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Series on Testing and Assessment

Number 1

GUIDANCE DOCUMENT FOR THE DEVELOPMENT OF OECD GUIDELINES FOR THE TESTING OF CHEMICALS

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IOMC

INTER-ORGANIZATION PROGRAMME FOR THE SOUND MANAGEMENT OF CHEMICALS

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

Environment Directorate
ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT
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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 the 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 (http://www.oecd.org/ehs/).

This publication was produced within the framework of the Inter-Organisation Programme for the Sound Management of Chemicals (IOMC).

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, OECD, UNEP, UNIDO, UNITAR and WHO. The World Bank and UNDP are observers. 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.

FOREWORD

This Guidance Document describes in detail the process of Test Guideline development, including the structure of the Test Guidelines Programme (TGP) and the responsibilities of those involved.

The most recent revision of the Guidance Document consisted in inserting a new Annex 2 between Annex 1 and the former Annex 2 to describe processes for specific cases. Former Annex 2 is now Annex 3.

This document is published on the responsibility of the Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology.

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ABBREVIATIONS

ASTM: ASTM International

BIAC: Business and Industry Advisory Committee to the OECD

DRP: Detailed Review Paper

EC: European Commission

EPOC: Environment Policy Committee

ICAPO: International Council on Animal Protection in OECD Programmes

ISO: International Organisation for Standardisation

JM: Joint Meeting of the Chemicals Committee and Working Party on Chemicals, Pesticides and Biotechnology

MAD: Mutual Acceptance of Data

NCs: National Co-ordinators

NGO: Non-Governmental Organisation

NPP: National Position Paper

OECD: Organisation for Economic Cooperation and Development

SPSF: Standard Project Submission Form

TG: Test Guideline

TGP: Test Guidelines Programme

WNT: Working Group of National Co-ordinators of the Test Guidelines Programme

SUMMARY

The first edition of the Guidance Document for the Development of OECD Guidelines for the Testing of Chemicals was published in 1993 and reformatted in 1995. It was developed following a decision of the 17th Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology[1] in 1991 that the responsibilities and various procedures for OECD Test Guideline development and updating should be set out in a single policy document. The present document describes the structure of the Test Guidelines Programme (TGP), the various responsibilities of those involved in the process and, in detail, the procedures that are followed during the development of new, or the updating of existing, Test Guidelines.

With an increase in the number of projects in the Test Guidelines Programme, a new procedure to standardise project submissions was adopted in 1999. This procedural change, together with other evolving activities in the Test Guidelines Programme, raised the need to update the present Guidance Document to reflect current practices in the development of OECD Test Guidelines for the Testing of Chemicals.

In 2005, the 38th Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology, agreed to a number of improvements in the management and review of proposals for projects, which are reflected in this revised Guidance Document and in the Standard Project Submission Form (SPSF). In particular when dealing with a proposal for a new OECD Test Guideline, the validation status, the regulatory needs, the use and limitations of the test method, and the project management process, including resource needs and timelines should be adequately characterised to enable the Working Group of National Coordinators to assess the suitability of the project for the work plan of the Test Guidelines Programme.

STRUCTURE AND REPONSIBILITIES

The National Co-ordinators (NCs) from the respective OECD member countries, non-member economies adhering to the Mutual Acceptance of Data[2] and the European Commission (EC) have a central position in the Test Guidelines Programme. They submit national proposals for new or revised Guidelines and provide comments agreed on at the national level on proposals circulated by the Secretariat. In order to be most efficient, NCs provide a national focal point to gather input from a network of experts and thus are required to be aware of developments related to test methods in their own country. The Working Group of National Co-ordinators of the Test Guidelines Programme (WNT) meets at least once a year. Collectively, the WNT oversees the Test Guidelines Programme and works towards the development of draft Test Guidelines based on a consensus.

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1 Formerly the Joint Meeting of the Chemicals Group and Management Committee.

2 The 1981 OECD Council Decision concerning the ***Mutual Acceptance of Data (MAD)*** in the Assessment of Chemicals is built on the OECD Test Guidelines and Good Laboratory Practice Principles (GLP). The Council Act requires OECD governments to accept chemical test data developed for regulatory purposes in another country if these data were developed in accordance with the OECD Test Guidelines and GLP Principles. This means new data for notifications or registrations of a chemical only have to be developed once, and are then used across OECD countries.

The Secretariat's main role is to provide the structural and administrative support to the Programme. It maintains and develops the three-year rolling work plan for the Programme (with annual updates), assists member countries in the steps necessary for developing or revising Test Guidelines, including the organisation of workshops and meetings, and circulates the various Test Guideline-related documents. Where necessary, the Secretariat takes initiatives in the revision of existing Test Guidelines. It is responsible for periodically revising the compendium of Guidelines.

The Joint Meeting generally oversees the implementation of the Programme, reviews and endorses draft Test Guidelines prior to adoption by the Council, and builds consensus to overcome policy differences that might otherwise jeopardise progress in Test Guideline development. The Joint Meeting also ensures that the allocation of resources is sufficient for the agreed work programme.

PROCEDURES FOR TEST GUIDELINE DEVELOPMENT

Proposals for new or updated Test Guidelines

Proposals for the development of new or updated Test Guidelines can be submitted by the member countries, the international scientific community, industry, non-governmental organisations, all via a National Co-ordinator. They can also be submitted by the EC or the Secretariat. A proposal for a new Test Guideline or the revision of an existing Test Guideline should undergo a critical appraisal concerning its scientific and regulatory justification (e.g. its existing or foreseen regulatory needs, validation status, relevance and reliability) prior to the addition of the project to the Programme's work plan.

A Standard Project Submission Form (SPSF) is available to NCs. The form specifies the information generally required to submit a proposal for new or updated Test Guidelines or related documents to the WNT, including the project description and the actions planned toward the development of the Test Guideline, the project milestones, and deliverables. Prior to a formal submission, there is a possibility for lead countries to signal their intention by submitting a preliminary proposal to gain support and seek comments to refine the definitive proposal. The proposal included in a SPSF is reviewed by the WNT and a project is considered for inclusion in the work plan when the NCs agree that the proposal meets the information requirements described in the SPSF.

Development and review of documents

In order to achieve broad acceptance of new and updated Test Guidelines, the views of recognised experts from member countries and of the NCs are sought by the Secretariat at various stages of Test Guideline development. Depending on the preferences of the member countries, documents for review can be sent both to the NC and to nominated National Experts (a list of which is made available to the Secretariat) or to the NC only, who subsequently circulates the documents for comment to selected National Experts. Whichever option is chosen, National Experts should always send their comments to their NC for his/her review. NCs then prepare a National Position Paper (NPP) on draft Test Guideline proposals and other documents circulated, and NPPs should preferably contain a consensus view on the issues raised in the document. When a single national position is not possible, the NPP should contain a compilation of alternative views. In addition to the review by member countries, the Secretariat may also request expert comment, drafted as a Position Paper, from the wider stakeholder groups involved in the Test Guidelines Programme, including the Business and Industry Advisory Committee to the OECD (BIAC), the International Council on Animal Protection in OECD Programmes (ICAPO), international scientific societies and/or other recognised organisations and NGOs, as appropriate.

OECD Workshops, Consultations and Expert Meetings

Depending on the extent and nature of comments received on draft documents circulated to the NCs and other stakeholders, the Secretariat, in consultation with the lead country, can choose to circulate a revised draft to the NCs in accordance with the comments received, or propose that an OECD Workshop, a Consultation of Experts, or an *ad hoc* Expert Meeting be held to resolve outstanding issues. The type of meeting held will depend on the scope and nature of issues identified during the commenting period, and the significance of these issues on the progress and/or finalisation of the Test Guidelines. These consultations/meetings vary in their purpose and in the level of national representation required from participants. The decision to organise an OECD Workshop or an *ad hoc* Expert Meeting is made in consultation with the NCs and, if necessary, the Joint Meeting if the subject is relevant to several Programmes under Joint Meeting supervision. The consultative processes described below are used to respond to comments received on draft documents or proposals, but can also be utilised in a proactive manner early in the development of a proposal if it would be useful to help resolve issues prior to a general commenting process.

An OECD Workshop can be organised when it is considered desirable to discuss various concepts of testing and/or to acquire insight into current scientific progress in a particular area of testing. OECD Workshops are normally open to interested scientists from both member countries and non-member economies. The recommendations from Workshops are advisory, but may be forwarded to OECD groups for their information and further consideration.

A Consultation of Experts can be arranged by the Secretariat when there are considerable differences of opinion concerning the technical/scientific content of the proposal, and when the resolution of these issues is important for the progress of the proposal. The number of invited experts to a Consultation Meeting should preferably be small. Experts participate in Consultation Meetings in a personal capacity, and so a consensus on all issues is not necessary for the further development of the proposal.

An *ad hoc* Expert Meeting can be arranged when, on the basis of comments received on a draft Test Guideline Proposal, it is anticipated that agreement among countries (member countries and non member economies adhering the MAD) on the proposal can be reached. Experts are nominated by their respective NC and formally represent their member country's position on the subjects discussed. In addition, stakeholder groups such as environmental NGOs, BIAC and ICAPO, when appropriate, may also be invited to nominate experts for these meetings.

Approval, endorsement and adoption

After sufficient agreement on a proposal has been reached, for example, by using some or all of the process described above, a draft Test Guideline is submitted to the NCs for their approval, either at the WNT meetings or by written procedure. Once approved by the NCs, the draft Test Guideline is forwarded to the Joint Meeting for their review and endorsement. A draft Test Guideline may be referred back to the National Co-ordinators or the Secretariat by the Joint Meeting with a request for further changes prior to endorsement, together with the rationale for such changes. After endorsement by the Joint Meeting, the Secretariat submits the proposal to the Environment Policy Committee (EPOC). Under written procedure, EPOC is invited to agree to the submission of the proposal to the Council for formal adoption.

Deletion of Test Guidelines

The procedures for review, approval and endorsement of the proposed deletion of (an) existing Test Guideline(s) are the same as those described for the development of new, or the update of existing, Test Guidelines.

INTRODUCTION

1. This document describes the supporting structure and procedures for Test Guidelines development, and the roles and interactions between member countries and other stakeholders in the Test Guidelines Programme.

BACKGROUND

2. In April 1990, a supporting structure and procedures for the development and updating of OECD Test Guidelines were proposed. The structure and procedures were discussed during the 14th Joint Meeting in May 1990, at which time several delegates identified the need for a "more precise allocation of tasks between the National Co-ordinators and the Joint Meeting".

3. In compliance with this request, the Chairman's report of the first Meeting of the National coordinators (which later became the WNT), held in April 1990, outlined in more detail the roles and responsibilities of the Joint Meeting, the National Co-ordinators and the Secretariat.

4. During the 17th Joint Meeting in November 1991 it was agreed that the responsibilities and procedures for Test Guideline development, as mentioned above, should be contained in a single policy document which would also include guidance on the role of National Co-ordinators, particularly with respect to commenting procedures to be used in the national review of Test Guideline proposals. That single policy document was made available in 1995 as OECD's Guidance Document 1.

5. In 1999, the WNT meeting reviewed the output of the Programme. The meeting noted that Test Guidelines were becoming more numerous and sophisticated in order to keep pace with progressing science. Thus the review of project proposals submitted for new or updated TGs was becoming more demanding in terms of the type and amount of information needed to evaluate the scope, applicability, validation status, performance of the test, additional work and resources needed for Test Guideline development. The National Co-ordinators agreed that project proposals should be submitted via a Standard Project Submission Form (SPSF), and included criteria in it for review of these proposals.

6. In 2005, following discussions at the 38th Joint Meeting and the 17th WNT Meeting on the need to refocus the Programme, a number of measures were agreed to improve the efficiency of the Test Guidelines development. Some of these measures aim to improve the review of project proposals by the WNT using existing or revised criteria, in order to better define intermediate steps and resources needed for Test Guideline development.

7. The present document has been prepared to update the guidance material on the development of Test Guidelines in the OECD and the responsibilities of the various participants in the process. A flow diagram of the various steps and procedures is provided in Annex 1 to this document.

STRUCTURE OF THE TEST GUIDELINES PROGRAMME

8. The Test Guidelines Programme provides the supporting structure for developing new and revising existing OECD Test Guidelines. A central position in this Programme is assigned to the National Co-ordinators from member countries and non-member economies adhering to the Mutual Acceptance of Data[3], plus the European Commission (EC). National Co-ordinators are appointed by member countries and non-member governments. They submit proposals on the work programme, and assess proposals for new and updated Guidelines, and Test Guideline-related documents. The Working Group of the National Co-ordinators of the Test Guidelines Programme (WNT) meets at least once a year.

9. Scientific input to the Test Guidelines Programme is obtained primarily through the National Co-ordinators, through consultation with National Experts nominated by the member countries. In addition, contributions by invited experts may be made to the Test Guidelines Programme from, for example, the Business and Industry Advisory Committee to the OECD (BIAC), the International Council on Animal Protection in OECD Programmes (ICAPO), Environmental Non-governmental organisations (NGOs) and the Trade Union Advisory Committee to the OECD (TUAC). These stakeholders can contribute via National Co-ordinators or directly on projects under the auspices of the WNT.

10. The Secretariat manages the administrative processes of the Test Guidelines Programme for the National Co-ordinators, including drafting meeting documents and organising Expert Meetings and Workshops. The Secretariat assists member countries in developing TGs by circulating draft guidelines, collecting comments, and addressing technical and policy issues with relevant experts, either by written procedure, in teleconferences, or in face-to-face meetings. Where necessary, the Secretariat takes initiatives in the updating of existing Test Guidelines. In addition, the Secretariat can obtain expert advice via consultancy or secondment arrangements, if necessary.

11. The Joint Meeting generally oversees the implementation of the Programme, and reviews and approves the work plan and priorities set by the WNT. The Secretariat provides each Joint Meeting with a progress report of activities and a proposed work plan, developed in consultation with the WNT.

[3] The 1981 OECD Council Decision concerning the ***Mutual Acceptance of Data (MAD)*** in the Assessment of Chemicals is built on the OECD Test Guidelines and Good Laboratory Practice Principles (GLP). The Council Act requires OECD governments to accept chemical test data developed for regulatory purposes in another country if these data were developed in accordance with the OECD Test Guidelines and GLP Principles. This means new data for notifications or registrations of a chemical only have to be developed once, and are then used across OECD countries

PROCEDURES FOR TEST GUIDELINE DEVELOPMENT

PROPOSAL FOR NEW OR UPDATED TEST GUIDELINES

12. Periodically, there is a need to develop new OECD Test Guidelines, or revise existing Test Guidelines, often to meet the regulatory needs of member countries, to reflect scientific progress in the area of hazard identification, to address animal welfare aspects, and to improve the cost-effectiveness of test methods. OECD Test Guidelines can be developed *de novo* or can be based on existing international and national standards, guidelines and guidance material (e.g. ISO, ASTM, EC and member countries' documents). Proposals to develop or update Test Guidelines can be made by the National Co-ordinators of the Test Guidelines Programme, the EC, industry, non-governmental organisations, scientific societies, and the Secretariat. Alternatively, a proposal may come from a Workshop or an Expert Meeting. A proposal should reflect the overall views of the member country or organisation making the proposal, and should be submitted via a National Co-ordinator or the EC, who has responsibility for the proposal. The proposal should be submitted by the National Co-ordinator or the EC to the Secretariat in the form of a Standard Project Submission Form (SPSF) and supporting documentation. The SPSF is used to describe the proposal and to provide information that demonstrates that it is suitable for consideration by the WNT.

13. In addition, the suggestion that there is a need to develop a Test Guideline (or update an existing one) may also arise from another area of the OECD Environment, Health and Safety Programme or even from a different, though related, OECD programme.

Preliminary proposal

14. To facilitate the preparation and submission of project proposals, iterative approaches may be used. The first step in the preparation of new or updated Test Guidelines may be relatively informal. For example, a lead country on an intended project may wish to develop a preliminary proposal, to gauge potential interest and availability of resources in other member countries. The first step in the process may take place through bilateral discussions among National Co-ordinators, without involvement of the Secretariat, but other means may also be explored to facilitate informal exchange of views (e.g. Electronic Discussion Group). This preliminary proposal might indicate the title of the project, the proposing country, and a brief description of what is being proposed and why. Comments received by the lead country would help to refine the proposal before a formal SPSF submission.

STANDARD PROJECT SUBMISSION FORM (SPSF)

15. Whatever the origin of the initiative, a proposal for developing a new or revised Test Guideline, a Guidance Document and any other Test Guideline-related document must be submitted via a Standard Project Submission Form (SPSF). The SPSF is completed by a National Co-ordinator, the EC or the Secretariat. The SPSF is completed by a National Co-ordinator when the initiative comes from a member country or the scientific community. The Secretariat and the EC complete a SPSF when the project proposal is their initiative.

16. The SPSF provides the mechanism by which proposals for new and updated Test Guidelines or Test Guidelines-related documents can be provided to the WNT in a consistent format. The SPSF should:

i. provide a detailed project description and the information needed by the WNT to reach agreement on project proposals, based on the information requirements described in the SPSF. Submission of supporting documentation, preferably in electronic format, in addition to the SPSF (e.g. regulatory need, validation status, relevance and reliability) will assist the WNT decision-making process;

and

ii. provide the proposing member country with the opportunity to describe the proposal work plan, including deadlines, milestones and deliverables for the steps leading to Test Guideline development.

17. The current information requirements described in the SPSF cover the following areas:

- the foreseen or existing regulatory need for such a test (or update);
- the contribution to international harmonization of data requirements;
- scientific arguments indicating the importance of the test or the modifications;
- animal welfare considerations indicating the advantages of the proposed test/procedure with respect to animal use/discomfort without loss of essential information;
- a rationale indicating the advantages of the proposed test/procedure with respect to reduced costs without loss of essential information.
- supporting documentation, e.g. on the performance of the test method, validation status, reliability and relevance of the method.

18. The SPSF identifies the anticipated outcome(s) of the project. Depending on the scientific understanding and regulatory advances in the area of concern, guidance material (e.g. Detailed Review Paper, Guidance Document, etc.) may be produced as a distinct project submitted via a SPSF, or as part of a project submitted via a SPSF along with a Test Guideline. The guidance material is, however, not covered by the Mutual Acceptance of Data (MAD) principle and is advisory in nature. The rationale for development of such guidance material should be identified from the start of the project. Information on the development of guidance material is described in Annex 2.

19. Timelines for developing the project should be provided whenever possible. An action plan with important milestones or deliverables is useful for WNT deliberation on the proposal. The proposing member country may identify the resources committed to the project, and whether partners and consortia in the proposing country, or in other countries, are needed and have been identified.

20. Once a lead country, the EC or the Secretariat has a well-developed proposal and supporting information that meets the needs of the WNT (based on the information needs described in the SPSF), a formal submission of the SPSF is made by the proposing member country, the EC or the Secretariat for consideration by the WNT meeting. The deadline for submission of SPSF is announced by the Secretariat in advance of the WNT meeting. If the WNT finds the proposal suitable for a new or updated Test Guideline, the project can be added to the work plan of the OECD Test Guidelines Programme.

21. Prior to a WNT Meeting, each National Co-ordinator and the EC should provide a rationale for their position on each proposal to develop a new, or update an existing, Test Guideline or Test Guideline-related document, based on the information requirements as described in the SPSF.

MEETINGS OF THE NATIONAL CO-ORDINATORS OF THE TEST GUIDELINES PROGRAMME (WNT)

22. All activities related to the Test Guidelines Programme, including proposals for Test Guidelines and development or updating of other documents, are normally discussed at the WNT meeting. The WNT meeting is chaired by one of the National Co-ordinators, who is elected for a period of three years in line with the timeline of the work plan of the Test Guidelines Programme. Vice-Chairs are also elected for that three-year period. The purpose of the WNT meeting is to reach consensus on the programme of work and on draft TG and related documents, to be proposed to the Joint Meeting. An overview of all (scheduled) activities related to the Test Guidelines Programme, together with a progress report on the Programme, is provided to the WNT together with each meeting's agenda. Occasionally, when it is appropriate to avoid unnecessary delay, agreement on a proposal for Test Guideline or other Test Guideline-related document development may also be reached by written procedure.

23. National Co-ordinators may either participate in the WNT meeting in person, or delegate their authority to competent officials/experts. They may also be accompanied at the WNT by such officials/experts as part of a national delegation. At the WNT meeting, a representative of the proposing country (either the National Co-ordinator or an expert in the area concerned) may give a presentation of the project proposed in the SPSF. Upon presentation of the project proposal, the WNT can decide to a) include the project on the work plan, or b) request that additional information or clarification be provided and conditionally include the project on the work plan, or c) decline to accept the project proposed in the SPSF. A rationale from the WNT should motivate the decision to request additional information or to decline to accept a project proposal.

24. In some cases, the WNT may receive a proposal that indicates that additional information, such as data on the performance of a test method, is required to meet the criteria of an SPSF. In such cases the WNT can decide to add the project to the OECD Test Guidelines Programme work plan on a provisional basis, until the information is provided to the WNT and a decision can be made on the suitability of the proposal for the Test Guidelines work plan. Alternatively, the WNT could decline to accept the proposal, with justification, and defer any decisions until a more comprehensive proposal is developed.

25. When it is recognised that there is a need for new or updated Test Guidelines for a particular area of hazard identification, the development of such Test Guidelines, as part of the work programme approved by the Joint Meeting, can be initiated in one of two ways: by developing a Detailed Review Paper (DRP) on the area of concern or, more directly, by drafting a draft Test Guideline Proposal. Details on the purpose of a DRP are provided in Annex 3 of this document.

DRAFT TEST GUIDELINES

26. The development or update of a Test Guideline is possible only when the proposed test method (or modifications to the existing Test Guideline) has undergone a critical appraisal concerning its validation and regulatory acceptance [4], including, where feasible and relevant, an inter-laboratory

[4] See OECD Guidance 34 on the Validation and International Acceptance of New and Updated Test Methods for Hazard Assessment.

comparative study (e.g. a ring test or equivalent) describing the performance of the test method. As described earlier, several steps in the project may be necessary prior to drafting the Test Guideline, ranging from a detailed assessment of existing information to additional testing to generate new data; these steps in the project will have been identified earlier in the SPSF.

27. The draft Test Guideline should be consistent with the same general content and format of current existing Test Guidelines. Components of the draft Test Guideline that are also addressed in an existing Test Guideline (such as the housing and feeding conditions of animals) should be consistent with the existing descriptions, unless scientific or animal welfare advancements require that changes be made. Explanatory notes should not be incorporated in the text of the proposal, but should be attached to it as an annex. Where an existing Test Guideline is being updated, the text of the existing version, annotated with the proposed changes, should be included with the draft proposal.

REVIEW OF DRAFT DOCUMENTS

28. OECD Test Guidelines are broadly accepted both by the international scientific community and by appropriate regulatory authorities of member countries. In order to achieve such broad acceptance, the opinion of recognised experts and authorities from the member countries is often requested by the Secretariat at various stages of Test Guideline development. Documents circulated for review include draft DRPs, Guidance Documents, Test Guidelines, and various other documents considered sufficiently important by the WNT or the Secretariat.

29. To assist in reaching agreement on a draft Test Guideline, National Co-ordinators should prepare a National Position Paper on the draft Test Guideline and other draft documents which have been circulated for review and comment. The National Position Paper should preferably contain a national view on each issue raised in the document under review, but could also be a compilation of alternative views when no scientific agreement on certain issues was possible within a member country.

30. In order to allow the views of individual experts to be seen by the WNT, National Co-ordinators should attach comments to the National Position Paper, either in their original form or as summarized by the National Co-ordinator. The professional affiliation of the consulted experts may be indicated so that the Secretariat and other member countries can obtain an insight into how broadly the scientific community has been consulted.

31. Together with each request for comment, a deadline for submission is given. In the absence of comments, or a request for more time to co-ordinate responses, the Secretariat will assume that the member country agrees with the document(s) concerned. The Secretariat will usually allow a period of 6-12 weeks for reply. When there is a need for markedly shorter commenting periods, a rationale for such deadlines will be provided.

32. The member countries decide how best to gather information from their National Experts and comment on documents circulated by the Secretariat. Generally there are two different approaches, depending on the needs and procedures of the member countries: experts nominated by National Co-ordinators may receive documents for review directly from the Secretariat or via National Co-ordinators.

33. Whichever process is chosen, the following general procedures are followed:

- The National Co-ordinator collects and collates the views of the consulted experts;

- Comments received by the Secretariat directly from individual experts, whether or not they are recognised as National Experts, are forwarded to the relevant National Co-ordinators for their consideration, and are not considered in isolation from the National Position Paper;

- On the basis of all comments received, each National Co-ordinator prepares a National Position Paper, as outlined earlier, and forwards it to the Secretariat.

34. In addition to the views of the member countries, as expressed in the National Position Papers, the Secretariat also seeks comment from the EC and from other stakeholders when appropriate, on documents circulated to the National Co-ordinators for review. Furthermore, when considered relevant, the Secretariat may also request comment on specific documents from international scientific societies and/or other international organisations. Stakeholder groups, such as environmental NGOs, BIAC and ICAPO, as well as international societies/organisations invited to comment on a particular document, should draft a Position Paper similar to the National Position Paper drafted by the member countries. These Position Papers should be sent directly to the Secretariat, which circulates them to National Co-ordinators for comment. Position Papers are submitted by an authorised officer of the committee/society/organisation and should reflect the overall views of its membership.

35. Draft Test Guidelines and other draft documents are also available from the OECD public website and are open for public comment. Public comments are directed to National Co-ordinators for building National Position Papers.

OECD WORKSHOPS, CONSULTATIONS AND EXPERT MEETINGS

36. Depending on the extent and nature of the comments received from the member countries, stakeholders and the international scientific community on draft documents, the Secretariat either circulates an updated draft or proposes that a consultation meeting of experts, a formal OECD Workshop, or an *ad hoc* Expert Meeting be held. The decision to organise a formal Workshop, a Consultation Meeting or *ad hoc* Expert Meeting is discussed with the National Co-ordinators.

37. An OECD Workshop may be organised when, at an early stage of Test Guideline development, or of other documents such as Guidance Documents or Detailed Review Papers, it is considered desirable to exchange views on basic aspects of a particular area of environmental safety or human health research, to discuss various concepts of testing, and/or to acquire insight into current scientific progress in the area concerned. Consequently, these Workshops may prove helpful when preparing a proposal for Test Guideline development, or for other documents such as Guidance Documents or Detailed Review Papers. Alternatively, an OECD Workshop may also be organised when it is anticipated, on the basis of comments received on a particular proposal, that agreement on basic issues or on the test approach might not easily be reached. An OECD Workshop may be preferred to a Consultation Meeting when discussions involving a larger forum are desirable and/or when there is no pressing time constraint. As appropriate, Workshop may be organised in consultation or jointly with other organisations.

38. Participation in OECD Workshops is not necessarily limited to member countries. These Workshops can be open to interested scientists from both member and non-member economies, as well as other stakeholder groups. Even when scientists are nominated by their member country, participation is only in a personal capacity.

39. Although an OECD Workshop may be organized by the Secretariat, usually a member country would host it and take care of all practical and logistical arrangements. The results of an OECD Workshop may be presented in a variety of forms, including a report from the Chair, Workshop Proceedings or a

Secretariat report. National Co-ordinators are provided with the report of the Workshop for their information.

40. A Consultation of Experts can be arranged by the Secretariat when there are considerable differences of opinion between the member countries on a particular proposal, and when it is anticipated that agreement on test principles or other basic issues will not be reached easily. The proposal to arrange a Consultation of Experts is normally discussed with the National Co-ordinators as part of the programme of work. Although it is essential that exponents of the different points of view be represented, the number of experts in Consultation Meetings should be limited for practical purposes. However, National Co-ordinators may indicate whether their country wishes to nominate participants for a particular Consultation Meeting. The Secretariat may invite experts in the area to participate in the Consultation of Experts. The Secretariat prepares the final list of experts to be consulted and invites them directly. Copies of all documents sent to these experts are also sent to their respective National Co-ordinators.

41. Experts consulted by the Secretariat participate in Consultation Meetings only in a personal capacity, even when they are nominated by their member country. The views of the experts are based on their scientific and technical knowledge and not the national position of their country.

42. Reports of Consultation Meetings are made available to the National Co-ordinators and stakeholders. Agreement reached at Consultation meetings may facilitate further discussions at Workshops or *ad hoc* Expert Meetings, or even allow the draft of an updated proposal to be circulated for comment.

43. An *ad hoc* Expert Meeting can be arranged when, on the basis of comments received on a draft Test Guideline Proposal (either as part of a written procedure or after a Consultation of Experts or an OECD Workshop), agreement among the member countries on the proposal is possible. The decision to hold an *ad hoc* Expert Meeting, and the aims of such a meeting, are discussed with the National Co-ordinators as part of the programme of work.

44. The Secretariat invites the National Delegations of member countries, via their National Co-ordinators, to nominate experts to attend *ad hoc* Expert Meetings. It may also invite specialised experts to attend the ad-hoc Expert Meetings. In addition, stakeholder groups such as BIAC and ICAPO may also be invited to nominate experts, if appropriate. Although Expert Meetings are mostly technical, and nominees should have broad experience in the technical matters to be discussed, these Meetings also have national policy implications in regard to Mutual Acceptance of Data. Consequently, at *ad hoc* Expert Meetings the Nominated Experts should not only express their personal opinions but also represent the national viewpoint

45. Meeting arrangements and circulation of documents are co-ordinated by the Secretariat.

46. The Report of an *ad hoc* Expert Meeting, usually drafted by the Secretariat and the Chair, summarizes the principal items of discussion, including minority views. It also includes detailed descriptions of the draft Test Guideline Proposal(s) on which agreement was reached. The Expert Meeting Report is circulated to all participants in the Expert Meeting for comment and the final report is circulated to National Co-ordinators.

RESPONSIBILITIES

47. Responsibility for overseeing and managing the Test Guidelines Programme is divided between the Joint Meeting, the WNT and the Secretariat. The respective responsibilities have evolved over the years, and the roles outlined in this section reflect current practices.

THE JOINT MEETING

48. The Joint Meeting's responsibilities in regard to the Test Guidelines Programme are to:

- inform the Environment Policy Committee (EPOC), as necessary, of the significance of the Programme's contribution to the overall chemical management process;
- set priorities in the Environment, Health and Safety Programme area that allow for the development of new Test Guidelines and for the updating of existing Test Guidelines as needed;
- ensure that the allocation of resources is adequate for the agreed work programme;
- provide general oversight of the implementation of the Programme and the work plan, including the setting of priorities and the need for new work in specific areas;
- endorse draft Test Guidelines, normally by written procedure or at the meeting if required, once they are approved by the WNT;
- agree to the publication of other Test Guideline-related documents, such as DRP, Guidance Documents, approved by the WNT;
- resolve issues that have implications for national regulatory requirements and build consensus to overcome policy differences that would otherwise jeopardise progress in Test Guideline development;
- review the implementation of the Council Decision on the Mutual Acceptance of Data (MAD), including its consequences for national regulations.

WORKING GROUP OF NATIONAL CO-ORDINATORS

49. The responsibilities of the WNT collectively are to:

i. Oversee the work of the Test Guidelines Programme which consists of:

- the development of new and the updating of existing Test Guidelines to cover regulatory data requirements for the human health and environmental assessment of chemical substances, including but not limited to pesticides and industrial chemicals, in member countries;
- involvement in the validation of new and updated test methods, as appropriate;

- the development of Guidance Documents providing: (i) further guidance on the use of Test Guidelines, (ii) testing strategies, or (iii) information on specific issues associated with the Test Guidelines Programme;

- the development of Detailed Review Papers, providing the current state-of-science in a particular test or hazard area; and

- facilitating the active involvement of member countries and non-member economies and other stakeholders in projects in the development of Test Guidelines, Guidance Documents and Detailed Review Papers;

- engagement in international co-operation, as appropriate, for the harmonisation of hazard and risk assessment of chemical substances to benefit both member countries and non-members.

ii. Direct and oversee the work of its subsidiary expert bodies, including:

- those for Endocrine Disrupters Testing and Assessment (EDTA) and Validation Management (VMGs);

- all *ad hoc* Expert Groups, established to assist in the development of specific Test Guidelines, Guidance Documents and/or Detailed Review Papers.

iii. Review the progress made in the conduct of this work, identify new projects and update annually the three-year work plan of the Test Guidelines Programme, taking into account other work under the Joint Meeting and work undertaken elsewhere, as appropriate;

iv. Maintain close working relations with other international organisations active in the area of method development for chemical hazard and risk assessment; and

v. Report on its activities to the Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology.

50. The responsibilities of each individual National Co-ordinator of the Test Guidelines Programme are to:

- ensure that project submissions, in the form of SPSF and supporting documentation, are prepared in a manner that will enable the WNT to review the proposal and to decide on its addition to the workplan for the Test Guidelines Programme;

- supervise and monitor the progress of those activities, including validation activities, of the Programme for which his country has taken the lead;

- maintain an efficient national network for consulting with experts that together provide a broad representation of his country's expertise in the area of hazard identification;

- provide, where possible, a national position on draft Test Guideline proposals, and other documents circulated by the Secretariat for review and comment;

- provide high level scientific and technical advice relevant to Test Guideline development (for example in areas of physico-chemistry, mammalian and in vitro toxicology and ecotoxicology), and also when addressing questions or issues raised by other countries or stakeholders;

- ensure, as far as possible, that the views of the National Experts nominated to represent their country at *ad hoc* Expert Meetings are consistent with current national views;

- provide input to the Secretariat on national developments relevant to the Test Guidelines Programme.

THE SECRETARIAT

51. The Secretariat's responsibilities in regard to the Test Guidelines Programme are to:

- provide the overall management and administration of the Programme;

- implement policy and other decisions of the Joint Meeting;

- develop a proposal for the three-year work plan, for consideration by the WNT and Joint Meeting, taking into account the relationship between the Test Guidelines Programme and the other programmes supervised by the Joint Meeting where activities may also require Test Guidelines development;

- convene a WNT meeting at least annually and provide an announcement of, and an agenda and appropriate documentation for, the WNT well in advance of the proposed date;

- circulate proposals for draft Test Guidelines and other draft documents to the WNT and/or appropriate groups of nominated experts, collect comments and revise drafts in consultation with the lead country for the project;

- alert the WNT to important issues relevant to the Programme and inform them on a regular basis of progress made in the Programme;

- organise (or assist lead countries in organising) Expert Meetings and workshops, obtain expert advice via consultancy or secondment arrangements, if necessary;

- prepare documents and historical background for circulation to EPOC and Council for the approval process;

- maintain a role in the facilitation and harmonisation of future validation activities.

ADOPTION AND PUBLICATION OF TEST GUIDELINES

APPROVAL OF TEST GUIDELINE PROPOSALS BY THE WNT

52. After their final development, and subsequent editing and formatting by the lead country and/or Secretariat, the draft Test Guideline Proposal(s) are submitted to the WNT for their approval. The National Co-ordinators are given sufficient time to review the proposals to ensure consistency with national regulatory requirements. Draft Test Guideline Proposals approved by the WNT, either at the WNT meeting or by written procedure, are forwarded as such to the Joint Meeting for their review and endorsement.

ENDORSEMENT BY THE JOINT MEETING

53. Preferably, a draft Test Guideline Proposal is forwarded to the Joint Meeting only when consensus on all aspects of the proposal has been reached by the WNT. The Joint Meeting is requested to review the proposal with respect to consistency with the agreed work programme and consequences for national policies, including the Council Decision on Mutual Acceptance of Data. If the Joint Meeting agrees that further changes are necessary to the draft Test Guideline Proposal prior to their endorsement, it may be referred back to the WNT, together with the rationale for changes. In some cases, the Joint Meeting may chose not to endorse the proposed Test Guideline and recommend that activity on the project ceases.

ENDORSEMENT BY THE ENVIRONMENT POLICY COMMITTEE AND SUBSEQUENT ADOPTION BY COUNCIL

54. After endorsement by the Joint Meeting, the Secretariat submits a draft Test Guideline Proposal to the Environment Policy Committee (EPOC) in both official languages of the OECD (English and French). Under the written procedure, EPOC is invited to review the draft Test Guideline Proposal before a certain date, and, as appropriate, agree to its submission to the Council for formal adoption.

55. When comments are received from EPOC, the Secretariat either provides information to clarify the issue directly to EPOC or refers the comments to the WNT for their consideration. In the latter case, the modified proposal is again submitted to the Joint Meeting and EPOC for their approval and endorsement.

56. When no comments are received from EPOC by the agreed deadline, the Secretariat submits the draft Test Guideline Proposal, together with a summary of its rationale and political/social implications for member countries, to the Council with the request to adopt the Test Guideline under the written procedure. After adoption by the Council, the new or updated Test Guideline becomes an integral part of the Decision of the Council of 12th May 1981 concerning the Mutual Acceptance of Data in the Assessment of Chemicals [C(81)30(Final)].

57. Test Guidelines adopted by the Council become effective from the date of Council adoption. The Secretariat then arranges for their publication at the earliest possible date.

DELETION OF TEST GUIDELINES

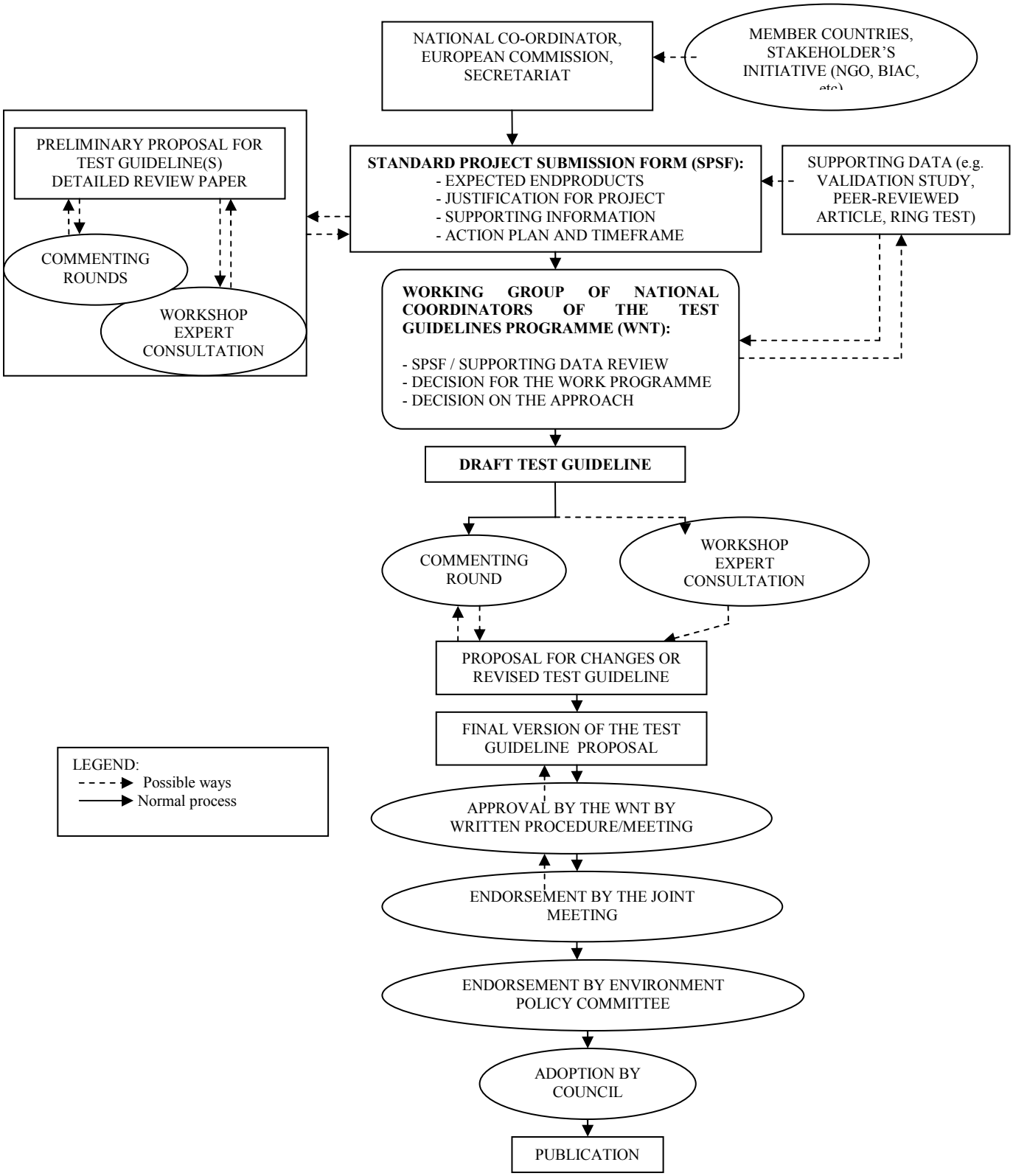
58. Because of changes in the specific needs for data in a particular area of hazard identification, or because new and better techniques, including those which bring animal welfare advantages, have become available, the need for particular existing Test Guideline(s) may no longer exist. In order to reduce redundancy, a proposal to delete Test Guideline(s) can be made by the Secretariat or the EC, or via a National Co-ordinator, by a member country or a stakeholder, in a manner similar to that used to develop or revise a Test Guideline (i.e. in the form of a SPSF, and subject to WNT agreement). Together with the proposal to delete an existing Test Guideline, it should be made clear that the proposed deletion:

- does not interfere with, compromise, or negate existing or foreseen regulatory needs; and
- is acceptable in relation to the Council Decision on the Mutual Acceptance of Data (MAD);

59. When the desirability of deleting existing Test Guideline(s) arises from a proposal to adopt new or updated Test Guideline(s), such deletion should be integrated in the proposal to adopt the new/updated Test Guideline(s) and be reviewed, approved and endorsed according to the same procedures described in this document for the development of new Test Guidelines or the updating of existing ones.

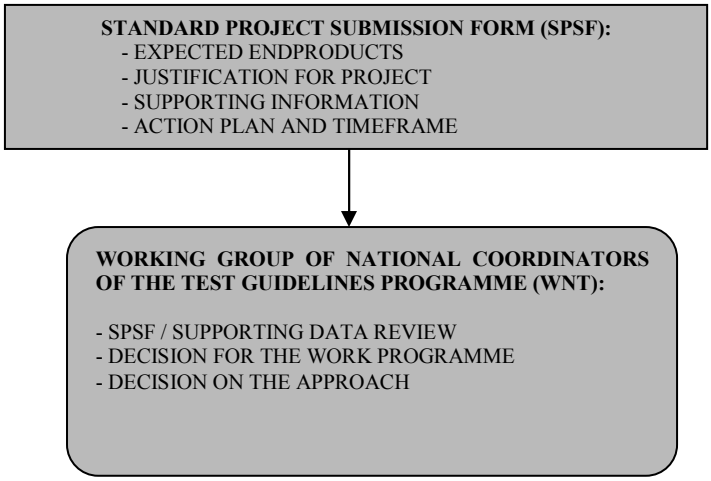
60. When a proposal to delete (an) existing Test Guideline(s) is not related to a proposal to adopt a new or updated Test Guideline(s), such a proposal should be supported by a valid argument. The Secretariat will distribute the proposal and rationale for deletion to the member countries for comment. The procedures for review, approval and endorsement of the deletion of (an) existing Test Guideline(s) will be the same as those described in this document for the development of new, or the updating of existing, Test Guidelines.

ANNEX 1: OECD Test Guidelines Development Flow Diagram



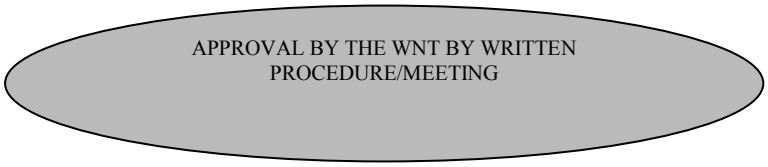
ANNEX 2: Processes for specific cases: (i) Test Guidelines and related documents developed by other groups under the Joint Meeting (e.g., the WGP, TFB, WPMN), and (ii) Test Guidelines developed to respond to countries' urgent regulatory needs.

I. WNT assessment of the SPSFs



Annex 1 gives the general procedure for SPSF Submission. In general, SPSFs can be submitted by (a) lead country (ies) at any time until 2 months before the WNT meeting, and assessments of the SPSFs are requested 1 month before the WNT meeting. The Secretariat prepares a compilation of all assessments. National Coordinators take decisions on inclusion/non inclusion of the projects in the work plan, or on the need for further information on the project, at the WNT meeting. For the specific cases (i) and (ii), the process is as described below:

(i) Test Guidelines and related documents developed by other groups under the Joint Meeting	Other groups will aim to submit a detailed SPSF preferably as soon as they want to start working on the project/proposal, but in any case no later than the first WNT commenting round for the proposal. If waiting for the WNT meeting delays the development of the project significantly, the National Coordinators' decision related to the project is made by written procedure. *If there is disagreement between the WNT and the other group, the Joint Meeting is asked to decide on the course of action.*
(ii) Test Guidelines developed to respond to countries' urgent regulatory needs.	In exceptional cases, if an urgent regulatory need is well justified, the decision related to the inclusion of the project in the work plan can be made by written procedure.



In general, proposals for Test Guidelines and related documents are approved by the WNT at the WNT meetings. For specific cases (i) and (ii), the process is as described below:

(i) Test Guidelines and related documents developed by other groups under the Joint Meeting	After at least one commenting round by the WNT and the other group, the draft Test Guideline or related document is submitted to the WNT for approval. If waiting for the WNT meeting significantly delays the publication of the Test Guideline or related document, and if no substantial comments are expected, the draft Test Guideline or related document is submitted to the WNT for approval by written procedure. *If there is disagreement between the WNT and the other group, efforts will be made to solve the issue. If it becomes clear that resolution is not possible within a reasonable time period, the Joint Meeting is asked to decide on the course of action.*
(ii) Test Guidelines developed to respond to countries' urgent regulatory needs	In exceptional cases, if an urgent regulatory need is well justified, and if no substantial comments are expected, e.g., after provisional approval by the WNT, the proposal for a Test Guideline is submitted to the WNT for approval by written procedure.

ANNEX 3

This Annex provides a description of documents developed prior to, or in parallel with, Test Guidelines. They are guidance material or reviews of a specific area of hazard identification, and as such are not part of the Council Decision on the Mutual Acceptance of Data. The initiative to develop any of these documents can come from member countries or stakeholders via a National Co-ordinator or from the EC, or the Secretariat.

Following their development, they are approved by the WNT. The Joint Meeting endorses the document which is then declassified (de-restricted) and published in the ***Series on Testing and Assessment***.

These documents are publicly available on the OECD website and in hard copy. Examples of Test Guideline-related documents are presented below.

DETAILED REVIEW PAPER (DRP)

A DRP can be developed when a specific area of hazard identification needs to be reviewed, prior to the development of a Test Guideline. A DRP is not needed if there is already an agreement on the test method to be developed for the intended purpose. When the area of concern needs further review before a particular test method raises interest for development of a Test Guideline, the following aspects should be covered in the DRP:

- a description of the scientific progress and new techniques available in the area under review;
- an inventory of existing test methods in that area, together with an appreciation of, *inter alias*, the scientific validity, sensitivity, specificity and reproducibility of these methods;
- an inventory of (inter)national data requirements with respect to the environmental safety and human health area under review, including those data used as part of existing hazard assessment procedures;
- identification of gaps with respect to significant endpoints not yet sufficiently covered by OECD Test Guidelines;
- identification of methods that are currently covered by OECD Test Guidelines but are to be replaced or updated in order to comply with current scientific views;
- proposals with respect to the development of new Test Guidelines and/or the updating of existing ones;
- indication of the relationship between the proposed and existing tests and of their limitations of use.

The proposal to develop a DRP should be submitted via a SPSF. It is normally led or sponsored by a member country. The preparation of a DRP may also be a joint activity of two or more member countries. As with Test Guidelines development, there should be timelines for the development of a DRP,

and efforts should be made to complete the work within the timelines to avoid publication of obsolete or outdated documents. Examples of DRPs include:

- Detailed Review Paper on Appraisal of Test Methods for Sex Hormone Disrupting Chemicals (2002);

- Detailed Review Paper on Aquatic Testing Methods for Pesticides and Industrial Chemicals-Part 1: Report (1998)

GUIDANCE DOCUMENT/GUIDANCE NOTES

Guidance Documents and Guidance Notes are developed either to supplement a Test Guideline or to provide assistance in the Test Guideline development. Like DRP (and other Test Guidelines related documents) they are advisory in nature. Consequently the procedure for their adoption and further publication is different from that for Test Guidelines. Situations where the development of a Guidance Document or Guidance Notes is deemed appropriate include:

- Guidance for the conduct of field or semi-field studies; examples include the *Guidance Document for the Performance of Outdoor Monolith Lysimeter Studies* (2000) and the *Guidance Document on Aquatic field Studies* (under preparation);

- Guidance for the conduct of specific studies; examples include: *Guidance Document on Aquatic Toxicity Testing of Difficult Substances and Mixtures* (2000);

- Guidance Notes concerning the analysis of specific studies; examples include: *Guidance Notes for Analysis and Evaluation of Repeat-Dose Toxicity Studies* (2000); *Guidance Notes for Analysis and Evaluation of Chronic toxicity and Carcinogenicity Studies* (2002);

- Guidance concerning suggested testing strategies (see below); examples include: *Guidance Document for Neurotoxicity Testing* (2004); *Guidance Document on Acute Oral Toxicity Testing* (2000); *Guidance Document for the Conduct of Skin Absorption Studies* (2004);

- Guidance on issues common to certain Test Guidelines, e.g. in the toxicological area the *Guidance Document on the Recognition, Assessment and Use of Clinical Signs as Humane Endpoints for Experimental Animals used in Safety Evaluation* (2000).

Proposals for Guidance Documents or Guidance Notes can be prepared by a member country, a scientific organisation, industry associations or other stakeholders. A schedule of work for their preparation should be agreed, and deadlines should be respected as far as possible. This information should be provided in the SPSF for such a project.

Testing Strategy

A testing strategy provides a suggested approach for the evaluation of existing information and a sequential or tiered approach for the generation of additional information for hazard identification of a substance. The use of testing strategies is dependent on the regulatory needs of member countries.

The purposes of a testing strategy may include:

1. ensuring best use of information including that obtained from testing and other sources;

2. prioritizing substances for evaluation or testing;

3. focusing additional testing to obtain data on specific endpoints for use in decision making or evaluation frameworks;

4. reduce, refine or replace lab animal methods or optimizing use of test information relative to the costs of testing without compromising the scientific foundation of decision making or evaluation frameworks.

Although not obligatory and not formally part of the Test Guideline, and thus not part of MAD, the testing strategy is often developed to facilitate acceptance of a particular Test Guideline (see TG 404, TG405).