

Annex F. Crop Management Practices

A consideration for the environmental risk/safety assessment of a transgenic plant is the evaluation of the potential for changes in crop management practices associated with its cultivation relative to those associated with the cultivation of the comparator, and if such changes could have adverse effects on the environment.

Concepts and terms

Crop management practices are agricultural practices used to increase the quality and yield of crops. Examples of crop management practices include: soil tillage; crop rotation; irrigation; fertilisation; as well as mechanical, biological, cultural, and chemical methods for managing weeds (including volunteers) and pests (including insects and diseases). The combination, timing, and sequence of the crop management practices used by farmers varies based on factors such as the crop species and its growth stage, the soil, climatic and weather conditions, pest pressure, and socio-economic factors.

Tillage is a crop management practice involving the preparation of soil by mechanical disturbance, such as digging, stirring, and overturning. Tillage is widely used to incorporate crop residues and manure into the soil, limit the growth of weeds during the intercropping period, prepare a seedbed, and control weeds in crop fields. Conventional tillage leaves the surface of the field relatively bare and susceptible to wind and water erosion. To avoid this risk, farmers have increasingly used reduced-till or no-till practices that are collectively referred to as conservation tillage practices because they protect the soil surface. A reduced-till system retains more crop residue cover than conventional tillage whereas a no-till system leaves the crop residue undisturbed from harvest through planting. Conservation tillage practices have been supported by agronomic developments such as herbicides for weed control, herbicide-tolerant crops (transgenic and non-transgenic), and improved farm machinery.

Crop rotation is a crop management practice involving growing different crops in succession in a particular area. Crop rotation can reduce weed and pest pressure, and maintain or restore nutrient balances in the soil.

The term organism is used in this annex for plants, animals, and micro-organisms.

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

The cultivation of a transgenic plant has the potential to alter crop management practices. However, such alterations are not unique to the cultivation of a transgenic plant. Crop management practices are

in constant flux in response to weed and pest pressure, climate and weather, economics, regulations, new crop varieties and technologies, and other forces that impact a farmer's land-use decisions. Potential changes in crop management practices associated with the cultivation of a transgenic plant are only considered in the environmental risk/safety assessment when the potential changes may lead to adverse environmental effects.

Two examples of assessment endpoints for evaluating the potential environmental impact of changes in crop management practices are: (1) the abundance of a valued organism in crop fields or field margins and (2) the quality of soil.

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

Certain characteristics of a transgenic plant linked to a genetic modification may lead to crop management practices being changed in specific ways. These changes may in turn alter weed and pest populations, for example leading to the evolution of herbicide resistance in weeds or pesticide resistance in target organisms. The adoption of integrated weed and pest management strategies are widely recommended to farmers to manage such issues (e.g. Anderson et al., 2019). Depending on their laws and policies, some countries will also consider the potential for changes in weed and pest populations prior to the release of a transgenic plant.

The identification of potential adverse effects on the environment resulting from changes in crop management practices should be informed by knowledge of the range of existing crop management practices used for the comparator and whether the characteristics of the transgenic plant might affect these practices. Agronomic studies can be useful in highlighting the differences in crop management practices between the transgenic plant and the comparator. However, caution should be exercised in interpreting such differences given that crop management practices are influenced by a wide range of factors (mentioned above) and ultimately determined by the farmer. Consequently, potential adverse effects from changes in crop management practices cannot always be predicted solely from the new characteristics of the transgenic plant because crop management practices involve many factors not directly related to the transgenic plant.

Nevertheless, consideration of the characteristics of the transgenic plant relative to the comparator aids in identifying potential adverse effects associated with changes in crop management practices. Thus, depending on the changes in characteristics of the transgenic plant in relation to the comparator, two examples of potential adverse effects on the environment according to the assessment endpoints identified above may include: (1) reduced abundance of a valued organism and (2) reduced quality of soil.

(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, two plausible pathways to harm are postulated. For each step of the postulated pathways to harm, a corresponding risk hypothesis is formulated that will enable the risk assessor to determine whether the pathways are likely to occur. Once it is shown that any step of the pathway is highly unlikely to occur, 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 reduced abundance of a valued organism

Cultivation of a transgenic plant with a trait (e.g. herbicide tolerance) that leads to changes in weed management practices may reduce the number of wild plants present in crop fields and field margins or induce population shifts in those wild plants. If a valued organism depends on those wild plants occurring

in the field or in field margins for food or habitat, such a change in crop management practices may result in reduced abundance of a valued organism.

One example of a postulated pathway to harm for this adverse effect is shown in the first column of Table A F.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 F.1. Postulated pathway leading to reduced abundance of a valued organism, corresponding risk hypotheses, and relevant information elements

Pathway steps	Risk hypotheses	Examples of information elements
The introduced trait confers herbicide tolerance	The introduced trait does not confer herbicide tolerance	Identity of the introduced gene; Activity of the new protein; response of the transgenic plant to herbicide applications
The transgenic plant is cultivated within the geographic distribution range of wild plants that are important for a valued organism	The transgenic plant is not cultivated within the geographic distribution range of wild plants that are important for a valued organism	Geographic distribution range of the valued organism; Dietary and habitat needs of the valued organism
There is a change in herbicide regime for the transgenic crop relative to the comparator crop(s)	The transgenic crop is not differently treated relative to the comparator crop(s)	Current herbicide regime used on comparator crop(s); Proposed herbicide regime for the transgenic crop
The abundance of wild plants that support the abundance of valued organisms is reduced by the change in herbicide applied	The abundance of wild plants that support the abundance of valued organisms is not reduced by the change in herbicide applied	Presence of valued organisms in the receiving environment; presence of wild plants that support the abundance of valued organisms in the receiving environment; Effect of the proposed herbicide regime on these plants; Alternate habitats available for valued organisms
The abundance of valued organisms is reduced		

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 could be relevant. Rationales for how such information elements may be used to evaluate the risk hypotheses include:

- The identity of the introduced gene, activity of the new protein and response of the transgenic plant when challenged with herbicides provides information on the new herbicide tolerance conferred to the transgenic plant;
- The geographic distribution range of the valued organism and its dietary and habitat needs provides baseline information about its presence and survival needs;
- The current herbicide regime used on the comparator crop(s) and the proposed herbicide regime for the transgenic crop (e.g. which herbicide groups, timing, and frequency of herbicide applications) provides information on any changes in the herbicides applied (e.g. the herbicide the transgenic plant is tolerant to);

- The proposed new herbicide regime and its known or anticipated effect on wild plant populations present in the receiving environment provides information on whether those habitat plants will be susceptible to the new regime; the existence of alternate habitats for the valued organism provides information on whether loss of wild plants in the crop or field margins due to changes in crop management practices may impact the abundance of the valued organism.

Postulated pathway leading to reduced quality of soil

Many crop management practices directly or indirectly impact the quality of soil. The adoption of reduced-till or no-till practices may improve the quality of agricultural soils (Derpsch et al., 2010; Busari et al., 2015). However frequent use of conventional tillage may result in soil compaction or erosion (FAO, 2022). As noted above, use of herbicides for weed control can support minimum tillage agriculture. However frequent application of any herbicide can result in the evolution of herbicide resistant weeds (Owen and Zelaya, 2005). If weed control in a herbicide-tolerant transgenic crop relies on the specific herbicide, then resistant weeds may arise. If this is the case, then crop management practices may revert to tillage for weed control which may lead to a reduction in soil quality.

One example of a postulated pathway to harm for this adverse effect is shown in the first column of Table A F.2. 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 F.2. Postulated pathway leading to reduced abundance of a valued organism, corresponding risk hypotheses, and relevant information elements

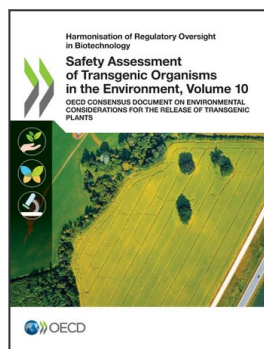
Pathway steps	Risk hypotheses	Examples of information elements
The introduced trait confers tolerance to a specific herbicide	The introduced trait does not confer tolerance to a specific herbicide	Identity of the introduced gene; Activity of the new protein; Response of the transgenic plant to herbicide applications
There is an increased use of the specific herbicide to control weeds in the transgenic crop relative to the comparator crop(s)	There is not an increased use of the specific herbicide to control weeds in the transgenic crop relative to the comparator crop(s)	Current herbicide regime used on comparator crop(s); Proposed herbicide regime for the transgenic crop
The abundance of herbicide-resistant weeds increases due to selection pressure from repeated application of the specific herbicide	The abundance of herbicide-resistant weeds does not increase due to selection pressure from repeated application of the specific herbicide	Identity of target weeds; presence and incidence of herbicide-resistant weed populations; Mitigation measures available to delay development of herbicide resistance in weeds; Mode of action of the specific herbicide
The specific herbicide does not control herbicide-resistant weeds and reliance on conventional tillage for weed control increases	The specific herbicide does control herbicide-resistant weeds and reliance on conventional tillage for weed control does not increase	Available options to control herbicide-resistant weeds
Additional passes of heavy machinery over the field and reductions in crop residues that protect the soil from wind and water erosion result in increased soil compaction, erosion, organic matter loss	There is no increased soil compaction, erosion, organic matter loss due to additional passes of heavy machinery over the field or reductions in crop residues that protect the soil from wind and water erosion	Available measures to maintain soil quality when conventional tillage is used; ability of soil to support crop growth
The quality of soil is reduced		

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 could be relevant. Rationales for how such information elements may be used to evaluate the risk hypotheses include:

- The identity of the introduced gene, activity of the new protein and the response of the transgenic plant when challenged with the specific herbicide provide information on the new herbicide tolerance conferred to the transgenic plant;
- The current herbicide regime used on the comparator crop(s) and the proposed herbicide regime for the transgenic crop (e.g. herbicide groups, timing and frequency of herbicide applications) provides baseline information for identifying the changes in herbicide use following the introduction of the transgenic crop, including more frequent use of a particular herbicide or increased amount of acreage treated with a particular herbicide;
- Knowledge of the weed species present in the receiving environment, the ability of these weed species to develop resistance to herbicides in general, the presence of any weed populations already resistant to the specific herbicide, and the mode of action of the specific herbicide provide information about the likelihood of weed species evolving resistance to the specific herbicide;
- Knowledge of the proposed herbicide regime for the transgenic crop and any mitigation measures available to delay the evolution of herbicide-resistance in weed populations also provides information on the likelihood of weed species evolving resistance to the specific herbicide;
- Knowledge of alternatives to the specific herbicide, including other herbicides or non-chemical methods provides information on the level of tillage that may be required to control herbicide resistant weeds and the level of impact on soil;
- The availability of measures to mitigate for the detrimental effects of conventional tillage on soil degradation provides information on the potential extent of reduction in soil quality.

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