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Revised points to consider on plant biology consensus documents

This chapter deals with the revised “points to consider on consensus documents on the biology of cultivated plants”, an update of the original 2006 publication. It provides a structured explanatory checklist, regarding both order and contents, of relevant points to consider when preparing or evaluating a consensus document on the biology of a cultivated vascular plant species or other taxonomic groups of interest, in relation to biotechnology and environmental risk/safety assessment. Existing consensus documents are mentioned as illustrative examples for each considered point.

Introduction

This chapter was prepared by the OECD Working Party on the Harmonisation of Regulatory Oversight in Biotechnology, with the **United States** as the lead country. It was initially issued in 2020 as the Revised Points to Consider on Consensus Documents on the Biology of Cultivated Plants, replacing the original document issued in 2006. It was completed in this publication with few examples of references to consensus documents published in 2020 and 2021.

Page numbers quoted in the examples provided throughout the chapter refer to the original consensus documents that can be consulted on the OECD BioTrack website: [Consensus Documents for the Work on Harmonisation of Regulatory Oversight in Biotechnology: By number - OECD](#).

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 biology consensus document intends 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.

This *Points to Consider* chapter 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 groups of interest, in relation to biotechnology and environmental risk/safety assessment. The general approach laid out here may also be pertinent to non-vascular plants (e.g. mosses), fungi, animals and micro-organisms; however, these groups are biologically and ecologically so different that further adaptation and refinement of the general approach will be necessary.

The biology consensus documents that have been published to date as well as most in preparation (excepting those on the oyster mushroom, Atlantic salmon, mosquito species and 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).

The points to consider as covered in the present chapter create a basic format and scope to be used for writing or reviewing new consensus documents and updating the earlier documents. While this chapter 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.

Authors of the draft of a plant biology consensus document should be familiar with this *Points to Consider* chapter 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,¹ particularly more recent ones, may provide detailed examples (some noted below) that are helpful models or thought-provoking for particular cases. Authors of plant biology consensus documents should also be familiar with

any corresponding food/feed composition consensus document developed by the OECD Working Party for the Safety of Novel Foods and Feeds to ensure consistency and avoid any unnecessary duplication ([Consensus documents: work on the safety of novel foods and feeds: Plants - OECD](#)).

Those interested in information on the evolution of how pertinent topics are covered in OECD biology consensus documents may specifically consult the “Analysis and Comparison of Consensus Documents” presented as background paper at the OECD Workshop on Review of Consensus Documents and Future Work in Harmonisation, held in Washington, DC, United States in 2003. This chapter on “Points to consider for consensus documents on the biology of cultivated plants” results from a recommendation of that meeting. It was originally declassified in 2006 and subsequently updated in 2020.

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* chapter 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. General description including taxonomy and morphology

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* chapter is also the species of interest, so appropriate adjustments will be necessary if the focus of the consensus document is broader or narrower.

Classification and nomenclature

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 (the family always, perhaps the order and possibly 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 is 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).

Describe the taxonomic relationships of the cultivated species: related species and related genera, particularly if there is a high likelihood for spontaneous hybridisation or the generic limits are unsettled. A list of related species (with brief geographic ranges) should be given and include all relatives with a potential for hybridisation (i.e. cross-compatible relatives). This topic is dealt with in detail in Section V. 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 Sections IV and V.

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 another 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 move via gene flow amongst related populations. The list of close relatives aids in understanding the range of diversity and variability in the gene pool.

Examples: OECD Series on Harmonisation of Regulatory Oversight in Biotechnology (SHROB) No. 16 (poplars, Section II, p. 15-18); No. 45 (cotton, Section II, p. 14-15); No. 56 (sugarcane, Section II, p. 17-18); No. 58 (*Eucalyptus*, Section I, pp. 12-14); No. 62 (sorghum, Section I, p. 11-13), and No. 70 (rice, Section I, p. 11-14).

Description

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). An illustration (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, with precise sentences and familiar words. A table of main differences or taxonomic key may be instructive (e.g. Table 1 in SHROB No. 62 on sorghum). If necessary, when based on recent information or a new approach for example, present or reference the analytical methods by which a differential identification of the similar plants (e.g. species) is now made.

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 is often based on experience (i.e. recognition) or regional publications, rigorous or subtle analysis using specialist resources is sometimes required.*

Examples: OECD SHROB No. 8 (potato, Section IV, p. 14-15); No. 28 (European white birch, Section I, p. 12-13); No. 45 (cotton, Section I, pp.11-13); No. 54 (*Brassica* crops, Section I, pp.19-31); and No. 62 (sorghum, Section I, pp.13-16).

Section II. Centres of origin, geographical distribution and agronomic practices

This section covers the primary or crop species of interest, including 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 IV and V.

Centres of origin and diversity

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 as well as the central areas of domestication and landrace diversity, with an indication of the centres' relative importance. Genetic diversity is covered in Section IV. 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).

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 centre 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.

Examples: OECD SHROB No. 9 (bread wheat, Section III, p. 13-16); No. 27 (maize, Section IV, p. 18-20); No. 31 (sunflower, Section I, p. 14-15); No. 58 (*Eucalyptus*, Section II, pp.15-16); and No. 63 (tomato, Section I, pp.14).

Geographic distribution

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

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.*

Examples: OECD SHROB No. 13 (white spruce, Section III, p. 15-16); No. 16 (poplars, Section II, p. 15-18); No. 54 (*Brassica* crops, Section I, pp.32-34); No. 57 (cassava, Section II, pp.15); and No. 60 (cowpea, Section I, pp.15-18).

Ecosystems and habitats where the species occurs natively and where it has naturalised

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 weedy species in disturbed waste (e.g. abandoned) areas would be included here, whereas the weedy species 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 VI.

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.*

Examples: OECD SHROB No. 28 (European white birch, Section III, p. 19-20); No. 49 (black spruce, Section VII, pp.30-31); No. 54 (*Brassica* crops, Section I, pp.34-37); No. 57 (cassava, Section II, pp.16); and No. 60 (cowpea, Section I, pp.18).

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

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 VI.

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.*

Examples: OECD SHROB No. 15 (soybean, Sections II and V, p. 13 and 14); No. 18 (sugar beet, Sections I and II, p. 16-17); No. 49 (black spruce, Section III, p. 34-38); No. 59 (common bean, Section I, p. 14-16); and No. 66 (apple, Section I, p. 16-18); and No. 70 (rice, Section II, p. 21-23).

Section III. Reproductive biology

Generation time and duration under natural circumstances and where grown or managed

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 natural and cultivated regions should be noted.

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.*

Examples: OECD SHROB No. 18 (sugar beet, Section I, p. 13-14); No. 57 (cassava, Section III, pp. 21); No. 60 (cowpea, Section III, p. 21); No. 62 (sorghum, Section II, pp. 21-22); and No. 66 (apple, Section II, p. 19).

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

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 the dependence of survival and reproduction on ecological and geographical factors.

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.*

Reproductive structure

In the case of angiosperms: Describe the general floral dynamics (e.g. flowering season, flowering time, anthesis, selfing and/or outcrossing, diagram and formula floral). Relevant genetic details of the outcrossing and/or selfing are addressed in Section IV.

In the case of gymnosperms: Describe the female (megasporeangium) and male (microsporangia) structure.

In both cases (angiosperms and gymnosperms), indicate if the plant is monoecious or dioecious.

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.*

Examples: OECD SHROB No. 8 (potato, Section VI, p. 17); No. 21 (Sitka spruce, Section III, p. 15); No. 49 (black spruce, Section III, p. 15); No. 53 (*Cucurbita*, Section V, p. 30-31); and No. 59 (common bean, Section II, p. 18).

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

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 IV and V. Details on pollination as they pertain to the plant are covered here, whereas details particularly pertinent to the pollinator are covered in Section VI.

Rationale: *Pollen biology is an important component in the assessment of the 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.*

Examples: OECD SHROB No. 8 (potato, Section VI, p. 17); No. 18 (sugar beet, Section IV, p. 22-23); No. 54 (*Brassica* crops, Section II, p. 59-61); No. 62 (sorghum, Section II, p. 22-23); and No. 63 (tomato, Section II, p. 21-22).

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

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 number 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 "Asexual propagation (apomixis, vegetative reproduction)".

Rationale: *The number of seeds and seed/fruit dispersal mechanisms is a factor to consider in understanding the potential for the 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.*

Examples: OECD SHROB No. 15 (soybean, Section IV, p. 14); No. 28 (European white birch, Section IV, p. 23); No. 53 (*Cucurbita*, Section V, p. 31-33); No. 54 (*Brassica* crops, Section II, p. 65-69); and No. 63 (banana, Section V, p. 34).

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

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.

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 is usually a primary limiting factor in continuing the life cycle.*

Examples: OECD SHROB No. 45 (cotton, Section IV, p. 26-27); No. 54 (*Brassica* crops, Section II, p. 70-72); No. 56 (sugarcane, Sections V and IX, p. 39-40 and 57-58); No. 58 (*Eucalyptus*, Sections IV and VII, p. 32-33 and 47-50); and No. 62 (sorghum, Section II, pp. 23-24).

Asexual propagation (apomixis, vegetative reproduction)

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.

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.*

Examples: OECD SHROB No. 16 (poplars, Section IV, p. 23); No. 49 (black spruce, Section III, pp.16-17); No. 53 (*Cucurbita*: Section V, p. 35); No. 56 (sugarcane, Section V, pp.37 and 40-41); and No. 57 (cassava, Section III, pp.24).

Section IV. Genetics

Relevant detailed genetic information on the species

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 otherwise discussed in Section V. In this Section IV (including subsections as needed), cover for example and if appropriate cytogenetics (e.g. karyology, meiotic behaviour), 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.

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.

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 detailed in a separate section (which follows) as intraspecific crossing is more likely (and familiar) and interspecific hybrids may bring in more extensive concerns.*

Examples: OECD SHROB No. 9 (bread wheat, Sections III and V, p. 13-17 and 2023); No. 12 (Norway spruce, Section VI, p. 21-23); No. 45 (cotton, Section V, p. 28-29); No. 54 (*Brassica* crops, Section III, p. 73-78); No. 66 (apple, Section III, p. 26-28); and No. 68 (safflower, Section III, p. 27-35).

Section V. Hybridisation and introgression

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

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 crossable relatives (other species) may 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 F_1 hybrids are potential 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).

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.*

Examples: OECD SHROB No. 9 (bread wheat, Section V, p. 20-23); No. 16 (poplars, Sections III and VI, p. 20 and 28-29); No. 54 (*Brassica* crops, Section II, p. 61-65); No. 56 (sugarcane, Section X, pp. 59-61); and No. 58 (*Eucalyptus*, Section IX and Appendix, pp. 53-55 and 58-61).

Experimental crosses

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 are the result of forced crosses employing special techniques (e.g. embryo rescue) would be relevant only if such studies help to clarify the 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.

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.*

Examples: OECD SHROB No. 8 (potato, Section VII, p. 19-21); No. 16 (poplars, Section VI, p. 28-29); No. 22 (eastern white pine, Section IV, p. 17); No. 59 (common bean, Section IV, p. 21); and No. 63 (tomato, Section IV, p. 27-29).

Information and data on introgression

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.

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.*

Examples: OECD SHROB No. 24 (*Prunus* sp. – stone fruits, Section II, p. 30); No. 53 (*Cucurbita*, Section VII, p. 41-43); No. 60 (cowpea, Section IV, p. 26); No. 62 (sorghum, Section III, p. 28-29); and No. 66 (apple, Section IV, p. 30).

Section VI. General interactions with other organisms (ecology)

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

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 (subsections “Ecosystems and habitats where the species occurs natively and where it has naturalised” and “Agronomic, silvicultural and other intensively managed ecosystems where the species is grown or occurs on its own, including management practices” list and briefly characterise the natural (unmanaged) and managed ecosystems and habitats in which the species of interest occurs). Topics addressed in Section VI could include, for example, symbiotic relationships (e.g. rhizobial and mycorrhizal symbioses, plant-pollinator interactions), food webs (e.g. fruit and seed consumers or predators), noxious/toxic or other important interactions, whether direct or incidental, with insects (e.g. chemical defence), other invertebrate and vertebrate animals (e.g. non-domesticated or wild animals), and with plants (e.g. through allelopathy). Tritrophic interactions may also be considered.

Topics related to consumption by humans and/or domesticated animals of plants consumed as food and/or feed are not addressed in consensus documents on the biology of cultivated plants as these topics are outside the scope of the OECD Working Party on Harmonisation of Regulatory Oversight in Biotechnology (WP-HROB). Topics related to consumption by non-domesticated or wild invertebrate and vertebrate animals are however within the scope of the WP-HROB. This section could address, for example, major natural toxicants and common properties of the plant as regards non-domesticated vertebrates (e.g. effects of ingestion of *Cucurbita*) as well as common environmental allergenic (e.g. contact irritants, dermal or aeroallergens) properties regarding humans and domesticated animals in incidental contact with the plant. In some cases, it may be relevant to mention similar information from related species (e.g. toxicants in sexually compatible wild relatives of the plant species).

Animal pollinators (e.g. bees, hummingbirds) and the importance of a pollination system to the animal pollinator is detailed here, whereas the importance of the pollination system to the plant is addressed in subsection “Pollination (wind, insects, both, etc.), pollen dispersal, pollen viability”. A listing of pertinent pests and pathogens (and diseases) may be presented as an appendix, with only those that are critically relevant discussed here.

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, including non-domesticated animals if relevant, will aid in determining whether any concerns may arise during cultivation from a change in the genetics of the species. If relevant, a brief description of the effects of cultivation of the plant species on the health of non-domesticated animals (e.g. levels of nitrate) may be included. Effects of incidental contact of humans (e.g. worker safety during cultivation and handling, windborne pollen) and domesticated animals to toxicants and allergens may be relevant. Effects of ingestion on the health of humans and/or domesticated*

animals would be thoroughly treated elsewhere, such as in an OECD consensus document on compositional considerations for food and feed issues. Corresponding OECD compositional documents for the considered plant species, if they exist (see [Consensus documents: work on the safety of novel foods and feeds: Plants - OECD](#)) should be referenced as appropriate.

Examples: OECD SHROB No. 13 (white spruce, Section VII, p. 28-31); No. 49 (black spruce, Section VII, pp.31-34); No. 53 (*Cucurbita*, Section IX, pp. 49-51); No. 54 (*Brassica* crops, Section V, pp.89-93); and No. 62 (sorghum, Section IV, p. 34-36).

Section VII. Additional information

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.

Examples: OECD SHROB No. 68 (safflower, Section VI, p. 48-49)

Section VII. References

As much as possible, the references should be peer-reviewed literature available internationally and mentioned in full format. After the references directly cited in the text, this section could include a subsection on additional useful references “for further reading”.

Example: OECD SHROB No. 66 (apple, p. 42-51).

Appendix 1. Common pests and pathogens

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

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 VI. The risk/safety assessment would then consider whether the transformation in the crop would be of environmental concern.*

Examples: OECD SHROB No. 18 (sugar beet, Appendix, p. 32-37); No. 31 (sunflower, Section V and Appendices 1 and 2, p. 31 and 37-47); No. 56 (sugarcane, Section VIII and Appendices 1 and 2, p. 46-56 and 65-68); No. 60 (cowpea, Section V and Appendix 1, p. 27 and 30-34); and No. 63 (tomato, Appendices I and II, p. 34-35 and 36-37).

Appendix 2. Biotechnological developments

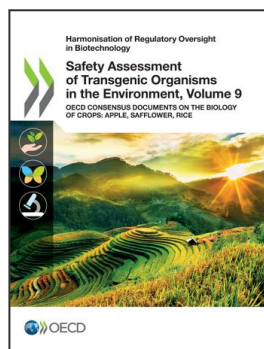
General information on the kinds of traits being introduced into the species may be included. Provide information directly necessary for defining the scope or detail of biological information that would be useful. For example, transgenes under experimental development for a crop might result in a change 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.

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.*

Examples: OECD SHROB No. 27 (maize, Appendix A, p. 39-41); No. 45 (cotton, Section VI, p. 33); No. 58 (*Eucalyptus*, Section II, p. 20-21); No. 63 (tomato, Appendix III, p. 38-40); and No. 66 (apple, Annex B, p. 35-36).

Note

¹ All consensus documents quoted as examples in the text below can be consulted on the OECD BioTrack public website ([Consensus documents: work on harmonisation of regulatory oversight in biotechnology - OECD](#)).



From:

Safety Assessment of Transgenic Organisms in the Environment, Volume 9

OECD Consensus Documents on the Biology of Crops: Apple, Safflower, Rice

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