the JR Dossier Submission (list all active ingredients in each formulation)	**Countries Involved in Formulation/EUP**						

APPENDIX 4: TEMPLATE FOR DETAILED CONTACT INFORMATION FOR EVALUATORS (PRIMARY REVIEWERS AND SECONDARY REVIEWERS) FOR EACH SCIENCE DISCIPLINE (FOR USE BY REGULATORY AUTHORITIES ONLY)

Regulatory Authority/ Company	Product Chemistry Lead for Primary Review: (*insert country*)	Acute Toxicology Lead for Primary Review (*insert country*)	Chronic Toxicology Lead for Primary Review: (*insert country*) NOTE: Include evaluator for occupational and residential exposure studies if different from evaluator for other toxicological studies	Plant/Livestock Metabolism and Core Residue Studies Lead for Primary Review: (*insert country*)	Field Residue Trials Based on Regional Gap Lead for Primary Review: (*insert country*)	Environmental Fate Lead for Primary Review: (*insert country*)	Ecotoxicology Lead for Primary Review: (*insert country*)	Efficacy/Crop Tolerance Lead for Primary Review: (*insert country*)
	Name: Position: Tel : Fax : Email:	Name: Position: Tel : Fax : Email:	Name: Position: Tel : Fax : Email:	Name: Position: Tel : Fax : Email:	Name: Position: Tel : Fax : Email:	Name: Position: Tel : Fax : Email:	Name: Position: Tel : Fax : Email:	Name: Position: Tel : Fax : Email:
	Name: Position: Tel : Fax : Email:	Name: Position: Tel : Fax : Email:	Name: Position: Tel : Fax : Email:	Name: Position: Tel : Fax : Email:	Name: Position: Tel : Fax : Email:	Name: Position: Tel : Fax : Email:	Name: Position: Tel : Fax : Email:	Name: Position: Tel : Fax : Email:
	Name: Position: Tel : Fax : Email:	Name: Position: Tel : Fax : Email:	Name: Position: Tel : Fax : Email:	Name: Position: Tel : Fax : Email:	Name: Position: Tel : Fax : Email:	Name: Position: Tel : Fax : Email:	Name: Position: Tel : Fax : Email:	Name: Position: Tel : Fax : Email:
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Company								

APPENDIX 5: SECTIONS OF A MONOGRAPH IN OECD FORMAT (BASED ON APPENDIX 4 OF THE OECD MONOGRAPH GUIDANCE DOCUMENT)

B.1	***Identity***
	B.1.1 Identity of the active substance
	B.1.2 Identity of the plant protection product
	B.1.3 References relied on
B.2	*Physical and chemical properties*
	B.2.1 Physical and chemical properties of the active substance
	B.2.2 Physical and chemical properties of the plant protection product
	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
	B.3.2 Data on application relevant to the plant protection product
	B.3.3 Summary of data on application
	B.3.4 Further information on the active substance
	B.3.5 Further information on the plant protection product
	B.3.6 References relied on
B.4	*Proposals for classification and labelling*
	B.4.1 Proposals for classification and labelling of the active substance
	B.4.2 Proposals for classification and labelling of the plant protection product
	B.4.3 References relied on
B.5	***Methods of analysis***
	B.5.1 Analytical methods for formulation analysis
	B.5.2 Analytical methods (residue) for plants, plant products, foodstuffs of plant and animal origin, feeding stuffs
	B.5.3 Analytical methods (residue) soil, water, air
	B.5.4 Analytical methods (residue) for body fluids and tissues
	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)
	B.6.2	Acute toxicity, including irritancy and skin sensitization
	B.6.3	Short-term toxicity
	B.6.4	Genotoxicity
	B.6.5	Long-term toxicity and carcinogenicity
	B.6.6	Reproductive toxicity
	B.6.7	Delayed neurotoxicity
	B.6.8	Further toxicological studies
	B.6.9	Medical data and information
	B.6.10	Summary of mammalian toxicology and proposed ADI, ARfD, AOEL and drinking water limit
	B.6.11	Acute toxicity, including irritancy and skin sensitization of preparations
	B.6.12	Dermal absorption
	B.6.13	Toxicological data on non-active substances
	B.6.14	Exposure data
	B.6.15	References relied on
B.7	***Residues data***	
	B.7.1	Metabolism, distribution and expression of residues in plants
	B.7.2	Metabolism, distribution and expression of residues in livestock
	B.7.3	Definition of the residue
	B.7.4	Use pattern
	B.7.5	Identification of critical GAPs
	B.7.6	Residues resulting from supervised trials
	B.7.7	Effects of industrial processing and/or household preparation
	B.7.8	Livestock feeding studies
	B.7.9	Residues in succeeding or rotational crops
	B.7.10	Proposed pre-harvest intervals for envisaged uses, or withholding periods, in the case of post-harvest uses
	B.7.11	MRLs in OECD countries
	B.7.12	Proposed MRLs and justification for the acceptability of those MRLs
	B.7.13	Proposed import tolerances and justification for the acceptability of those residues
	B.7.14	Basis for differences, if any, in conclusions reached regarding established or proposed CAC MRLs
	B.7.15	Estimates of potential and actual dietary exposure through diet and other means
	B.7.16	Summary and evaluation of residue behaviour
	B.7.17	References relied on
B.8	***Environmental fate and behaviour***	
	B.8.1	Route and rate of degradation in soil
	B.8.2	Adsorption, desorption and mobility in soil
	B.8.3	Predicted environmental concentrations in soil (PEC_S)

	B.8.4 Fate and behaviour in water
	B.8.5 Impact on water treatment procedures
	B.8.6 Predicted environmental concentrations in surface water and in ground water (PEC_{SW}, PEC_{GW})
	B.8.7 Fate and behaviour
	B.8.8 Predicted environmental concentrations in air (PEC_A)
	B.8.9 Definition of the residue
	B.8.10 References relied on
B.9	***Ecotoxicology data and assessment of risks for non-target species***
	B.9.1 Effects on birds
	B.9.2 Effects on aquatic organisms
	B.9.3 Effects on other terrestrial vertebrates
	B.9.4 Effects on bees
	B.9.5 Effects on other arthropod species
	B.9.6 Effects on earthworms
	B.9.7 Effects on other soil non-target macro-organisms
	B.9.8 Effects on soil non-target micro-organisms
	B.9.9 Effects on other non-target organisms (flora and fauna) believed to be at risk
	B.9.10 Effects on biological methods of sewage treatment
	B.9.11 References relied on
B.10	***Efficacy***
	B.10.1 Effectiveness against target organisms, or with respect to the effect achieved (level, consistency and duration)
	B.10.2 Possible occurrence of the development of resistance
	B.10.3 Effects on the quality of plants or plant products
	B.10.4 Effects on transformation processes
	B.10.5 Effects on the yield of treated plants or plant products
	B.10.6 Phytotoxicity to target plants or target plant products
	B.10.7 Impact on succeeding crops, adjacent crops, and treated plants or plant products used for propagation
	B.10.8 Tank mixing recommendations
	B.10.9 References relied on
Appendix 1	Standard terms and abbreviations
Appendix 2	Specific terms and abbreviations
Appendix 3	Compilation of chemical, common and code names and synonyms
Appendix 4	Listing of endpoints

APPENDIX 6: OUTLINE OF THE OECD MONOGRAPH FORMAT

MONOGRAPH

Volume 1

Level 1	Statement of subject matter and purpose
Level 2	Summary of data evaluation and hazard assessment To be used as a basis for decision documents*
Level 3	(Optional) The decision and the conditions and restrictions, if any, associated with any approval or registration, where appropriate
Level 4	(Optional) Statement of the further studies and information necessary to make a decision and/or necessary for the removal of conditions and restrictions associated with any approval or registration

Volume 2	Annex A	List of studies submitted (active substance and formulation), information available or provided by other interested parties, annotated to indicate those conducted to GLP/GEP standard, whether published or not, and for which data protection was claimed
Volume 3	Annex B	Summary, evaluation and assessment of the data and information examined and the list of studies relied on, annotated as to the periods(s) for which particular studies are to be protected.
Volume 4	Annex C	Confidential information and, in the case of existing active substances, where relevant, information concerning task force membership and ownership of access to test and study reports

(*) To include
Appendix 1 – Standard terms and abbreviations
Appendix 2 – Specific terms and abbreviations
Appendix 3 – Compilation of chemical, common and code names and synonyms
Appendix 4 – Consolidated list of endpoints and reference values for use in risk assessment.

* Extract from OECD Guidance for Country Data Review Reports on Plant Protection Products and their Active Substances, Monograph Guidance

APPENDIX 7: GLOSSARY OF KEY TERMS

Active ingredient = active substance: The ingredient(s) of a control product to which the effects of the pest control product are attributed, including a synergist, but not including a solvent, diluent, emulsifier or component that by itself is not primarily responsible for the control effect of the product.

CIRCA = Communication and Information Resource Centre Administrator: a central electronic depository for project-related documents to which all participating regulatory authorities may be granted access.

Maximum residue limits (MRL) = tolerances: The quantity of residues that are likely to remain in or on the food when the pesticide is used according to label directions, after a determination has been made that such residues will not be a concern to human health. An MRL applies to the identified raw agricultural food commodity, as well as to any processed food product that contains it, except where separate MRLs are specified for the raw agricultural commodity and a processed product made from it.

Observer: A regulatory authority, agreed to by the applicant, to receive the joint review dossier in addition to having access to all discussions and documents generated during the joint review process, for information purposes and/or the provision of comments.

Primary project contact: A representative from each participating regulatory authority, as well as the company, who serves as the primary contact point for the project lead. (Note: For regulatory authorities, the primary project contact is also known as the "country lead").

Primary reviewer = lead reviewer: The evaluator from the regulatory authority assigned the lead for each science discipline who does the initial data review and drafts the primary review (study evaluation).

Project lead = overall administrative lead: The regulatory authority that administers and coordinates the joint review on behalf of all participating regulatory authorities.

Secondary project contact: On behalf of his or her organization, a back-up for the primary project contact.

Secondary reviewer = peer reviewer: For each science discipline, the evaluators from the participating regulatory authorities assigned to peer review the primary reviews.

Note: This draft list will expand as new terms are added.