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NUMBER 1

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

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FOREWORD

This Monograph describes in detail the process of Test Guideline development, including the structure of the Test Guidelines Programme, the responsibilities of those involved and the procedures which should be followed.

The National Co-ordinators reached full consensus on this document, which was subsequently endorsed by the 20th Joint Meeting of the Chemicals Group and Management Committee in May 1993.

It is anticipated that this Monograph will contribute to a better understanding of the development of OECD Test Guidelines in general, will encourage and stimulate the scientific community to participate in this process where desirable, and will be of assistance to those who are professionally involved in test guideline development.

This document was reformatted in May 1995 so that it could be published as No. 1 in the new "OECD Series on the Test Guidelines Programme". However, no revisions have been made to the text. Derestriction of this Environment Monograph was recommended by the Joint Meeting of the Chemicals Group and Management Committee of the Special Control of Chemicals. It has been made public under the responsibility of the Secretary-General of the OECD.

A French version is also available under the title: *Série OCDE Programme des Lignes Directrices pour les Essais No. 1, Document d'orientation pour la mise au point des lignes directrices pour les essais de produits chimiques* (Monographie sur l'Environnement No. 76).

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SUMMARY

During the 17th Joint Meeting it was agreed 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, the various responsibilities and, in detail, the procedures that could be followed during the development of new, or updating of existing, Test Guidelines.

STRUCTURE AND RESPONSIBILITIES

The National Co-ordinators (NCs) have a central position in the structure. They submit national proposals for new Guidelines or revised Guidelines and provide nationally agreed comments on proposals circulated by the Secretariat. In order to be efficient, NCs need a well-built network of experts and thus should be aware of developments in their country with regard to test methods. A meeting of NCs is convened by the Secretariat at least once a year. Collectively, NCs oversee the programme and work towards consensus on draft Guidelines.

The Secretariat's main duty is to give the structural support to the Programme. It develops a proposal for the annual work programme and directs various activities, including drafting of documents and organisation of meetings. Where necessary, the Secretariat takes initiatives in the development of new and updated Test Guidelines. It has the responsibility of revising periodically the compendium of Guidelines, and to this end, launches and/or oversees the production of Detailed Review Papers (DRPs).

The Joint Meeting provides general oversight of the implementation of the Programme, reviews and endorses draft Test Guidelines, and builds consensus to overcome policy differences that would otherwise jeopardise progress in Test Guideline development. The Joint Meeting also ensures that the allocation of resources is sufficient to enable the agreed work programme to be carried out.

PROCEDURES FOR TEST GUIDELINE DEVELOPMENT

Proposals

Proposals for the development of new or updated Test Guidelines can be made by the NCs, by the international scientific community via a National Co-ordinator, and by the Secretariat. A proposal for a new Test Guideline or the revision of an existing Guideline should have undergone a critical appraisal concerning its scientific justification, its sensitivity and reproducibility.

DRPs

A DRP should be prepared when it is considered essential that the "state-of-the-art" in the area under review first be assessed. A DRP should be extensive and include: a description of scientific progress; an inventory and appreciation of existing methods and current (inter)national data requirements; the identification of gaps in the current set of OECD Test Guidelines and of Guidelines that need updating; proposals as to the development/updating of Guidelines; and an indication of the relationship between the proposed and existing tests and of their possibilities and limitations of use.

Review

In order to achieve a broad acceptance, the opinion of recognised experts from Member countries and views of the NCs are requested by the Secretariat at various stages of Test Guideline development. Depending on the Member country's preference, documents for review are sent either 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 comment to their NC for his/her review. NCs should prepare a National Position Paper (NPP) on DRPs and Draft Test Guideline Proposals. NPPs should preferably contain a consensus view on the issues raised in the document. When consensus is not possible, they should contain a compilation of alternative views. In addition to the review by Member countries, the Secretariat will also request comment, drafted as a Position Paper, from the Business and Industry Advisory Committee to the OECD (BIAC) and, when relevant, from international scientific societies and/or other recognised organisations.

Consultations, OECD Workshops and Expert Meetings

Depending on the extent and nature of comments received on documents circulated, the Secretariat will either circulate a revised draft, or propose that a Consultation of Experts, an OECD Workshop or an ad hoc Expert Meeting be held. The decision to organise an OECD Workshop or an ad hoc Expert Meeting will be made in consultation with the NCs and will require both their prior approval and that of the Joint Meeting.

A Consultation of Experts will be arranged by the Secretariat when there are considerable differences of opinion concerning the technical/scientific content of the proposal. The number of invited experts to a Consultation Meeting should preferably be small. Experts will participate in Consultation Meetings only in their personal capacity.

An OECD Workshop will be organised when it is considered desirable to exchange views on basic aspects, 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 and non-Member countries.

An ad hoc Expert Meeting will be arranged when, on the basis of comments received on a Draft Test Guideline Proposal, it is anticipated that consensus among Member countries on the proposal can be reached. Experts will be nominated by their respective NC and will formally represent their Member country's viewpoint on the subjects discussed. In addition, BIAC will also be invited to nominate experts for these meetings.

Approval, endorsement and adoption

After sufficient consensus has been reached, a Draft Test Guideline is submitted to the NCs for their approval, either at the NCM 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 rejected by the Joint Meeting will be referred back to the NCs, together with the reason for its rejection. After endorsement by the Joint Meeting, the Secretariat submits the proposal to the Environment Policy Committee (EPOC). Under a 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) will be the same as those described for the development of new, or the update of existing, Test Guidelines.

INTRODUCTION

1. In April 1990, a new supporting structure and procedures for the development and updating of OECD Test Guidelines were proposed following consultation with the Bureaux of the Chemicals Group and Management Committee of the Special Programme on the Control of Chemicals and with what was then called the Updating Panel [ENV/CHEM/CM/90.11]. The document in which they were presented was discussed during the 14th Joint Meeting of the Chemicals Group and Management Committee in May 1990, at which time several Delegates called for a "more precise allocation of tasks between the National Co-ordinators and the Joint Meeting".

2. In compliance with this request, the Chairman's report of the first Meeting of the National Co-ordinators of the Test Guidelines Programme [ENV/MC/CHEM(90)8], submitted to the 15th Joint Meeting in November 1990, outlined in more detail the roles and responsibilities of the Joint Meeting, the National Co-ordinators and the Secretariat. During the discussion of this document, several points were further clarified and subsequently summarized in the Record of the 15th Joint Meeting [ENV/MC/CHEM/M(90)2].

3. During the 17th Joint Meeting it was agreed that the responsibilities and procedures for Test Guideline development, as described in the two documents referenced above, should be set out 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 [ENV/MC/CHEM/M(91)2]. The present document has therefore been prepared to that end. A flow diagram of the various steps and procedures is given in the Annex to this document.

STRUCTURE OF THE TEST GUIDELINES PROGRAMME

4. The supporting structure for developing new Test Guidelines or updating existing ones is provided by the Test Guidelines Programme. A central position in this Programme is assigned to the National Co-ordinators from Member countries including the Commission of the European Communities (CEC). National Co-ordinators are appointed by their respective National Delegations to the Joint Meeting. They make proposals for the work programme and for priorities, and review proposals for new and updated Guidelines. A National Co-ordinators Meeting (NCM) takes place at least once a year.

5. Scientific input to the Test Guidelines Programme is obtained primarily through the National Co-ordinators, by consulting with national experts nominated by Member countries. In addition, international scientific societies may contribute to the Test Guidelines Programme either on their own initiative by submitting proposals to any National Co-ordinator (and thus be subject to his/her review and approval) or, when requested formally by the Secretariat, by contributing to the overall comments. As appropriate, the Business and Industry Advisory Committee to the OECD (BIAC) will be given sufficient opportunity to comment on proposals. In addition, individuals may also act as consultants to the Secretariat.

6. The Secretariat sees to the daily management and subsequent administration of the Test Guidelines Programme. It directs routine activities related to the Programme, including drafting of proposals and other documents and organisation of Expert Meetings and workshops. Where necessary, the Secretariat takes initiatives and provides leadership in the development of new Test Guidelines and the updating of existing ones.

7. The Joint Meeting provides general oversight of the implementation of the Programme, reviews and approves the general lines of the work programme and sets priorities. The Secretariat provides each Joint Meeting with a progress report of activities and with proposals for future work.

RESPONSIBILITIES

8. Responsibility for overseeing and managing the Test Guidelines Programme is divided among the Joint Meeting, the National Co-ordinators and the Secretariat. The respective responsibilities have evolved over the years, and the roles outlined in this section are either the reflection of these evolved practices, or drawn from existing documents.

THE JOINT MEETING

9. 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 Chemicals Programme area that allow for the development of new Test Guidelines as needed, and for the updating of existing Test Guidelines to ensure that they remain at the forefront of science;
- ensure that the allocation of resources is sufficient to enable the agreed work programme to be carried out;
- provide general oversight of the implementation of the Programme and to decide on the policy and general lines of the work programme, including the setting of priorities for agreed activities and the need for new work in a specific area;
- endorse draft Test Guidelines;
- 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, including its consequences for national regulations.

NATIONAL CO-ORDINATORS

10. The responsibilities of the National Co-ordinators of the Test Guidelines Programme collectively are to:

- contribute to the continuity of the Programme by providing the Joint Meeting with relevant information pertaining to national appreciation and support for the Test Guidelines;

- report to and advise the Joint Meeting, via the Secretariat, on all matters relating to the development and approval of Test Guidelines;

- agree upon and propose the annual work programme for presentation to the Joint Meeting, including priorities for agreed activities and the need for new work in a specific area;

- oversee the implementation of the work programme, as decided on general lines by the Joint Meeting;

- agree on technical and policy matters and, where efforts to overcome differences in points of view have not been successful, define the issues for resolution by the Joint Meeting;

- propose tasks for, and the extent of involvement of, the Secretariat, Member countries and other parties (*inter alia* international scientific societies and industry associations) that participate in the Test Guidelines Programme, and to monitor their progress;

- reach consensus, where possible, on draft Test Guidelines before their submission to the Joint Meeting.

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

- supervise those activities of the Programme for which their country has volunteered to take the lead;

- maintain an efficient national network for consulting with national experts who should together represent as broadly as possible their country's expertise in the area of hazard identification;

- provide, where possible, a national consensus view on Detailed Review Papers (DRPs), draft Test Guideline proposals, and other documents circulated by the Secretariat for review and comment;

- 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

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

- provide for the overall management and administration of the Programme;
- implement policy and other decisions of the Joint Meeting;
- develop a proposal for the annual work programme, for consideration by the National Co-ordinators and Joint Meeting, particularly taking into account the interrelation between the Test Guidelines Programme and the Hazard Assessment Programme and priorities resulting therefrom;
- convene a National Co-ordinators Meeting (NCM) at least annually and provide an announcement of, and an agenda and appropriate documentation for, the NCM well in advance of the proposed date;
- develop proposals and detailed plans for work in specific areas;
- alert National Co-ordinators to issues of (national) importance and inform them on a regular basis of progress made in the Programme;
- organise (or assist lead countries in organising) Expert Meetings and workshops;
- seek the advice of consultants when necessary.

PROCEDURES FOR TEST GUIDELINE DEVELOPMENT

INITIATIVES

13. In order to respond efficiently to scientific progress in hazard identification and related data generation, the possibility of making official proposals for the development of new and/or the updating of existing Test Guidelines should not be limited to OECD Member countries or the Secretariat, but should also be offered to the international scientific community. Consequently, official proposals can be made at the initiative of:

- The OECD Secretariat: Initiatives will mainly result from the Periodic Review activities (as directed by the Third High Level Meeting in 1986) and/or Detailed Review Papers. 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 Chemicals Programme or even from a different, though related, OECD programme;

- An OECD Member country: Proposals may be submitted to the Secretariat by a single Member country, and thus do not necessarily need to be seconded by other Member countries;

- The scientific community: Proposals from the scientific community should be submitted by the relevant officer of a recognised society, association or organisation and should reflect the overall views of the membership of that society, association or organisation. Proposals from the scientific community should be submitted to a National Co-ordinator who will review the proposal and, when considered acceptable, forward it to the Secretariat.

PRIORITY SETTING AT THE NATIONAL CO-ORDINATORS MEETING

14. All activities related to the Test Guidelines Programme, including proposals for Test Guideline development and updates, are normally discussed at the National Co-ordinators Meeting (NCM). This meeting will be held at least once a year, preferably at a convenient time prior to a Joint Meeting. The NCM will be chaired by one of the National Co-ordinators, who should be elected for a period of three years. At the end of the second year, a co-chair will be elected who will become Chairman at the end of the NCM the following year. The purpose of the NCM is aimed at achieving agreement, based on consensus, on the programme of work and on the priorities for the agreed activities therein, to be proposed to the Joint Meeting. For the convenience of the National Co-ordinators, an overview of all (scheduled) activities related to the Test Guidelines Programme, together with a progress report on the Programme, should be distributed well in advance of the NCM together with the meeting's agenda. Occasionally, when it seems appropriate to avoid any unnecessary delay, agreement on a proposal for Test Guideline development may also be reached by written procedure.

15. National Co-ordinators may either participate in the NCM in person, or delegate their authority to competent officials/experts. They may also be accompanied at the NCM by such officials/experts. The Secretariat would appreciate being informed in advance when a National Co-ordinator has delegated his/her authority and will not be attending the NCM in person. For practical reasons, the Secretariat would also appreciate being informed of the size of each national delegation well in advance of the meeting.

APPROACH

16. Any proposal to develop a new, or update an existing, Test Guideline should be supported by valid arguments. These should include at least one of the following:

- need for such a test (or update);

- achievement of further progress in international harmonization of data requirements;

- scientific arguments indicating the importance of the test or the modifications;

- ethical arguments indicating the advantages of the proposed test/procedure with respect to animal use/discomfort without loss of essential information;

- arguments indicating the advantages of the proposed test/procedure with respect to reduced cost without loss of essential information.

17. When it is recognised that new Test Guidelines need to be developed and/or existing ones need to be updated for a particular area of hazard identification, the development of these (series of) Test Guidelines, as part of the work programme approved by the Joint Meeting, can be realised in one of two ways: by starting with a Detailed Review Paper of the area concerned or, more directly, by drafting a Draft Test Guideline Proposal.

Detailed Review Papers

18. In order to identify the specific needs for data in a particular area of hazard identification, or to confirm the need to update a specific cluster of existing Test Guidelines or even a single Test Guideline, it is considered essential that the "state-of-the-art" in that area first be assessed. For this purpose the Secretariat will arrange for the preparation of a Detailed Review Paper (DRP). A DRP should review a well-defined area of environmental safety and human health research being considered for Test Guideline development or updating. The review should be extensive and should include:

- 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 alia*, 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.

19. Once the decision is made that a particular DRP should be prepared, the Secretariat will inquire if a National Co-ordinator is willing to take the responsibility for its preparation by his/her Member country. The preparation of a DRP may also be a joint activity of two or more Member countries.

20. When no National Co-ordinator volunteers to prepare the DRP within a reasonable time, the Secretariat may consider other options. These include: requesting the assistance of recognised (international) scientific societies; accepting offers from industry, including their (international) associations; or hiring a consultant.

21. Deadlines agreed upon for the preparation of a DRP should be respected as far as possible. Where the Secretariat arranges for the work to be done under contract, firm commitments by the contracted consultant(s) are envisaged.

Draft Test Guideline Proposals

22. When the need to develop or update a Test Guideline covering well-defined endpoints is clear-cut, the Secretariat may arrange for the preparation of a Draft Test Guideline Proposal without a DRP. The proposal should properly address the endpoints concerned. Further, the proposed test should have undergone a critical appraisal concerning its scientific justification, its sensitivity and its reproducibility, including, where feasible and relevant, a comparative study (e.g. a ring test) supporting the validity of the test proposed. In addition, the described procedures should allow for standardisation and should not normally require unique equipment or technical experience.

23. The Draft Test Guideline Proposal should follow the same lay-out and format as the standard existing at the time. Parts of the Draft Test Guideline Proposal that are also addressed in an existing Test Guideline (such as the housing and feeding conditions of animals) should be in harmony with the existing descriptions, unless scientific 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.

24. A Draft Test Guideline Proposal can be prepared by a Member country, a scientific organisation, industry associations or a consultant. A schedule for the preparation of the Draft Test Guideline Proposal should be agreed, and deadlines should be respected as far as possible.

REVIEW OF DRAFT DOCUMENTS

25. 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 Member countries is requested by the Secretariat at various stages of Test Guideline development. Documents circulated for review include DRPs, Draft Test Guideline Proposals, and various other documents considered sufficiently important by the NCM or the Secretariat.

26. To assist in reaching consensus, all National Co-ordinators should prepare a National Position Paper on the DRPs and Draft Test Guideline Proposals which have been circulated for review and comment. The National Position Paper should preferably contain a consensus view

on each issue raised in the document under review, but could also be a compilation of alternative views and/or a government position when no scientific consensus was possible within a Member country.

27. In order to allow individual experts' comments to be reviewed and, more importantly, to allow for comparison of "minority views" in different Member countries, each expert's comments, when submitted on paper rather than being expressed only at a discussion meeting, should be attached to the National Position Paper, either in their original form or summarized by the National Co-ordinator. The names and professional affiliation of the consulted experts should be indicated in order that the Secretariat and other Member countries can obtain an insight into how broadly the scientific community has been consulted and, when relevant, to indicate the involvement of a particular expert whose views are internationally considered to be of particular importance.

28. Together with each request for comment, a deadline for submission will be set. When no comment, or request for more time to co-ordinate responses, has been received by this submission date, the Secretariat will assume that the Member country agrees with the document(s) concerned. The Secretariat will usually allow a minimum period of three months for reply. When there is a particular urgency, however, a shorter deadline will be set and explanations given for doing so.

29. Member countries may select one of two options as their Member country's standard procedure for review and comment on documents circulated by the Secretariat:

Option 1:

- The Member country will supply the Secretariat with lists of Nominated National Experts in the areas covered by the Test Guidelines Programme. These lists will be updated as appropriate;

- Together, these experts should represent the Member country's expertise as broadly as possible and should therefore preferably be selected from Government agencies or institutions, academia and private laboratories, as well as from industry;

- The Secretariat will circulate documents for comment to the National Co-ordinator and to Nominated National Experts for the area concerned. The Experts will be instructed to respond via their National Co-ordinator;

- National Co-ordinators may also distribute the documents for comment to a more extensive network of national experts used as a basis for their consultative framework on Test Guidelines.

Option 2:

- The Member country will **not** supply the Secretariat with any list of national Experts;

- The Secretariat will circulate documents for comment **only** to the National Co-ordinator;

- The National Co-ordinator will circulate the documents for comment to national experts whose opinions are considered of relevance to the National Position on that particular subject.

30. Whichever option is chosen, the following procedures will be followed:

- The National Co-ordinator should collect and collate the views of the consulted experts;

- Comments received by the Secretariat directly from individual experts, whether or not they are recognised as National Experts, will not be taken into account. These comments will be forwarded to the relevant National Co-ordinators for their consideration;

- On the basis of all comments received, each National Co-ordinator should prepare a National Position Paper, as outlined in paragraphs 26 and 27, and forward it to the Secretariat.

31. In addition to the views of Member countries, as expressed in the National Position Papers, the Secretariat will also request comment from BIAC on all 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. BIAC, 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 Member countries. These Position Papers should be sent directly to the Secretariat, which will circulate them to National Co-ordinators for comment. Position Papers should be submitted by an authorised officer of the committee/society/organisation and should reflect the overall views of its membership.

CONSULTATIONS, OECD WORKSHOPS AND EXPERT MEETINGS

32. Depending on the extent and nature of the comments received from Member countries and the international scientific community on draft documents, the Secretariat will either circulate an updated draft or propose that a consultation meeting of experts, a formal OECD Workshop, or an ad hoc Expert Meeting be held. The decision to circulate an updated draft version of the document will be made when it is anticipated either that several rounds of comment are necessary before a meeting would be opportune, or that consensus on the proposal might be reached without a meeting. The decision to organise a formal Workshop or ad hoc Expert Meeting will be made in consultation with the National Co-ordinators and will require their prior approval and that of the Joint Meeting.

33. A Consultation of Experts will be arranged by the Secretariat when there are considerable differences of opinion between Member countries on a particular proposal, and when it is anticipated that consensus on test principles or other basic issues will not be reached easily. The proposal to arrange a Consultation of Experts will normally be 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. However, National Co-ordinators may indicate whether their country

wishes to participate in a particular Consultation Meeting. Considering the preferences of Member countries, the Secretariat will prepare the final list of experts to be consulted and invite them directly. Copies of all documents sent to these experts will also be sent to their respective National Co-ordinators.

34. Experts consulted by the Secretariat will participate in Consultation Meetings only in their personal capacity, even when they are proposed by their Member country.

35. Chairman's reports of Consultation Meetings will be circulated to Member countries and the international scientific community as described under "Review of Draft Documents" (paragraphs 25-31). Consensus reached at Consultation meetings may well facilitate further discussions at Workshops or ad hoc Expert Meetings, or even allow the draft of an updated proposal to be circulated for comment.

36. An OECD Workshop may be organised when, at an early stage of Test Guideline development, 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 drafting a DRP. On the other hand, an OECD Workshop could also be organised when it is anticipated, on the basis of comments received on a particular proposal, that consensus 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.

37. Participation in OECD Workshops is not necessarily limited to Member countries. These Workshops could very well be open to interested scientists from both Member and non-Member countries including those representing industry. Even when scientists are nominated by their Member country, participation will only be in their personal capacity.

38. Although an OECD Workshop could be organized by the Secretariat, usually a Member country will offer to host it and take care of all practical and logistical arrangements. The results of an OECD Workshop could be presented in a Chairman's report, Workshop Proceedings or a Secretariat report. National Co-ordinators will be provided with the report of the Workshop for their information as soon as available. When considered relevant, comments on such reports will be requested using the procedure described under "Review of Draft Documents".

39. An ad hoc Expert Meeting will 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), it is anticipated that consensus among Member countries on the proposal could be achieved. Whether or not to hold an ad hoc Expert Meeting, and the aims of such a meeting, will be discussed with the National Co-ordinators as part of the programme of work and must have their approval and mandate, as well as that of the Joint Meeting.

40. The Secretariat will invite the National Delegations of Member countries, via their National Co-ordinators, to nominate experts to attend the ad hoc Expert Meeting. In addition, BIAC will also be invited to nominate experts. 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 on the subjects discussed. These

viewpoints should be in harmony with current views of their country on the same subjects, as received by the Secretariat via their National Co-ordinator.

41. Once nominated, the Experts will be contacted directly by the Secretariat and provided with all relevant documents. Copies of these documents will also be sent to the National Co-ordinators for their files and/or for distribution to other interested parties.

42. The Report of an ad hoc Expert Meeting is usually drafted as a joint activity of the Secretariat and the Chairman and should summarize the principle items of discussion, including minority views. It should also include detailed descriptions of the Draft Test Guideline Proposal(s) on which consensus was reached. The Expert Meeting Report will be circulated to National Co-ordinators and all participants in the Expert Meeting for comment. The procedure for review of the Chairman's report will be as described under "Review of Draft Documents".

APPROVAL OF TEST GUIDELINE PROPOSALS BY NATIONAL CO-ORDINATORS

43. After their final development, and subsequent editing and formatting by the Secretariat, the Draft Test Guideline Proposal(s) will be submitted to the National Co-ordinators for their approval. The National Co-ordinators will be given sufficient time to review the proposals, in both official languages, not only with respect to their technical content but also with respect to policy issues such as animal welfare, cost effectiveness and consistency with national requirements. Draft Test Guideline Proposals approved by the National Co-ordinators, either at the NCM or by written procedure, will be forwarded as such to the Joint Meeting for their review and endorsement.

ENDORSEMENT BY THE JOINT MEETING

44. A Draft Test Guideline Proposal will preferably only be forwarded to the Joint Meeting when consensus on all aspects of the proposal has been reached by the National Co-ordinators. The Joint Meeting will be 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. A Draft Test Guideline Proposal rejected by the Joint Meeting will be referred back to the National Co-ordinators, together with the reason(s) for its rejection.

ENDORSEMENT BY THE ENVIRONMENT POLICY COMMITTEE AND SUBSEQUENT ADOPTION BY COUNCIL

45. After endorsement by the Joint Meeting, the Secretariat will submit a Draft Test Guideline Proposal to the Environment Policy Committee (EPOC). Under the written procedure, EPOC will be invited to review the Draft Test Guideline Proposal before a certain date, which should be at least six weeks after submission, and, as appropriate, agree to its submission to the Council for formal adoption.

46. When comments are received from EPOC, the Secretariat will either provide information to clarify the issue directly or refer the comments to the National Co-ordinators for their consideration. In the latter case, the modified proposal will again be submitted to the Joint Meeting and EPOC for their approval and endorsement.

47. When no comments from EPOC have been received by the deadline set, the Secretariat will submit 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 will become 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)].

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

DELETION OF TEST GUIDELINES

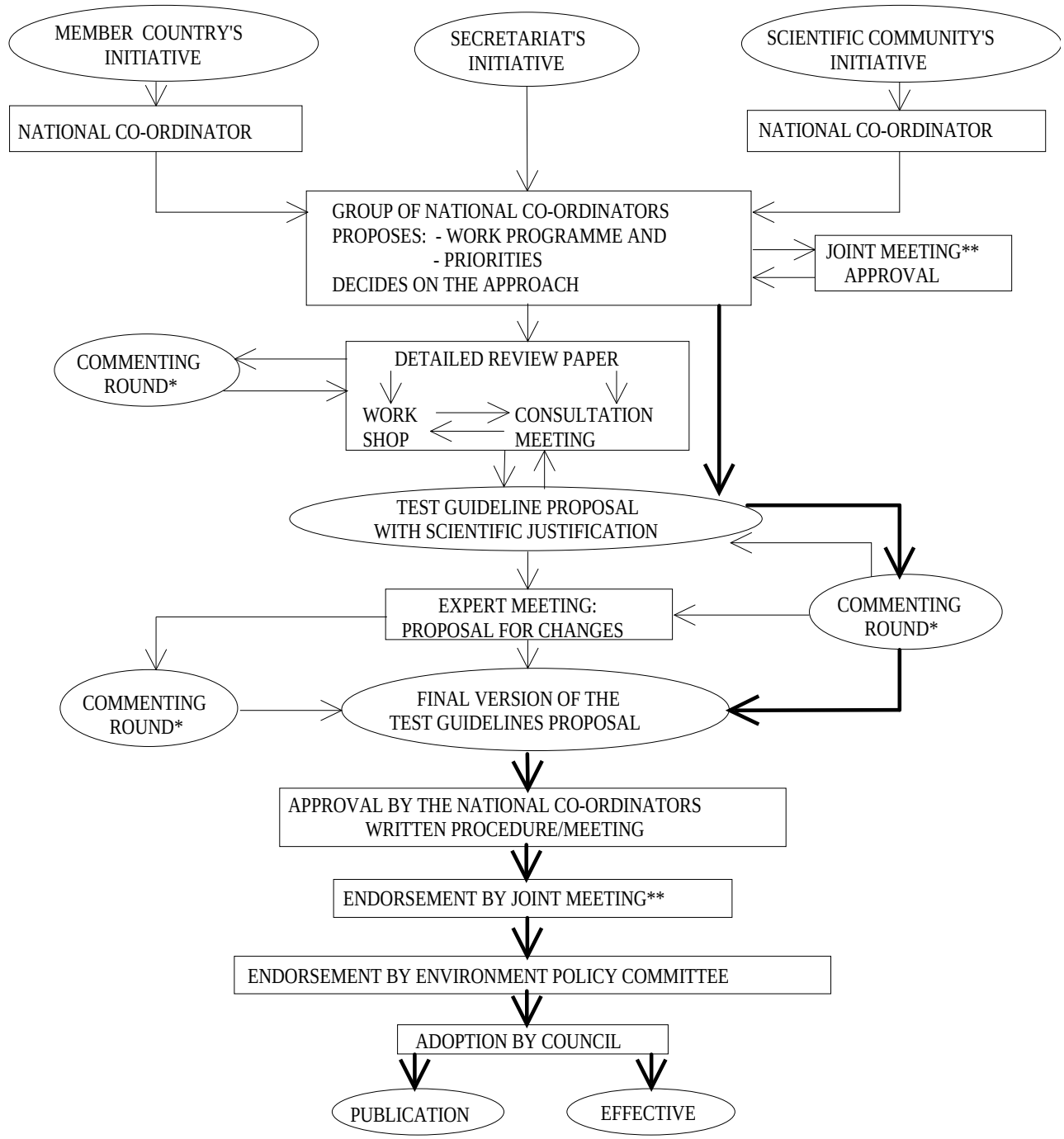
49. Because of altered views with respect to the specific needs for data in a particular area of hazard identification, or because new and better techniques have become available, the need for particular existing Test Guideline(s) may no longer exist. A proposal to delete Test Guideline(s) could be made by the Secretariat, a Member country or the international scientific community, in a manner similar to that outlined in paragraph 13. Together with the proposal to delete an existing Test Guideline, it should be made clear that the proposed deletion:

- does not interfere with existing hazard assessment needs;
- is acceptable in relation to the Council Decision on the Mutual Acceptance of Data (MAD); and
- avoids unwanted duplication for a given endpoint.

50. 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.

51. When a proposal to delete existing Test Guideline(s) is not related to a proposal to adopt new/updated Test Guideline(s), such proposal should be supported by valid arguments. The Secretariat will distribute the proposal for deletion and the rationale given for deletion to 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.

OECD TEST GUIDELINE DEVELOPMENT FLOW DIAGRAM



* Commenting rounds would include Member countries, BIAC, and scientific societies, as appropriate.

** Joint Meeting of the Chemicals Group and Management Committee of the Special Programme on the Control of Chemicals.

→ = fast track procedure.