Annex B. Vertical Gene Flow

A consideration for the environmental risk/safety assessment of a transgenic plant is the evaluation of the potential for transfer of transgenes via vertical gene flow to sexually-compatible plants to result in adverse effects on the environment, relative to the comparator. Vertical gene flow may be considered an “exposure pathway” and as such this annex differs from the other annexes in that vertical gene flow in and of itself is not an adverse effect.

This annex provides a two-step process for evaluating gene flow and its potential consequences. First, the annex provides an illustrative example to assist the assessor when considering whether transgene introgression is plausible. Second, it includes an example to assist the assessor when considering whether gene flow of a transgene, if it occurs, could have the potential to adversely affect the environment due to a change in the viability of populations of a valued species.

Concepts and terms

Vertical gene flow refers to the sexual transfer of genetic material between genetically distinct populations including the movement of genes from one population into other populations of the same species (intraspecific gene flow) or other sexually-compatible species (interspecific gene flow). Vertical gene flow is a natural process mediated by plant sexual reproduction and thus gene flow is not an adverse effect *per se*. Cultivated plant species are known to transfer genes to sexually-compatible wild relatives (Ellstrand et al., 2013).

Important steps in vertical gene flow are the spread of genetic material between donor and recipient plants, the formation of hybrids, and the stable establishment of the genetic material from the donor in the recipient population via introgression. In flowering plants, vertical gene flow is mediated by pollen, which can be dispersed by pollinators, wind, and very occasionally by water.

Introgression is the stable incorporation of genetic material (genes, alleles) in a population, generally through the repeated backcrossing of an interspecific or intraspecific hybrid with one of its parent species.

Population viability is the ability of a population to survive and persist in the environment.

Natural hybridisation involves successful mating between individuals of two genetically distinct populations or groups of populations (Harrison, 1990; Arnold, 1997). The rate of hybridisation varies between different cultivated plants and their relatives in frequency and magnitude, and mating can be uni- as well as bi-directional. Natural hybridisation is typically the first of many steps by which vertical gene flow occurs between populations (Ellstrand et al., 2013). Hybridisation may be intraspecific or interspecific.

Hybrid is the progeny from hybridisation between two genetically distinct plants.

Seed dispersal and vegetative propagation are mechanisms that plants use to spread and persist. Dispersed seed may include spatially dispersed seed from a given plant or seed from plants established via vegetative propagation. The potential for vertical gene flow can extend beyond the site where a plant was originally located/cultivated if its seed and/or vegetative propagules are spatially dispersed and establish successfully. The resulting plants may be in closer proximity to sexually-compatible relatives thus increasing the likelihood of cross-pollination.

Transgene, generally defined as a gene from a different species, is the introduced gene that confers/ determines the trait that modifies the phenotype of the transgenic plant.

Problem formulation

For this consideration, below are simple examples that illustrate the approach for planning an environmental risk/safety assessment. It includes a discussion of assessment endpoints, potential adverse effects, and a linear pathway to harm with corresponding risk hypotheses and information elements to illustrate the approach. As previously indicated in the document (section 1.2.6), the process is often more complex.

(a) Determination of assessment endpoints

Gene flow is a natural process that is common among sexually-compatible plants. Gene flow between cultivated plants, including a few transgenic plants and their sexually-compatible relatives, is well documented in the scientific literature (e.g. Kwit et al., 2011). Gene flow from a transgenic plant (i.e. the donor population) may result in the transfer of a transgene into the population of a sexually-compatible plant (i.e. the recipient population). The transgene may be permanently incorporated (introgressed) into the recipient population through several generations of hybridisation and backcrossing, especially if the transgene confers a fitness advantage. The occurrence of a hybrid progeny may lead to adverse environmental effects, depending on the trait (conferred by the transgene) under consideration.

An example of an assessment endpoint that could be affected by the occurrence of gene flow from a transgenic plant is population viability of a valued species.

(b) Identification of potential adverse effects on the assessment endpoints

As noted above, vertical gene flow is not an adverse effect *per se.* The identification of potential adverse effects on the environment resulting from vertical gene flow from a donor transgenic plant to a sexually-compatible recipient plant should be informed by the characteristics of the donor species and the trait and phenotype of the transgenic plant (conferred by the transgene), and of the potential receiving environment(s) including the characteristics of the recipient species.

If the transgenic plant is cultivated or dispersed near to a sexually-compatible plant (e.g. a weedy relative) population, interspecific hybridisation may occur and particularly if the transgene confers a fitness advantage it may be subsequently acquired by the recipient population through introgression. An example of a potential adverse effect on the environment to the assessment endpoint identified above is decreased population viability of a valued species because of increased competition from the hybrid progeny. It should be noted that depending on the trait, the types of potential adverse effects and pathways to harm detailed in the other environmental considerations annexes for transgenic plants might be relevant to such hybrid or introgressed progeny.

(c) Identification of plausible pathways to harm, formulation of risk hypotheses, and identification of information elements relevant to evaluating the risk hypotheses

In this section, a plausible pathway to harm is postulated. For each step of the postulated pathway to harm, a corresponding risk hypothesis is formulated that will enable the risk assessor to determine whether the pathway is likely to occur. Once it is shown that any part of the pathway is highly unlikely, one does not need to continue evaluating the subsequent steps in the pathway and can conclude that the specific pathway to harm is unlikely to occur. In addition, examples of information elements that can be used to evaluate the risk hypotheses are given along with their rationales.

Postulated pathway leading to decreased population viability of a valued species

Vertical gene flow may be considered as an ‘exposure pathway’ because, unlike most of the other environmental considerations, the focus is not on the cultivated transgenic plant itself but rather on whether recipient plants have the potential to have adverse effects on the environment.

The initial focus is therefore necessarily on whether successful hybridisation can occur between the transgenic plant and a sexually-compatible plant (e.g. weedy relative). The occurrence of gene flow is dependent on many factors, including the mating system, the degree of sexual compatibility, the life history and pollinators. The transgenic (donor) and sexually-compatible weedy relative (recipient) plants must have overlapping flowering phenology, be sufficiently close for pollination to occur, and the cross must result in viable and fertile interspecific hybrid progeny. The occurrence of introgression requires several generations of interspecific hybrids backcrossing with the recipient population.

If the transgene provides a fitness advantage in the hybrid-derived weedy population, this may increase the likelihood of introgression of the transgene into the weedy relative population. Increased competition from interspecific hybrids or introgressed plants (with a fitness advantage due to the transgene) could lead to decreased population viability of a valued species.

One example of a postulated pathway to harm for this adverse effect is shown in the first column of Table A B.1. Risk hypotheses for each step of the pathway are formulated in the second column and the third column provides examples of information elements for evaluating the hypotheses.

Table A B.1. Postulated pathway leading to gene flow occurring and decreased population viability of a valued species, corresponding risk hypotheses, and relevant information elements

Pathway steps	Risk hypotheses	Examples of information elements
The transgenic plant is cultivated within the geographic distribution range of a sexually-compatible weedy relative	The transgenic plant is not cultivated within the geographic distribution range of a sexually-compatible weedy relative	The presence of a sexually-compatible weedy relative in the receiving environment
The transgenic plant and sexually-compatible weedy relative have overlapping phenology	The transgenic plant and sexually-compatible weedy relative do not have overlapping phenology	Flowering time of the transgenic plant and sexually- compatible weedy relative within the receiving environment
The transgenic plant and sexually-compatible weedy relative hybridise in the receiving environment, producing viable and fertile transgenic progeny	The transgenic plant and sexually-compatible weedy relative do not hybridise in the receiving environment, or they do not produce viable and fertile progeny	Known hybridisation between the comparator and the sexually-compatible weedy relative and occurrence of natural hybridisation between the transgenic plant and weedy relative (e.g. indicated by a phenotypic or genotypic marker)
The vertical gene flow pathway would end here. The additional steps illustrate how transfer of the transgenic trait to a sexually-compatible weedy relative may lead to an adverse effect on the environment[1]		
The transgene has the potential to result in a fitness-advantage in the hybrid-derived weedy population	The transgene has no potential to result in a fitness-advantage in the hybrid-derived weedy population	The nature of the trait and phenotype of the transgenic plant informs identification of potential adverse effects
Presence of the transgene results in a change in fitness-associated trait(s) in the hybrid-derived weedy population	The transgene and fitness-associated trait(s) are not found in the hybrid-derived weedy population	Presence of the transgene and fitness-associated trait(s) in the hybrid-derived weedy population
The introgressed trait increases the reproductive potential of the hybrid-derived weedy relative, conferring a fitness advantage compared to the non-transgenic hybrid-derived population	The introgressed trait does not affect the reproductive potential of the hybrid-derived weedy relative compared to the non-transgenic hybrid-derived population	Propagule production and/or competitive ability of the hybrid-derived weedy relative compared to the non-transgenic hybrid-derived population Increased abundance and distribution of the hybrid-derived weedy relative
Increased fitness of the hybrid-derived weedy relative confers a competitive advantage over a valued species compared to the non-transgenic hybrid-derived population	Increased fitness of the hybrid-derived weedy relative does not affect a valued species compared to the non-transgenic hybrid-derived population	Level of competition between the valued species and the non-transgenic hybrid
The population viability of a valued species is decreased in the local habitat		

Note:
1. Since vertical gene flow is an exposure pathway, not an impact, the only assessment endpoint of gene flow is the occurrence of a transgene in the recipient population. This is reflected in the table with the demarcation of the gene flow exposure pathway.

It is important to note that examples of information elements in this table are intended to illustrate the types of information that can be used in evaluating a risk hypothesis, i.e. to determine whether particular pathway steps are likely to occur. However, for any step there might be other information that would be relevant. Rationales for how such information elements may be used to evaluate the risk hypotheses include:

- The presence of a sexually-compatible weedy relative in the receiving environment provides information as to whether it exists near transgenic plants;
- Flowering time of the transgenic plant and sexually- compatible weedy relative within the receiving environment provides information on overlapping phenology;
- Known hybridisation between the comparator and the sexually-compatible weedy relative and occurrence of natural hybridisation between the transgenic plant and weedy relative (e.g. indicated by a phenotypic or genotypic marker) provide information regarding the probability of fertile hybrid formation;
- The nature of the trait and phenotype of the transgenic plant inform identification of potential adverse effects;
- Presence of the transgene and fitness-associated trait(s) in the hybrid-derived weedy population provide information on the potential degree of phenotypic change affecting population fitness of the hybrid-derived weedy relative;
- Propagule production and/or competitive ability of the hybrid-derived weedy relative compared to the non-transgenic hybrid-derived population provides information on the impact of the transgene on reproductive potential of the hybrid-derived weedy relative. Increased abundance and distribution of the hybrid-derived weedy relative provides information on the impact of the transgene on the fitness of the sexually- compatible weedy relative;
- Level of competition between the valued species and the hybrid-derived weedy species containing transgene compared to non-transgenic hybrid-derived provides information on the potential for the non-transgenic hybrid hybrid-derived population provides information on the relative fitness of the hybrid containing transgene.

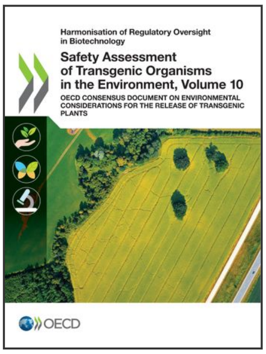
References

Arnold, M.L. (1997), *Natural Hybridization and Evolution*, Oxford Series in Ecology and Evolution, Oxford University Press, New York.

Ellstrand, N.C. et al., (2013), "Introgression of Crop Alleles into Wild or Weedy Populations" *Annual Review of Ecology, Evolution, and Systematics.* 2013. Vol. 44, pp. 325-345, https://www.annualreviews.org/doi/10.1146/annurev-ecolsys-110512-135840.

Harrison, R.G. (1990), "Hybrid zones: Windows on evolutionary process", *Oxford Surveys in Evolutionary Biology*, Vol. 7, pp. 69–128, https://www.cabdirect.org/cabdirect/abstract/19910191041.

Kwit, C. et al., (2011), "Transgene introgression in crop relatives: molecular evidence and mitigation strategies", *Trends in Biotechnology*, Vol. 29, pp. 284-293 https://doi.org/10.1016/j.tibtech.2011.02.003.



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