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ENVIRONMENT DIRECTORATE
JOINT MEETING OF THE CHEMICALS COMMITTEE AND
THE WORKING PARTY ON CHEMICALS, PESTICIDES AND BIOTECHNOLOGY

GUIDE FOR PREPARATION OF BIOLOGY CONSENSUS DOCUMENTS

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English - Or. English

Also published in the Series on Harmonisation of Regulatory Oversight in Biotechnology:

No. 1, Commercialisation of Agricultural Products Derived through Modern Biotechnology: Survey Results (1995)

No. 2, Analysis of Information Elements Used in the Assessment of Certain Products of Modern Biotechnology (1995)

No. 3, Report of the OECD Workshop on the Commercialisation of Agricultural Products Derived through Modern Biotechnology (1995)

No. 4, Industrial Products of Modern Biotechnology Intended for Release to the Environment: The Proceedings of the Fribourg Workshop (1996)

No. 5, Consensus Document on General Information concerning the Biosafety of Crop Plants Made Virus Resistant through Coat Protein Gene-Mediated Protection (1996)

No. 6, Consensus Document on Information Used in the Assessment of Environmental Applications Involving Pseudomonas (1997)

No. 7, Consensus Document on the Biology of *Brassica napus* L. (Oilseed Rape) (1997)

No. 8, Consensus Document on the Biology of *Solanum tuberosum* subsp. *tuberosum* (Potato) (1997)

No. 9, Consensus Document on the Biology of *Triticum aestivum* (Bread Wheat) (1999)

No. 10, Consensus Document on General Information Concerning the Genes and Their Enzymes that Confer Tolerance to Glyphosate Herbicide (1999)

No. 11, Consensus Document on General Information Concerning the Genes and Their Enzymes that Confer Tolerance to Phosphinothricin Herbicide (1999)

No. 12, Consensus Document on the Biology of *Picea abies* (L.) Karst (Norway Spruce) (1999)

No. 13, Consensus Document on the Biology of *Picea glauca* (Moench) Voss (White Spruce) (1999)

No. 14, Consensus Document on the Biology of *Oryza sativa* (Rice) (1999)

No. 15, Consensus Document on the Biology of *Glycine max* (L.) Merr. (Soybean) (2000)

No. 16, Consensus Document on the Biology of *Populus* L. (Poplars) (2000)

No. 17, Report of the OECD Workshop on Unique Identification Systems for Transgenic Plants, Charmey, Switzerland, 2-4 October 2000 (2001)

No. 18, Consensus Document on the Biology of *Beta vulgaris* L. (Sugar Beet) (2001)

No. 19, Report of the Workshop on the Environmental Considerations of Genetically Modified Trees, Norway, September 1999 (2001)

No. 20, Consensus Document on Information Used in the Assessment of Environmental Applications Involving Baculoviruses (2002)

No. 21, Consensus Document on the Biology of *Picea sitchensis* (Bong.) Carr. (Sitka Spruce) (2002)

No. 22, Consensus Document on the Biology of *Pinus strobus* L. (Eastern White Pine) (2002)

No. 23, Revised 2006: OECD Guidance for the Designation of a Unique Identifier for Transgenic Plants (2006)

No. 24, Consensus Document on the Biology of *Prunus* spp. (Stone Fruits) (2002)

No. 25, Module II: Herbicide Biochemistry, Herbicide Metabolism and the Residues in Glufosinate-Ammonium (Phosphinothricin)-Tolerant Transgenic Plants (2002)

No. 26, Output on the Questionnaire on National Approaches to Monitoring/Detection/Identification of Transgenic Products (2003)

No. 27, Consensus Document on the Biology of *Zea mays* subsp. *mays* (Maize) (2003)

No. 28, Consensus Document on the Biology of European White Birch (*Betula pendula* Roth) (2003)

No. 29, Guidance Document on the Use of Taxonomy in Risk Assessment of Micro-organisms: Bacteria (2003)

No. 30, Guidance Document on Methods for Detection of Micro-organisms Introduced into the Environment: Bacteria (2004)

No. 31, Consensus Document on the Biology of *Helianthus annuus* L. (Sunflower) (2004)

No. 32, An Introduction to the Biosafety Consensus Documents of OECD's Working Group for Harmonisation in Biotechnology (2005)

No. 33, Consensus Document on the Biology of Papaya (*Carica papaya*) (2005)

No. 34, Consensus Document on the Biology of *Pleurotus* spp. (Oyster Mushroom) (2005)

No. 35, Points to Consider for Consensus Documents on the Biology of Cultivated Plants (2006)

No. 36, Consensus Document on the Biology of *Capsicum annuum* Complex (Chili peppers, Hot peppers and Sweet peppers) (2006)

No. 37, Consensus Document on Information Used in the Assessment of Environmental Application involving *Acidithiobacillus* (2006)

No. 38, Consensus Document on the Biology of Western White Pine (*Pinus monticola* Dougl. ex D. Don) (2008)

No. 39, Abstracts of the OECD Expert Workshop on the Biology of Atlantic Salmon (2006)

No. 40, Consensus Document on the Biology of *Pinus banksiana* (Jack Pine) (2006)

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No. 42, Consensus Document on the Safety Information on Transgenic Plants Expressing *Bacillus thuringiensis* – Derived Insect Control Protein (2007)

No. 43, Consensus Document on the Biology of Douglas-Fir (*Pseudotsuga Menziesii* (Mirb.) Franco (2008)

No. 44, Consensus Document on the Biology of Lodgepole Pine (*Pinus contorta* Dougl. *ex*. Loud.) (2008)

No. 45, Consensus Document on the Biology of Cotton (*Gossypium* spp.) (2008)

No. 46, Consensus Document on Information Used in the Assessment of Environmental Applications Involving *Acinetobacter* (2008)

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OECD Environment, Health and Safety Publications

Series on Harmonisation of Regulatory Oversight in Biotechnology

No. 47

Guide for Preparation of Biology Consensus Documents

Environment Directorate

Organisation for Economic Co-operation and Development

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ABOUT THE OECD

The Organisation for Economic Co-operation and Development (OECD) is an intergovernmental organisation in which representatives of 30 industrialised countries in North America, Europe and the Asia and Pacific region, as well as the European Commission, meet to co-ordinate and harmonise policies, discuss issues of mutual concern, and work together to respond to international problems. Most of the OECD's work is carried out by more than 200 specialised committees and working groups composed of member country delegates. Observers from several countries with special status at the OECD, and from interested international organisations, attend many of the OECD's workshops and other meetings. Committees and working groups are served by the OECD Secretariat, located in Paris, France, which is organised into directorates and divisions.

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FOREWORD

The Working Group on Harmonisation of Regulatory Oversight in Biotechnology (The Working Group) began drafting consensus documents in 1995. The first biology consensus documents (BCDs) were published in 1997 with others following steadily over subsequent years. The BCDs contain scientific information that is pertinent to the risk/safety assessment of transgenic organisms.

After more than 10 years of effort in the preparation of BCDs, the Working Group has gained a wealth of experience in drafting and publishing such documents. This is an opportune time, therefore, to review this experience and to prepare guidance on those areas in need of clarification and those practices that have been most useful.

The focus of this document is to provide guidance to all those involved in the preparation of BCDs to improve the efficiency and quality of their preparation. As such, it should be seen as a companion text to two previous publications prepared by the Working Group: (1) *An Introduction to the Biosafety Consensus Documents of OECD's Working Group for Harmonisation in Biotechnology (No. 32)*; and (2) *Points to Consider for Consensus Documents on the Biology of Cultivated (No. 35).*

The draft had been prepared by the delegations of the United States and Japan together with the Secretariat and reviewed by the Bureau. It was also considered at the 21st meeting of the Working Group (25-26 June 2008). This document is published on the responsibility of the Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology of the OECD.

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GUIDE FOR PREPARATION OF BIOLOGY CONSENSUS DOCUMENTS: LEAD COUNTRIES, AUTHORS, AND DELEGATIONS TO THE WORKING GROUP

I. Introduction: Background

1. Main outputs of OECD's Working Group on Harmonisation of Regulatory Oversight in Biotechnology (Working Group or WG) are its consensus documents, which provide scientific information which is used in the biosafety assessment of transgenic organisms (OECD, 2005, 2006c). They are published in an OECD General Distribution series, the Series on Harmonisation of Regulatory Oversight in Biotechnology (SHROB). All published documents are made available on the BioTrack website (http://www.oecd.org/biotrack/) on a routine basis. The majority of the documents published in the series, as well as those in preparation, are biology consensus documents (BCDs) that address vascular plant species of importance in agriculture or forestry (Table 1, and OECD, 2006c, 2008).

2. The drafting of the first BCDs began in 1995, and in 1997 the first consensus documents on the biology of species were published. As of June 2008, nineteen biology consensus documents on vascular plants are available in the series, including annual and perennial herbaceous agricultural crops (nine BCDs), fruit trees (two BCDs), and trees for timber or fibre (eight BCDs) (Table 1). These documents usually cover a single species, but in a few cases they focus on a single subspecies, a group of species or even an entire genus. The biological scope and content of each document is related to the agricultural or silvicultural crop taxa under consideration. Some of the world's most important crop species are already included in this series. BCDs on other major crop species are in preparation.

3. The visibility and usefulness of the OECD biology consensus documents has increased with time; they are now well known internationally and provide substantial credibility to OECD's Working Group. These documents are helpful to regulators and, in some cases, are used as a part of dossiers submitted to national regulatory agencies for approval. It is important for lead countries and individual authors as well as the WG as a whole to have an understanding of the process for drafting BCDs. This *Guide* is intended to increase efficiencies in the development of quality BCDs and streamline the process.

4. In July 2006, the OECD published a "for sale" compilation of the SHROB consensus documents in two volumes (821 pp.) with the title *Safety Assessment of Transgenic Organisms: OECD Consensus Documents* (see Figure 1). Volume 1 includes an "*Introduction*" to the biosafety consensus documents [ENV/JM/MONO(2005)5], "*Points to Consider*" for preparation of a BCD [ENV/JM/MONO(2006)1], and seventeen of the BCDs on vascular plants (all but the most recently published documents on several species of trees in the pine family, Pinaceae). In addition, it includes four consensus documents on certain fungi and micro-organisms. The compilation also includes four consensus documents that relate to introduced traits in transgenic crops.

5. The publication of this large compendium has given additional visibility to the successful decade of co-operative effort reflected in these many documents, and has brought them into additional use. OECD's Publications Service has reported that the initial print run of these volumes was exhausted. The Secretariat has distributed 324 copies of the two-volume set at international events, for example, at the Convention on Biological Diversity's Cartagena Protocol on Biosafety COP-MOP 3 (Curitiba, 2006). An additional 518 copies of the two-volume set have been purchased directly by others through OECD's Publications Service.

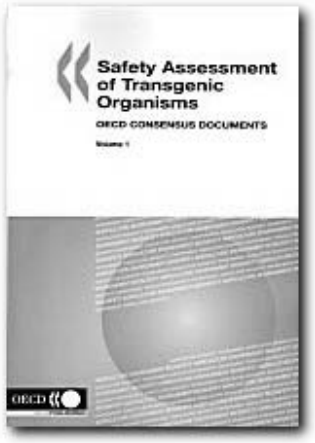

Figure 1. Two-volume compilation of SHROB consensus documents, 2006

II. Goal and Context

6. With respect to the preparation of BCDs by the Working Group, the goal of this *Guide* is to provide information which authoring countries can use to ensure an efficient process and a clear pathway for drafting which results in a timely synthesis of diverse materials useful for a broad global readership. Key principles in this range of guidance are to produce an objective summary through a collaborative process, using interdisciplinary scientific expertise and editorial expertise to manage the manuscript's initial preparation (scientific text as well as format, layout and editing) as well as revision of the draft (ideally just once) based on a review of the comments provided by other delegations to the WG.

7. In addition to providing the BCD product, the Working Group and authoring countries benefit from this co-operative integrating process. The WG's Bureau and all other WG members are responsible for providing general direction and thorough comments to specific drafts, primarily focused on the scientific aspects. The Secretariat is responsible for adding the standard OECD and WG text to a BCD as well as formatting and publishing the final text (see section IV). The lead country preparing a BCD provides the scientific expertise for drafting and revising the text, but is equally the main editorial centre for the manuscript. Within the lead country, the author(s) drafting a BCD work(s) closely with the country's BCD manager, who is responsible for coordinating both the scientific and the technical editorial functions.

III. Biology Consensus Document Initiation, Development and Working Group Review Process

8. Typically, a proposal for a new BCD is made by a delegation in a formal meeting of the Working Group. In making its decision on whether to accept such a proposal, the WG considers whether the proposed document is consistent with its terms of reference and its current programme of work. It also takes into account the global importance of the crop in agriculture or silviculture and existing information on that crop species. It additionally takes into account whether the WG can accommodate work on a new BCD within its current and planned workload, considering the future work needed by delegations to review and provide comments to the first and subsequent draft(s).

9. A BCD is prepared on a voluntary basis either by a lead country, or by two (or more) countries in collaboration. Modifications to this model are possible. For example, work is underway on a large BCD addressing *Brassica* species. In order to undertake focused work on this document, the WG formed a Steering Group (in 2005) which comprises a lead country and several additional interested countries.

10. The internal process of text preparation by the lead country varies considerably.

11. The initial draft of a BCD, which has been submitted by a lead country, is first reviewed by the Bureau of the Working Group. The role of the Bureau is to ensure that the document is of sufficient quality to merit comments from all delegations. The draft is then submitted to the WG online (internally) before a regular meeting, which takes place approximately every 8 months. (In the atypical case of the draft BCD on *Brassica* spp., a draft Table of Contents was submitted first.) Member countries sometimes provide no comments or few comments. Alternatively, they may provide extensive substantive scientific and editorial comments prior to a meeting of the WG, at a meeting, or soon after a meeting. During the WG review process, sometimes collaboration develops with another member country to revise the draft.

12. The comments that are received during the review are taken into account by the lead country or collaborating countries, and a revised draft is resubmitted for consideration at a subsequent meeting. Usually development of the text has taken some years. Sometimes a final draft is prepared after a WG meeting, taking the minimal last comments on the mature draft into account, and the final draft is made available to the WG online for a final consideration, after which it is accepted by the Bureau and moved forward by the Secretariat in the process of declassification without waiting for another WG meeting. An intended function of this *Guide* is to streamline this process.

13. The final text, approved by the Working Group, is forwarded to the oversight body of the WG, the OECD's Joint Meeting of the Chemical Committee and the Working Party on Chemicals, Pesticides and Biotechnology, which typically agrees to its declassification without further input. The final text is published in hard copy as a booklet (Figure 2), and electronically through the OECD Biosafety – BioTrack Online website (OECD, 2008), where the document is freely available to all interested parties to be viewed or downloaded and printed. Generally individual authors and institutions are not noted in the final published document but the lead country or collaborating (co-lead) countries that led the preparation of the BCD are always recognised.

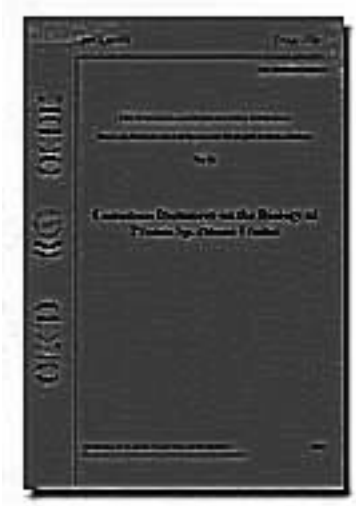

Figure 2. An OECD SHROB biology consensus document (BCD)

IV. The Role of the Secretariat: Managing Documents

14. The role of the Secretariat is important in general management of the text of a BCD as it evolves through various drafts. It is important, therefore, for all those involved in the preparation of documents to understand the tools that the Secretariat uses in its work. The tools and methods used to manage documents at OECD have evolved over the years.

15. When the WG began drafting its first consensus documents in 1995, the majority of delegates did not have access to e-mail, let alone the benefit of the Internet. Today, the methods used for drafting documents and providing input to such documents have been transformed; and most of the work is done electronically.

16. The most important tool overall is OECD's Online Information System (OLIS), which is the main mechanism by which OECD documents are disseminated to member countries and other stakeholders. All OECD "For Official Use" documents, that is, documents that are submitted for OECD meetings (including drafts of BCDs for review by the WG) must be submitted to OLIS. OLIS is not just a means by which delegates to specific meetings are able to access documents. OLIS is also used by Permanent Delegations of member countries to OECD who have the responsibility to monitor them and engage capitals as necessary. OLIS is also used by various parts of the OECD Secretariat (including senior line management) that need to monitor the use and distribution of such documents.

17. Consequently, all documents prepared for OLIS must be in a style and format that is accessible to all users. The use of OLIS also needs to take into account the possibility that certain documents will be published eventually. The documents need to be in a style and format in which they can be transmitted efficiently through the publication process. In addition, all "For Official Use" documents are deposited in the OECD archives, so use of OLIS must take into account the needs of the OECD archive service.

18. The Secretariat therefore needs to convert all official documents into OECD's "Authoring Environment" (AE) so that they can be transmitted via OLIS. AE is essentially an OECD-customised system of MS Word "macros" which control the style and format of OECD documents. Any formatting done by outside authors of BCDs, as well as any written comments included in official documents, need to be re-formatted by the Secretariat into OECD's AE. In other words, it is important for authors to follow the contents and headings that are consistent with BCDs (see section IX). But it is not essential for authors to spend time formatting documents with respect to paragraph numbering, and consistency of page numbers with headings in the table of contents, as these matters will be automatically adjusted by the macros.

19. Most of the delegates to the Working Group use the WG's password-protected website (known in OECD parlance as a committee website) to access documents. The documents posted on the password-protected website are derived from OLIS. In the past, the WG has also used an Electronic Discussion Group (EDG) where documents could be posted and comments made by delegations. However, the system of EDGs used at OECD is being retired and replaced in the near future.

20. OECD's Information Technology and Network Services (ITN) and OECD's Public Affairs and Communications Directorate (PAC) continue to improve the ways in which documents are managed. Currently, ITN and PAC are planning to launch a new system based on MS SharePoint (which will be available to the WG later in 2008). This system will allow OLIS documents (and others) to be made directly available to delegates. Amongst other things, it will allow delegates to post comments to each draft document in a structured way. In other words, this new system will integrate the features of the password-protected website and the EDG. It will be linked with OLIS.

21. An additional tool used by the OECD Secretariat is the *OECD Style Guide* (OECD, 2007b). This Guide is important for authors of BCDs to consult for a variety of reasons. It explains the general approach of OECD to its publications. It also offers drafting guidance on a wide range of issues including the use of language, vocabulary, addressing gender-sensitive issues, grammar, and acronyms.

22. The *OECD Style Guide* has been prepared to address the whole range of topics covered by the OECD. The BCDs however have a heavy scientific content, and so the *OECD Style Guide* is not to supersede the information given in this WG document on, for example, scientific nomenclature and scientific citations (sections VIII and IX). Rather, the *OECD Style Guide* should be seen as a useful complement.

V. Guidance for Lead Countries: Managing the Scientific Content

23. The person in the lead country responsible for a BCD (the manager of a document) must be familiar with the Working Group process of drafting, which is provided in this *Guide for Preparation of BCDs*. The WG's document *The Process for Drafting* (OECD, 2007a)) provides further information, giving a detailed background and discussion on the WG context and evolving BCD process (and is thus a part of the background to this *Guide*). Management by the lead country includes the following responsibilities:

a) The lead country should incorporate internal scientific and technical review (peer review) into its process before initial and subsequent drafts are submitted to the Bureau and Working Group. The actual authoring, or at minimum the review, should include persons with multidisciplinary expertise in botany (taxonomy and ecology), not solely experts in plant science, agriculture, horticulture or silviculture. Because these are international consensus documents, it is preferable to name only countries and not individuals or institutions as authors of the BCD.

b) The lead country should incorporate formatting and complete editing in BCD style (see below) into the process of text preparation before initial and revised drafts are submitted to the Working Group.

c) The lead country should complete the layout of the last draft prior to submission of this final text to the Working Group. Only essential, quite minimal formatting of the text (including checking table layout, legends, *etc*.) may be undertaken by the Secretariat, which will instead focus on adding the OECD and WG standard material (*e.g.* About the OECD, Preamble, Questionnaire) and the OLIS and AE needs (section IV).

d) In the case of a final draft, the Secretariat will prepare the documents for OLIS. It will submit the ready-to-publish document to the lead country, which gives a prompt final check and editorial approval, prior to the actual publication of the BCD.

VI. Further Points for Consideration in the Preparation of Biology Consensus Documents

1. Objectives and Approach

This section identifies some additional points to consider in the preparation of BCDs as follows:

a) Fully comprehensive inputs of information (structure and content) are done at the beginning;

b) Minimise lengthy repetition of cycles of the WG commenting and further drafting by lead country or co-lead countries, reducing time from initiation to publication, ideally to one cycle and 2 years, or perhaps two cycles and 3 years, from initiation of the project to the WG recommendation for declassification (*i.e.* OECD publication);

c) Avoid "ageing" of information during the drafting process;

d) A very intensive initial draft is prepared by the lead country before submission to the WG;

e) Intensive internal scientific and editorial reviews on structure, content and format of the initial draft and subsequent draft(s) are carried out by the lead country prior to submission to the WG;

f) Near the draft completion, if necessary, utilise a senior scientist, an expert scientific writer, and/or a technical editor; and

g) The WG, via comments on the draft(s), shares in responsibility with the authoring country.

2. Sources of Information for a BCD: Priorities

This section notes the main sources of information for a BCD in order of priority:

a) Peer-reviewed scientific articles;

b) Scientific books;

c) Official government and international agency publications;

d) Reports or proceedings of scientific meetings;

e) Websites only if there is no on-paper published source for the information; and

f) Personal communication only as a last resort, to address essential information.

3. Information Appropriate for a BCD, and the Manner of its Presentation

24. A BCD should include neutral baseline biological information, collected with an awareness of the context of risk/safety assessment. Value judgements should be avoided. The information is not intended to be encyclopaedic for a given crop species, nor for purely academic use. The focus is on the biology and ecology of the species, thus on information that may be useful for an evaluation of genetically engineered crop plants that might be released into the environment, typically, for commercial planting. Actual evaluations of transformed plants are done separately (typically on a "case-by-case" basis) by individual countries.

25. Information should be collected, integrated and synthesised from a variety of sources. Lengthy verbatim text (direct quotation) should be avoided. The material used should be documented carefully by citations. The references serve as documentation but can also be a resource and an entry point for users into the relevant literature.

4. Role of Lead Country, and Any Partnering (Directly Participating) Co-lead Countries

26. A single lead country is needed to ensure responsibility, quality and consistency, and efficiency. The lead country may collaborate with another country (co-lead) in drafting. More than two countries may become problematic. A Steering Group of interested countries may be formed for particularly complex BCDs, to assist the lead country prior to the initiation of drafting (or at a subsequent stage if needed).

5. Drafting

27. An intensive and lengthy drafting effort is undertaken by the lead country, over perhaps 6 months for the production of a quality initial draft. The lead country remains prepared to receive subsequent comments submitted by members of the WG, and is fair and flexible in considering and integrating them. The lead country (perhaps with a co-lead country) develops the final text and carries out scientific peer-review and technical editing approval of this final draft.

VII. Working Group Review

1. Draft review

28. All Working Group members should review each draft of a BCD submitted to the WG. Providing comments is a serious responsibility — more than (or minimally as much as) the scientific peer review of a journal manuscript. Timely and significant attention is to be given, with members' comments posted via the WG intranet system (internally online) to the lead country of observations and information important for revising the draft.

2. Points for Future Consideration in Preparation of BCD Manuscripts

29. The following two points are not established WG procedures, but might be considered as the BCD process evolves, either for advance of a particular BCD or more generally.

30. After the submission of a quality initial draft of the BCD for a WG meeting, the WG might consider decoupling subsequent draft submission to the WG from the 8-month cycle of WG meetings, so that completion could proceed at a quicker pace. WG commenting on revised or final drafts by established deadlines could proceed online internally at a WG's intranet BCD preparation site. At WG meetings, BCD projects would still be individually reported on, but the focus would shift to BCD efforts needing such a group discussion.

31. The WG's extensive information in this *Guide* and the other recent guidance documents, along with the many published BCDs resulting from a decade of experience, indicate that this decentralised scientific and editorial process can be a successful approach. The co-operative, integrative work within countries and between countries is itself an important result from this process. Even so, if circumstances warrant, the WG might find it helpful to utilise an expert scientific writer/editor (perhaps via a paid contract) for a selected BCD (or even most late-draft manuscripts), to ensure both formatting and copy-editing uniformity for SHROB publications and the overall scientific quality of the BCDs.

VIII. Guidance for Authors

32. To assist BCD authors in orientation and pragmatic matters for preparing the plant profile for SHROB, this section is provided. Two other WG documents address different aspects of the project.

33. The author of a BCD must become thoroughly familiar with the WG's *Points to Consider* document (OECD, 2006b, 2006c), which indicates biological and ecological topics of relevance, noting specific examples from various BCDs on particular annual or perennial crops and trees. The *Points to Consider* document gives the

primary scientific guidance for the project. The document also provides a potential outline for the BCD, but it is not to be regarded as a structurally rigid standard.

34. In addition, other (particularly recent) BCDs should be consulted as questions arise (Table 1) (OECD, 2006c, 2007a, 2008). The BCD on the *Capsicum annuum* complex (chilli peppers, hot peppers and sweet peppers) (OECD, 2006a) should be used as an exemplar for style matters. This *Guide* gives specific examples (from that BCD) on many matters of style that have varied in manuscripts and need to be standardized in preparing the BCD manuscript for SHROB. The WG guidance supplements and makes specific the general guidance given in the *OECD Style Guide* (2007b). If further style guidance is needed, the Council of Science Editors exhaustive manual (CSE, 2006) could be consulted. An axiom in the technical matters of style is to be internally consistent throughout the document.

35. The WG emphasises that the manuscript should undergo sufficient scientific peer review, and as well careful editorial screening, before the lead country submits it for WG comment, and for final approval (OECD, 2007a). The peer-review process covered extensively by Hames (2007) is more exhaustive than is necessary for SHROB, but those guidelines may stimulate an awareness of the authoring country (or co-lead countries) to enhance their internal procedures and improve the quality of the draft BCD.

36. BCD authors should be familiar with this entire *Guide for Preparation of BCDs*, to help focus their obligations in the process, and to clarify the role and responsibilities of the BCD manager, as well as those of the Working Group and the Secretariat.

IX. Style Standardization Specifics for BCDs

1. Layout, Spelling, Nomenclature

37. Headings throughout the text have a hierarchical structure, and have generally used Roman and Arabic numerals and letters, capitalisation and lowercase, and sometimes bolding or italicisation. This would follow the approach in the *Capsicum* BCD (OECD, 2006a), with suitable modifications as needed (see other recent BCDs). Alternatively, rather than using letters, a step-down sequential Arabic numbering system may be preferable to adopt within each main Section, for example:

- SECTION II. MAIN TOPIC
- 2.1. Topic
- 2.2. Next Topic
- 2.2.1. Subtopic
- 2.2.2. Next Subtopic
- 2.3. Next Topic
- SECTION III. MAIN TOPIC
- 3.1. Topic
- 3.2. Next Topic
- Etc.

38. If the BCD has Appendices, they precede the section on References.

39. OECD documents use British English spelling.

40. In general, do not give the authority, *i.e.* author(s), for the scientific name of a species or other taxon. However, for the featured species of the BCD, the authorities are provided usually once, often in a table (see Table 2 in the *Capsicum* BCD — OECD, 2006a). The author names are either written in full or abbreviated as provided online in the author database of the International Plant Names Index. Scientific names conform to the

rules in the current *International Code of Botanical Nomenclature* (which includes algae and fungi), *International Code of Nomenclature for Cultivated Plants*, *International Code of Zoological Nomenclature*, and *International Code of Nomenclature of Bacteria* (covering prokaryotes). Nomenclature of viruses follows one of the modern standards (such as the International Committee on Taxonomy of Viruses online database).

2. References (see Capsicum BCD — OECD, 2006a)

2.1. Citations in text

41. Cite references in chronological order with oldest first, for example: (Rylski, 1972; Aloni *et al.*, 1999; Walsh and Hoot, 2001; FAO, 2003).

42. Place a comma between the author(s) and year, for example: (Rylski, 1972; Aloni *et al.*, 1999).

43. Separate references by different authors with a semicolon, for example: (Rylski, 1972; IPGRI *et al*., 1995; Walsh and Hoot, 2001).

44. Separate multiple references by the same author(s) or same first authors with a comma, for example: (Prince *et al.*, 1992, 1995; Zewdie and Bosland, 2001, 2003; Zewdie *et al.*, 2004).

45. List authors in alphabetic order for any given year, for example: (Dabauza and Peña, 2001; Denevan, 2001; Huh *et al.*, 2001).

46. For two or more publications by the same author or first author in the same year, distinguish by lowercase letters with the year, for example: (Tanksley, 1984b; Hernández-Verdugo *et al*., 2001a). This distinction is determined by the alphabetical order of the titles in the References section (see example below on this page in subsection 2.2, for the citations of Brubaker *et al*., 1999a, 1999b); thus (Tanksley, 1984b) may be cited in the text before (Tanksley, 1984a).

47. In complex citations, maintain the basic principles above (chronological, alphabetical, and differentiating authors or first authors). In the following complex example, two different authors are named Smith, whereas the same Prince is first author for both publications with different co-authors: (Smith, 1980; Prince *et al.*, 1992, 1995; Zewdie and Bosland, 2000a, 2000b, 2003; Hernández-Verdugo *et al*., 2001b; Smith, 2001; Kim *et al*., 2002; Rao *et al.*, 2003; Zewdie *et al.*, 2004; Sung *et al.*, 2005).

2.2. Citations in References section

48. Citations are listed alphabetically by first author's surname and then initials, with a comma between his or her surname and initials, another comma, then initials followed by the surname for subsequent authors, and no comma after the "and" that precedes the final author, as in the following example:

Prince, J.P., V.K. Lackney, C. Angeles, J.R. Blauth and M.M. Kyle. 1995. A survey of DNA polymorphism within the genus *Capsicum* and the fingerprinting of pepper cultivars. *Genome* 38: 224-231.

49. For a first author who has several titles cited, the single-author titles are listed first, followed by those with two authors, and then the multi-author titles. These multi-author articles are listed in chronological order, not alphabetised instead based on the subsequent authors, as in the following example:

Brubaker, C.L., J.A. Koontz and J.F. Wendel. 1993. Bidirectional cytoplasmic and nuclear introgression in the New World cottons, *Gossypium barbadense* and *G. hirsutum* (Malvaceae). *American Journal of Botany* 80: 1203-1208.

Brubaker, C.L., A.H.D. Brown, J.M. Stewart, M.J. Kilby and J.P. Grace. 1999a. Production of fertile hybrid germplasm with diploid Australian *Gossypium* species for cotton improvement. *Euphytica* 108: 199-213.

Brubaker, C.L., F.M. Bourland and J.F. Wendel. 1999b. The origin and domestication of cotton. Pp. 3-31 in W.C. Smith and J.T. Cothren, eds., Cotton: Origin, History, Technology and Production. John Wiley & Sons, New York.

50. If the article has an unwieldy proliferation of numerous authors (*i.e.* more than about fifteen), cite only the first three authors, followed by *et al*., as in the following example:

Chen, Z.J., B.E. Scheffler, E. Dennis, *et. al*. 2007. Toward sequencing cotton (*Gossypium*) genomes. *Plant Physiology* 145: 1303-1310.

51. The name of the journal is not abbreviated, and is italicised. Only the volume number is given, unless each issue of the volume is separately paginated beginning with page 1. The volume number is not bolded. All pages in the article are given (not just the first page), as well as those in all or the pertinent part of the online supplementary material. The article's title is primarily in lowercase. Examples:

Berke, T.G. 2000. Hybrid seed production in *Capsicum*. *Journal of New Seeds* 1(3/4): 49-67.

Huang, J., S. Rozelle, C. Pray and Q. Wang. 2002. Plant biotechnology in China. *Science* 295: 674-677 + Supplement D (48 pp.).

52. Books, bulletins and other separate publications are referenced with capital letters for most words and without italicising the title, with no or minimal abbreviations, but using acronyms when necessary, and giving complete information including the total number of pages. Examples:

Bosland, P.W., and E.J. Votava. 2000. Peppers: Vegetable and Spice Capsicums. Crop Production Science in Horticulture 12. CAB International Publishing, Wallingford, England, UK. 204 pp.

FAO (Food and Agriculture Organization of the United Nations). 2003. FAO Production Yearbook 2001, Vol. 55, Statistics Series No. 170. FAO, Rome. 333 pp.

IPGRI, AVRDC and CATIE. 1995. Descriptors for Capsicum (*Capsicum* spp.). International Plant Genetic Resources Institute, Rome, Italy; Asian Vegetable Research and Development Center, Taipei, Taiwan; and Centro Agronómico Tropical de Investigación y Enseñanza, Turrialba, Costa Rica. 54 pp.

Mabberley, D.J. 1998. The Plant-Book: A Portable Dictionary of the Higher Plants, 2nd ed., rev. printing. Cambridge University Press, Cambridge, England, UK. 858 pp.

53. The title of the chapter in a book or the article in the proceedings of a scientific meeting or conference is given primarily in lowercase (as with a journal article). The chapter's designation (*e.g.* Chapter 6) is not part of the chapter's title, and so omitted. The pages are given following the chapter or article title, and the book or conference proceedings information is then given in full. Examples:

Greenleaf, W.H. 1986. Pepper breeding. Pp. 69-127 in M.J. Bassett, ed., Breeding Vegetable Crops. AVI Publishing Co., Westport, Connecticut, USA.

Hunziker, A.T. 1979. South American Solanaceae: A synoptic survey. Pp. 49-85 in J.G. Hawkes, R.N. Lester and A.D. Skelding, eds., The Biology and Taxonomy of the Solanaceae. Linnean Society Symposium Series No. 7. Academic Press, London and New York.

Montes Hernández, S., E. Heredia García and J.A. Aguirre Gómez. 2004. Fenología del cultivo del chile (*Capsicum annuum* L.). Pp. 43-48 in Primera Convención Mundial del Chile, 2004 / First World Pepper Convention, 2004. León y Celaya, Guanajuato, Mexico.

X. References Cited in This Guide for Preparation of Biology Consensus Documents

54. CSE. 2006. Scientific Style and Format: The CSE Manual for Authors, Editors, and Publishers, 7th ed. Council of Science Editors, Reston, Virginia and Rockefeller University Press, New York. 658 pp.

Hames, I. 2007. Peer Review and Manuscript Management in Scientific Journals: Guidelines for Good Practice. Association of Learned and Professional Society Publishers, Brighton, UK and Blackwell Publishing, Oxford, UK. 312 pp.

OECD. 2005. An Introduction to the Biosafety Consensus Documents of OECD's Working Group for Harmonisation in Biotechnology. OECD Series on Harmonisation of Regulatory Oversight in Biotechnology No. 32. ENV/JM/MONO(2005)5, OECD, Paris. 19 pp.

OECD. 2006a. Consensus Document on the Biology of the *Capsicum annuum* Complex (Chili Peppers, Hot Peppers and Sweet Peppers). OECD Series on Harmonisation of Regulatory Oversight in Biotechnology No. 36. ENV/JM/MONO(2006)2, OECD, Paris. 48 pp.

OECD. 2006b. Points to Consider for Consensus Documents on the Biology of Cultivated Plants. OECD Series on Harmonisation of Regulatory Oversight in Biotechnology No. 35. ENV/JM/MONO(2006)1, OECD, Paris. 24 pp.

OECD. 2006c. Safety Assessment of Transgenic Organisms: OECD Consensus Documents, Volumes 1 & 2. OECD, Paris. 821 pp.

OECD. 2007a. Consensus Documents on the Biology of Plants: The Process for Drafting. ENV/JM/BIO(2007)8. WG19, OECD WG-HROB, Paris. 9 pp.

OECD. 2007b. OECD Style Guide, 2nd ed. (v1.2). OECD, Paris. 105 pp.

OECD. 2008. Consensus Documents for the Work on Harmonisation of Regulatory Oversight in Biotechnology. Website, OECD Environment Directorate, OECD, Paris. http://www.oecd.org/document/51/0,3343,en_2649_34385_1889395_1_1_1_1,00.html

Table 1. OECD Series on Harmonisation of Regulatory Oversight in Biotechnology

Biology Consensus Documents: Vascular Plants

Family	Species, Subspecies, Group of Species, or Genus	Common Name	When Published (d/m/yr)	OECD SHROB No.	Country Lead(s)	Category
Asteraceae (Compositae)	*Helianthus annuus*	sunflower	21/01/2005	31	France	herbaceous crop
Betulaceae	*Betula pendula*	European white birch, silver birch	22/07/2003	28	Finland	tree
Brassicaceae (Cruciferae)	*Brassica napus*	oilseed rape, rapeseed, canola	15/05/1997	7	Canada	herb. crop
Caricaceae	*Carica papaya*	papaya	21/10/2005	33	USA	fruit tree
Chenopodiaceae	*Beta vulgaris*	sugar beet	5/12/2001	18	Switzerland	herb. crop
Fabaceae (Leguminosae)	*Glycine max*	soybean	13/11/2000	15	Canada	herb. crop
Malvaceae	*Gossypium* spp.	cotton	05/12/2008	45	Spain	herb. crop
Pinaceae	*Larix* spp. (pro parte: 3 spp.)	North American larches	16/05/2007	41	Canada	trees
	Picea abies	Norway spruce	1/06/1999	12	Norway	tree
	Picea glauca	white spruce	6/12/1999	13	Canada	tree
	Picea sitchensis	Sitka spruce	8/01/2002	21	Canada	tree
	Pinus banksiana	jack pine	6/09/2006	40	Canada	tree
	Pinus contorta	lodgepole pine	05/12/2008	44	Canada	tree
	Pinus monticola	western white pine	04/12/2008	38	Canada	tree
	Pinus strobus	eastern white pine	8/01/2002	22	Canada	tree
	Pseudotsuga menziesii	douglas-fir	28/11/2008	43	Canada	tree
Poaceae (Gramineae)	*Oryza sativa*	rice	6/12/1999	14	Japan	herb. crop
	Triticum aestivum	bread wheat	15/04/1999	9	Germany	herb. crop
	Zea mays subsp. *mays*	maize, corn	23/07/2003	27	Mexico	herb. crop
Rosaceae	*Prunus* spp. (pro parte: 7 spp.)	stone fruits	11/04/2002	24	Austria	fruit trees
Salicaceae	*Populus*	poplars	5/03/2001 (“2000”)	16	Canada	trees
Solanaceae	*Capsicum annuum* complex	chili peppers, hot peppers, sweet peppers	30/06/2006	36	Korea, Mexico, USA	herb. crop
	Solanum tuberosum subsp. *tuberosum*	potato	15/09/1997	8	The Netherlands, with UK	herb. crop
SHROB = OECD Series on Harmonisation of Regulatory Oversight in Biotechnology						