

Unclassified

ENV/JM/MONO(2006)1



Organisation de Coopération et de Développement Economiques
Organisation for Economic Co-operation and Development

30-Mar-2006

English - Or. English

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

ENV/JM/MONO(2006)1
Unclassified

Series on Harmonisation of Regulatory Oversight in Biotechnology No. 35

**POINTS TO CONSIDER FOR CONSENSUS DOCUMENTS ON THE BIOLOGY OF CULTIVATED
PLANTS**

JT03206674

Document complet disponible sur OLIS dans son format d'origine
Complete document available on OLIS in its original format

English - Or. English

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

- 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 Baculovirus* (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, *OECD Guidance for the Designation of a Unique Identifier for Transgenic Plants* (2002)
- No. 24, *Consensus Document on the Biology of Prunus sp. (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)

© OECD 2006

***Applications for permission to reproduce or translate all or part of this material should be made to:
Head of Publications Service, OECD, 2 rue André-Pascal, 75775 Paris Cedex 16, France.***

OECD Environment, Health and Safety Publications

Series on Harmonisation of Regulatory Oversight in Biotechnology

No. 35

**Points to Consider for
Consensus Documents on the Biology of Cultivated Plants**

Environment Directorate

Organisation for Economic Co-operation and Development

Paris 2006

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 Pacific, 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 subsidiary 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 subsidiary groups are served by the OECD Secretariat, located in Paris, France, which is organised into Directorates and Divisions.

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

This publication is available electronically, at no charge.

**For the complete text of this and many other Environment,
Health and Safety publications, consult the OECD's
World Wide Web site (<http://www.oecd.org/ehs/>)**

or contact:

**OECD Environment Directorate,
Environment, Health and Safety Division**

**2 rue André-Pascal
75775 Paris Cedex 16
France**

Fax: (33-1) 45 24 16 75

E-mail: ehscont@oecd.org

FOREWORD

The OECD's Working Group on Harmonisation of Regulatory Oversight in Biotechnology decided at its first session, in June 1995, to focus its work on the development of *consensus documents* which are mutually acceptable among Member countries. These consensus documents contain information for use during the regulatory assessment of a particular product. In the area of plant biosafety, consensus documents are being published on the biology of certain plant species, on selected traits that may be introduced into plant species, and on biosafety issues that may arise from certain general types of modifications made to crops.

This *Points to Consider* document is meant as a structured explanatory checklist, regarding both order and contents, of relevant points to consider in preparing or evaluating a consensus document on the biology of a cultivated vascular plant species. Authors of the draft of such a consensus document should be familiar with this document as well as existing consensus documents in order to develop the appropriate scoping and presentation of information and data and for general editorial style.

This document had its origins in the Washington Workshop on the Review of Consensus Documents and Future Work in Harmonisation (October 2003), and was prepared by the Extended Bureau to follow-up to the Workshop with contributions especially from the Netherlands and the United States. At the 17th meeting of the Working Group (24-26 October 2005), it was agreed that the document be forwarded to the Joint Meeting of OECD's Chemicals Committee and Working Party on Chemicals, Pesticides and Biotechnology, which agreed that this document be declassified.

TABLE OF CONTENTS

FOREWORD	5
INTRODUCTION	7
SECTION I. SPECIES OR TAXONOMIC GROUP	9
1.1. Classification and nomenclature	9
1.2. Description	10
1.3. Geographic distribution, natural and managed ecosystems and habitats, cultivation and management practices, and centres of origin and diversity	10
SECTION II. REPRODUCTIVE BIOLOGY	13
2.1. Generation time and duration under natural circumstances, and where grown or managed	13
2.2. Reproduction (production of flowers or cones, fruits, seeds, and vegetative propagules)	13
SECTION III. GENETICS	16
3.1. Relevant detailed genetic information on the species	16
SECTION IV. HYBRIDISATION AND INTROGRESSION	17
4.1. Natural facility of interspecific crossing (extent, sterility/fertility)	17
4.2. Experimental crosses	17
4.3. Information and data on introgression	17
SECTION V. GENERAL INTERACTIONS WITH OTHER ORGANISMS (ECOLOGY)	19
5.1. Interactions in natural ecosystems, and in agronomic, silvicultural or other ecosystems where the species is cultivated or managed	19
SECTION VI. HUMAN HEALTH AND BIOSAFETY	20
6.1. Plant characteristics relevant for human health	20
SECTION VII. ADDITIONAL INFORMATION	21
SECTION VIII. REFERENCES	22
APPENDIX 1 – COMMON PESTS AND PATHOGENS	23
APPENDIX 2 – BIOTECHNOLOGICAL DEVELOPMENTS	24

INTRODUCTION

1. Most environmental risk/safety assessments of transformed (genetically modified or engineered) plants are based upon a broad body of knowledge and experience with the untransformed species (variety, *etc.*), *i.e.* familiarity with the crop plant. The intent of the biology consensus document is to describe portions of this body of knowledge directly relevant to risk/safety assessment in a format readily accessible to regulators. The document is not an environmental risk/safety assessment of the species. Rather, the consensus document provides an overview of pertinent biological information on the untransformed species to help define the baseline and scope (the comparator against which transformed organisms will be compared), in the risk/safety assessment of the transformed organism. Consensus documents are not detailed crop handbooks or manuals of agricultural or silvicultural practice or economic botany, but rather focus on the biological information and data that may be clearly relevant to the assessment of newly transformed plants.

2. This *Points to Consider* document is meant as a structured explanatory checklist, regarding both order and contents, of relevant points to consider in preparing or evaluating a consensus document on the biology of a cultivated vascular plant species or other taxonomic group of interest, in relation to biotechnology and environmental risk/safety assessment. The general approach laid out in this document may also be pertinent to non-vascular plants (*e.g.* mosses), and fungi and micro-organisms; however, these groups are biologically and ecologically so different that further adaptation and refinement of the general approach will be necessary.

3. The biology consensus documents that have been published to date as well as most in preparation [excepting the documents on *Pleurotus* spp. (oyster mushrooms) and several on micro-organisms] are on annual crops, timber trees, and fruit trees. The plants of interest that have been the subject of the documents are primarily row crops, or trees managed silviculturally or grown in plantations or orchards. They are vascular plants, either flowering plants (angiosperms) or conifers (gymnosperms).

4. The points to consider as covered in the present document create a basic format and scope to be used for writing or reviewing new consensus documents and updating the earlier documents. While this *Points to Consider* document is meant to provide a basic format and scope, it is not intended to be rigid or inflexible. Of the biology consensus documents to date, some have addressed a particular point in depth, others lightly, and some not at all, depending on the relevance of the point to the plant species or other group of interest. Should additional points beyond those covered in this document be needed for a particular plant, the additional information can be included in the body of the consensus document, or in appendices. If a particular point is not covered in a consensus document, the text may briefly explain why the point, in the particular case, is not relevant.

5. Authors of the draft of a plant biology consensus document should be familiar with this *Points to Consider* document as well as existing consensus documents in the OECD Series on Harmonisation of Regulatory Oversight in Biotechnology (SHROB), in order to develop the appropriate scoping and presentation of information and data and for general editorial style. Existing consensus documents, particularly more recent ones, may provide detailed examples (some noted below) that are helpful models or thought-provoking for particular cases. Those interested in gaining perspective on coverage of pertinent topics such as these covered in these documents, have evolved and been fine-tuned for the varied cultivated plants in relation to environmental risk/safety assessment may consult especially *Analysis of Consensus*

Document's Section I: Analysis and Comparison of Consensus Documents [ENV/JM/BIO(2003)16]. This review was presented at the OECD Workshop on Review of Consensus Documents and Future Work in Harmonisation, held in Washington, D.C., USA in October 2003. This document on points to consider for consensus documents on the biology of cultivated plants results from a recommendation of that meeting.

6. An understanding of the biology of the species or other group of interest will aid in determining the kinds of information pertinent to the environmental risk/safety assessment. This *Points to Consider* document provides an explanation of why the point (as enumerated below) is important in risk/safety assessment of the transformed plant, and presents a rationale for how the information in the point relates to risk/safety assessment. For a particular environmental risk/safety assessment, biological or ecological information in addition to that presented in the consensus document may be needed to address the regional environments into which the genetically engineered plant is proposed to be released.

SECTION I. SPECIES OR TAXONOMIC GROUP

7. The focus of each biology consensus document has usually been a species, but in some cases the focus has been a group of species or a genus, or just a subspecies or a cultivar group (examples are below). The primary focus of this *Points to Consider* document also is the species of interest, so appropriate adjustments will be necessary if the focus of the consensus document is more broad or narrow.

1.1. Classification and nomenclature

8. Give the scientific name of the cultivated species of interest, with its authors, and pertinent synonyms (*i.e.* actively used alternative scientific names, if any). If necessary to delimit the plant, also give the horticultural name, *e.g.* the cultivar group (*e.g.* *Beta vulgaris* subsp. *vulgaris* Sugar Beet Group). Provide main international common name(s) at least in English for the species of interest. Give the taxonomic context of the species (family always, perhaps the order, and perhaps the subfamily, tribe, subgenus or section). If the taxonomy is not settled, be relatively conservative in choosing the taxonomy, and briefly explain the alternative(s). The latest taxonomic or nomenclatural study is not necessarily definitive, and may need time for scientific consensus before it becomes adopted. A common name for the crop species of interest can be introduced here, to be used in much of the document as a more familiar name (*aide-memoire*).

9. Describe the taxonomic relationships of the cultivated species: related species, and related genera particularly if there is good potential for spontaneous hybridisation or the generic limits are unsettled. A list of related species (with brief ranges) should be given and include all the relatives with a potential for hybridisation (*i.e.* crossable relatives). This topic is dealt with in detail in Section IV. The listing here may provide brief information on chromosome numbers and ploidy if these data are pertinent to the taxonomic differentiation of the species, whereas a more complete coverage of the relevant details is provided in Section III or IV.

10. **Rationale:** *The scientific name enables an unequivocal understanding (i.e. a circumscription) of the plant of interest, at the appropriate level, such as the species or the subspecies. This addresses what the species (or other group) is and what it is called (i.e. circumscription and name). The list of close relatives could help in subsequent analysis to form an idea of the kinds of pertinent traits such as disease resistance or stress tolerance that may already occur in these direct relatives of the cultivated plant, and may help elucidate how genes/traits are shared and may move via gene flow amongst related populations. The list of close relatives may aid in understanding the range of diversity and variability between the species and its naturally crossable relatives.*

11. **Examples:** OECD Series on Harmonisation of Regulatory Oversight in Biotechnology (SHROB) No. 14 (rice, Section II, pp. 12-14); No. 16 (poplars, Section II, pp. 15-18); No. 18 (sugar beet, Section I, pp. 11-12); No. 22 (eastern white pine, Section II, p. 12); and No. 31 (sunflower, Section I, pp. 11-13).

1.2. Description

12. Give a brief non-technical description of the species of interest, understandable to the non-specialist. Provide the habit and general characteristics of the plant, for example that it is an annual, a long-lived tree, or a biennial cultivated as an annual crop, and that it is, for instance, grown for fibre, fruit, or seeds. Also provide a concise technical (taxonomic) description sufficient to make a positive identification of the plant (or part). Illustration (a line drawing or black-and-white photo) may be useful. To clarify distinctiveness, emphasise the practical diagnostic or distinguishing morphological or other characters. Limit jargon, by the precise use of phrases and familiar words. A table of main differences or taxonomic key may be instructive (*e.g.* *Oryza sativa* and *O. glaberrima* in SHROB No. 14). If necessary, for example when based on recent information or a new approach, present or reference the analytical methods by which a differential identification of the similar plants (*e.g.* species) is now made.

13. **Rationale:** *These descriptions provide broad orientation, and as well accurate identification. They briefly explain how the species of interest is actually identified in relation to others. Additionally, the description may give particular characteristics of the plant to aid in defining the scope of a risk/safety assessment. Although an exact identification often is based on experience (i.e. recognition) or on regional publications, rigorous or subtle analysis using specialist resources sometimes is required.*

14. **Examples:** OECD SHROB No. 8 (potato, Section IV, pp. 14-15) and No. 28 (European white birch, Section I, pp. 12-13).

1.3. Geographic distribution, natural and managed ecosystems and habitats, cultivation and management practices, and centres of origin and diversity

15. This subsection covers the primary or crop species of interest, including the plants that are wild or free-living (whether native or naturalised) or weedy, and as cultivated or managed in the field. Crossable relatives with the relevant information and data on their intraspecific and interspecific crossing are discussed in Sections III and IV.

1.3.1. Geographic distribution

16. Describe the overall geographic distribution (if helpful including altitudinal range or climatic region), indicating broadly where the species of interest is native (*i.e.* indigenous), where it has been naturalised (introduced but free-living), and where it is in cultivation. A general map may be useful.

17. **Rationale:** *Knowledge of the geographic distribution sets the context for understanding the potential interaction of the species with its relatives and with the surrounding ecosystems. For example, it is important to make a distinction between the species' native and naturalised occurrence when assessing the potential effects and the importance of gene flow.*

18. **Examples:** OECD SHROB No. 8 (potato, Sections II & III, pp. 12-13); No. 13 (white spruce, Section III, pp. 15-16); and No. 16 (poplars, Section II, pp. 15-18).

1.3.2. Ecosystems and habitats where the species occurs natively, and where it has naturalised

19. Indicate the natural and non-cultivated or non-managed ecosystems where populations of the species of interest are native (indigenous) and where introduced and now naturalised (free-living) components of the vegetation. Designated natural areas (*e.g.* protected reserves, parks) where the species may be an invasive problem would be noted here. A species weedy in disturbed waste (*e.g.* abandoned) areas would be included here, whereas the species weedy in intensively managed areas would be discussed in the following subsection. Those ecosystems and habitats in which the species of interest occurs and its

abundance are indicated here, whereas its ecological interactions with biotic components of the ecosystems and habitats are developed in Section V.

20. **Rationale:** *The focus of this subsection is the relatively natural, self-sustaining context, rather than the land areas strongly managed for plant production. Knowledge of where the species occurs indigenously or is free-living provides baseline information for understanding the range of habitats in which the species exists, the range of behaviours exhibited in those habitats, and how characteristics of the species determine the range of habitats where it occurs. This information provides an understanding of the species' potential for interaction with its relatives and surrounding habitats.*

21. **Example:** OECD SHROB No. 28 (European white birch, Section III, pp. 19-20).

1.3.3. Agronomic, silvicultural, and other intensively managed ecosystems where the species is grown or occurs on its own, including management practices

22. Describe where the species is dependent on management for survival or persistence over several years of usual conditions. Areas where the plant may be a weed problem would be discussed here. Areas to be discussed could include habitats such as annual row crops or bordering areas, tree plantations, orchards and vineyards, along regularly managed roadsides, rights-of-way, irrigation ditches, etc. Identify the pertinent general agronomic or other practices, and if relevant, regional differences in practices (including various practices within a region). Information might briefly encompass site preparation after clear-cutting, tillage, sowing or planting, weed control, control of volunteers, harvesting, plant protection practices during crop growth and after harvest, transport practices, and the use of harvested materials (e.g. for silage). The relevant ecological interactions of the species with particular organisms in these managed ecosystems are discussed in Section V.

23. **Rationale:** *The focus of this subsection is on the plant's survival in agro-ecological, silvicultural, and other such managed areas, to provide the baseline environmental information on how the plant responds to or is managed by accepted agronomic, silvicultural or similar intensive practices. Identification of significant cultivation or management practices provides an understanding of measures available to manage or control the plant.*

24. **Examples:** OECD SHROB No. 7 (oilseed rape, Section III, p. 13); No. 14 (rice, Section VII, pp. 26-27); No. 15 (soybean, Sections II & V, pp. 13 & 14); and No. 18 (sugar beet, Sections I & II, pp. 16-17).

1.3.4. Centres of origin and diversity

25. Describe the known or probable primary centre(s) of origin, as well as secondary centres where additional important variability or biodiversity may occur, whether naturally (e.g. *Beta*) or through the process of domestication (e.g. *Zea mays*, *Solanum tuberosum* subsp. *tuberosum*). The evolutionary centres important for natural biodiversity should be mentioned, and the central areas of domestication and landrace diversity, with indication of the centres' relative importance. Genetic diversity is covered in Section III. Provide a brief sketch of the history or extent of domestication including mention of relevant domestication traits (e.g. non-shattering, loss of seed dormancy).

26. **Rationale:** *The interaction of the cultivated plant with close relatives especially in a centre of origin is an important consideration because gene flow, varietal competition, or a change in cultivation practices may alter this especially rich and valuable diversity. If the plant is not expected to be grown near a center of diversity, the absence of such relatives would also be important. A brief review of domestication may provide insight showing the continuity of modification of the species and the degree of the crop plant's adaptation to or dependence on the managed environment.*

27. **Examples:** OECD SHROB No. 9 (bread wheat, Section III, pp. 13-16); No. 27 (maize, Section IV, pp. 18-20); and No. 31 (sunflower, Section I, pp. 14-15).

SECTION II. REPRODUCTIVE BIOLOGY

2.1. Generation time and duration under natural circumstances, and where grown or managed

28. Important aspects of generation time and duration include the time to first flowering and total life cycle of the plant, and time from planting to plow-down. Include the effects of agronomic, silvicultural, and similar practices when describing generation time and duration of the cultivated plant. Important differences within both the natural and the cultivated regions should be noted.

29. **Rationale:** *The generation time and duration are indications of the terms in which environmental effects may occur. Precocious generation times and shorter durations in agriculture affect the likelihood of outcrossing with free-living (wild) relatives, and give a general indication of when outcrossing may first occur.*

30. **Examples:** OECD SHROB No. 14 (rice, Sections V & VII, pp. 21 & 26-27) and No. 18 (sugar beet, Section I, pp. 13-14).

2.2. Reproduction (production of flowers or cones, fruits, seeds, and vegetative propagules)

31. Include a characterisation of the key stages in the life cycle necessary for the plant to survive, reproduce, and disperse. Particular attention is given to any uncommon survival structures or strategies and their importance under natural and cultivation conditions, and to the dependence of survival and reproduction on ecological and geographical factors.

32. **Rationale:** The reproductive capabilities of a plant determine the means by which the plant can produce progeny and spread or disperse. Both the plant and its progeny may affect the environment, including other organisms, and thus the time frame and geographic area over which effects might occur.

2.2.1. Floral biology

33. Describe the general floral dynamics (*e.g.* flowering season, flowering time, anthesis, selfing and/or outcrossing). Relevant genetic details of the outcrossing and/or selfing are addressed in Section III.

34. **Rationale:** *This information will assist in understanding some of the factors that affect the potential for gene flow, and in assessing particular management strategies for reducing gene flow when outcrossing may occur. Such management strategies may include induced male sterility or asynchronous flowering times.*

35. **Examples:** OECD SHROB No. 8 (potato, Section VI, p. 17); No. 14 (rice, Section V, p. 21); and No. 21 (Sitka spruce, Section III, p. 15).

2.2.2. Pollination (wind, insects, both, etc.), pollen dispersal, pollen viability

36. Describe observed modes of pollen dispersal, indicating the most prevalent way. Important insect or other animal pollinators should be indicated. Give data on the range of pollen dispersal through the air and/or by the animal vectors, if known. Note how climatic or regional (*e.g.* geographic) differences can affect pollination. Provide available information or data on the influence of pollen quantity, movement, viability, load and competition on outcrossing, which is discussed in Sections III and IV. The details on pollination as they pertain to the plant are covered here, whereas details particularly pertinent to the pollinator are covered in Section V.

37. **Rationale:** *Pollen biology is an important component in the assessment of potential for gene flow, and in the evaluation of a need for and the type(s) of pollen confinement strategies such as buffer rows or isolation distances.*

38. **Examples:** OECD SHROB No. 8 (potato, Section VI, p. 17) and No. 18 (sugar beet, Section IV, pp. 22-23).

2.2.3. Seed production, and natural dispersal of fruits, cones, and/or seeds

39. Briefly describe the sexual reproductive structures, including relevant morphological characteristics of fruits (or cones) and seeds, and note any inherent means of dispersal (*e.g.* shattering, fruit splitting, ballistic). Note the quantity of seeds produced by a plant (*e.g.* seeds per fruit and number of fruits). Provide information on the means and range of dispersal (*e.g.* by gravity, wind, water, on and/or in animals), and if there are several means indicate their relative importance. Cover apomixis below, in Subsection 2.2.5.

40. **Rationale:** *The number of seeds and seed/fruit dispersal mechanisms is a factor to consider in understanding the potential for establishment of free-living plants or populations, and thus the time and geographic area over which environmental effects might occur. The range of variability of these factors is also an important consideration.*

41. **Examples:** OECD SHROB No. 15 (soybean, Section IV, p. 14) and No. 28 (European white birch, Section IV, p. 23).

2.2.4. Seed viability, longevity and dormancy, natural seed bank; germination, and seedling viability and establishment

42. Discuss factors in the establishment of any seed bank, including its transience or persistence, and the viability, longevity and dormancy of seeds under natural conditions. Note any special conditions that affect dormancy and/or germination (*e.g.* depth of burial, light and/or temperature, passage through an animal's digestive tract, or need for fire) that might be particularly relevant. Note any special requirements for the establishment and survival of seedlings (*e.g.* soil qualities or regime), as the organism's fitness may be revealed at this challenging phase in the life cycle.

43. **Rationale:** *Seed viability is a key factor to consider in assessing the likelihood of survival of non-cultivated plants. Natural seed banks are often the main source of weeds in cultivated fields, whether they are previous-crop volunteers or non-crop weedy relatives. Whether seedlings can establish usually is a primary limiting factor in continuing the life cycle.*

44. **Example:** OECD SHROB No. 7 (oilseed rape, Section VI, p. 17).

2.2.5. Asexual propagation (apomixis, vegetative reproduction)

45. Take into account natural vegetative cloning (*e.g.* in grasses and poplars), the kinds of propagules (special structures, and/or fragmented plant pieces), dispersal of the propagules, and their viability. Discuss the relative importance of asexual reproduction for the plant, including any differences dependent on habitat or region. For apomixis (non-sexual production of seeds), similarly consider its relative importance and effectiveness.

46. **Rationale:** *If a plant has a strategy that includes asexual propagation, this could be a means for considerable or quite different dispersal or spread, and consequently may also affect the time frame and geographic area over which environmental effects might occur.*

47. **Example:** OECD SHROB No. 16 (poplars, Section IV, p. 23).

SECTION III. GENETICS

3.1. Relevant detailed genetic information on the species

48. Give a basic overview of the relevant genetic constitution and genetic dynamics of the species. If more appropriate in a particular case, some basic genetic information (*e.g.* ploidy, ancestral/progenitor genomes) may be more fully or instead discussed in Section IV. In this Section III (including subsections as needed), cover for example and if appropriate cytogenetics (*e.g.* karyology, meiotic behavior), nuclear genome size, possible extent of repetitive or non-coding DNA sequences, main genetic diversity or variability (*e.g.* among or within populations or varieties, and of alleles at a locus), evidence of heterosis or inbreeding depression, maternal and/or paternal inheritance of organellar genomes, and methods of classical breeding (*e.g.* utility from employing mutagenesis with the species). The relevance of the information to the species' variability and the potential effects of transformation are paramount in deciding what to include, as the focus is not to provide this genetic characterisation for plant development.

49. Intraspecific crossing with both non-cultivated strains (*e.g.* weedy races) and among non-transformed cultivars is appropriately covered here (perhaps with a table or diagram), including any genetic or cytoplasmic constraints or limitations to crossing (*e.g.* cytoplasmic or nuclear sterility, incompatibility systems). Interspecific crosses are addressed in the following section.

50. **Rationale:** *The information in this section includes genetic and breeding data, such as details of genomic or genetic stability (including gene silencing) and intraspecific outcrossing behaviour and potential, only to the extent that such information describes parameters that influence how genetic material (including new material) behaves in particular genetic backgrounds, and in outcrossing. Interspecific hybridisation is in a separate section (which follows) because intraspecific crossing is more likely (and familiar), and interspecific hybrids may bring in broader or more extensive concerns.*

51. **Examples:** OECD SHROB No. 9 (bread wheat, Sections III & V, pp. 13-17 & 20-24); No. 12 (Norway spruce, Section VI, pp. 21-23); No. 13 (white spruce, Section V, pp. 22-24); No. 14 (rice, Section VI, pp. 23-25); No. 24 (*Prunus* spp. – stone fruits, Section II, pp. 15-20); and No. 31 (sunflower, Section IV, pp. 27-28).

SECTION IV. HYBRIDISATION AND INTROGRESSION

4.1. Natural facility of interspecific crossing (extent, sterility/fertility)

52. Describe interspecific (including intergeneric) crosses observed under natural conditions. Provide a list and perhaps a diagram of the documented hybrids, *i.e.* the crossings that may occur unaided under usual environmental conditions — if the crossable relatives (other species) might be present. The information could include a discussion of ploidy (and ancestral/progenitor genomes). Provide an indication or review of the likelihood of first-generation (F_1) hybrids and later generations of these F_1 hybrids, and as well whether the F_1 hybrids may be bridges for genes to cross into other (non-parental) species. Rare plant species are considered here and in the following subsection. Indicate naturally hybridising species that are weedy (including invasive) in the list of hybridising species (detailed discussion of their weediness in a local environment would be covered in an environmental risk/safety assessment).

53. **Rationale:** *The ability of a cultivated species to hybridise with other cultivated or wild species is a significant factor in determining whether genes or traits could be transferred to other species.*

54. **Examples:** OECD SHROB No. 7 (oilseed rape, Section VII, pp. 18-21); No. 9 (bread wheat, Section V, pp. 20-24); and No. 16 (poplars, Sections III & VI, pp. 20 & 28-29).

4.2. Experimental crosses

55. Discuss the experimental data available on outcrossing under controlled conditions, and theoretical possibilities for and barriers to outcrossing. This information is in contrast to that in the previous subsection, which indicates the outcrossing to readily crossable relatives. Experimental data that is the result of forced crosses employing special techniques (*e.g.* embryo rescue) would be relevant only if such studies help to clarify degree of relatedness and likelihood of natural crossing. Theoretical considerations or experimental information might be, for example, on cytogenetic data and meiotic behaviour, or sexual incompatibility systems.

56. **Rationale:** *Experimental data and theoretical considerations may broaden the understanding of potential (or as yet unknown) unaided (natural) gene transfer. The information and data are only relevant if unaided crossing in the field can occur.*

57. **Examples:** OECD SHROB No. 8 (potato, Section VII, pp. 19-21); No. 13 (white spruce, Section VI, pp. 25-26); No. 16 (poplars, Section VI, pp. 28-29); and No. 22 (eastern white pine, Section IV, p. 17).

4.3. Information and data on introgression

58. Provide an indication or review of the likelihood of F_1 hybrids backcrossing into one or both parents. Provide information on both natural and experimental introgression (extensive backcrossing), and on the (types of) genes or the traits for which introgression has been demonstrated. For example, extensive backcrossing and introgression may be only in one direction, rather than into both parental lines or species'

populations. Information should include the extent of likely natural (*i.e.* unaided) introgression or generations of experimental backcrossing, and the fertility and fecundity of the resultant plants.

59. **Rationale:** *Of primary consideration is whether interspecific crossing will lead to the introgression of genes. Interspecific crossing is a necessary but typically not a sufficient step for considerable introgression to occur. Even if introgression occurs, it is not the presence but the expression of the gene or trait that may be of primary importance.*

60. **Examples:** OECD SHROB No. 7 (oilseed rape, Section VII, pp. 20-21); No. 24 (*Prunus* spp. – stone fruits, Section II, p. 30); and No. 31 (sunflower, Section IV, pp. 28-29).

SECTION V. GENERAL INTERACTIONS WITH OTHER ORGANISMS (ECOLOGY)

5.1. Interactions in natural ecosystems, and in agronomic, silvicultural or other ecosystems where the species is cultivated or managed

61. Provide a general overview (including subsections as needed) of main functional ecological interactions of the species of interest within these natural and managed ecosystems and habitats, for example symbiotic relationships, food webs (*e.g.* fruit and seed consumers or predators), noxious/toxic or other important interactions with insects (*e.g.* chemical defense) and other animals, and with plants (*e.g.* allelopathy). Tritrophic interactions may also be considered. Subsections 1.3.2 and 1.3.3 list and briefly characterise the natural (unmanaged) and managed ecosystems and habitats in which the species of interest occurs. The importance of a pollination system to the animal pollinator is detailed here, whereas the importance to the plant is addressed in Subsection 2.2.2. A listing of pertinent pests and pathogens (and diseases) may be presented as an appendix, with only those that are critically relevant discussed here.

62. **Rationale:** *The description of the basic general ecology of the species of interest is useful when determining the scope of interactions that may be used as a baseline for understanding the influences the cultivated plant may have on organisms that are in usual close contact. A general understanding of the interactions of the species with other organisms will aid in determining whether any concerns may arise with a change in the genetics of the species.*

63. **Examples:** OECD SHROB No. 7 (oilseed rape, Section VII & Appendix, pp. 21 & 29) and No. 13 (white spruce, Section VII, pp. 28-31).

SECTION VI. HUMAN HEALTH AND BIOSAFETY

6.1. Plant characteristics relevant for human health

64. Provide brief information on major natural toxicants and common allergenic or medicinal properties of the plant. In some cases, it may be relevant to mention similar information from related species (e.g. glycoalkaloids in crossable wild relatives of *Solanum tuberosum* subsp. *tuberosum*, potato).

65. **Rationale:** *This theme can be regarded as human ecology, a subset of Section V that warrants coverage separately. Baseline information is briefly described, relating to human health as it might be affected by cultivation of the plant (e.g. levels of latex or psoralen). Potential effects on human health would be thoroughly treated elsewhere, such as in an OECD plant compositional consensus document for dietary issues.*

66. **Example:** OECD SHROB No. 8 (potato, Section IV, p. 14).

SECTION VII. ADDITIONAL INFORMATION

67. The possibility is expressly left open for topics of additional information that is pertinent to environmental risk/safety assessment, as a section in the main text of the document, and/or as appendices.

SECTION VIII. REFERENCES

68. As much as possible, the references should be peer-reviewed literature available internationally. After the references directly cited in the text, this section could include a subsection on additional useful references 'for further reading'.
69. **Example:** OECD SHROB No. 7 (oilseed rape, Section IX, pp. 27-28).

APPENDIX 1 – COMMON PESTS AND PATHOGENS

70. Provide a list of causative organisms for diseases (pathogens) and pests that commonly occur in the crop under agronomic, silvicultural, or equivalent conditions.

71. **Rationale:** *Provide as considered useful for risk/safety assessment rather than usual production management. Critically important organisms and ecological relationships (e.g. a virus disease that is a principal management issue) are covered in Section V. The risk/safety assessment would then consider whether the transformation in the crop would be of environmental concern.*

72. **Examples:** OECD SHROB No. 18 (sugar beet, Appendix, pp. 32-37 and No. 31 (sunflower, Section V & Appendices 1 & 2, pp. 31 & 37-47).

APPENDIX 2 – BIOTECHNOLOGICAL DEVELOPMENTS

73. General information on the kinds of traits being introduced into the species may be included. Provide information directly necessary for defining the scope or detail of biological information that would be useful. For example, transgenes under experimental development for a crop might result in a change in environmental fitness or range and habitats of the plant or its relatives (*e.g.* disease resistance, and drought, frost or salinity tolerance). Other biotechnological developments (*e.g.* to assist in marketing) may not be pertinent to address here.

74. **Rationale:** *An overview of biotechnological developments may help to assure that the biological information included in a consensus document is pertinent to the environmental risk/safety assessments anticipated. Consensus documents that include the biotechnological developments to bring traits into the crop can be quite useful in explaining the relevance of assessing certain kinds of biosafety information.*

75. **Examples:** OECD SHROB No. 14 (rice, Appendix III, pp. 42-45) and No. 27 (maize, Appendix A, pp. 39-41).