June 2019

Risk Assessment Reference
Unintended effects

Introduction

Genetic modifications involving the introduction of genes have the potential to cause unintended effects due to the process used to insert new genetic material, or by producing a gene product that affects multiple traits. Unintended effects may arise in addition to, or instead of, those that are the purpose of the genetic modification (Fernandez and Paoletti, 2018). Such effects may include:

- altered expression of endogenous genes by random insertion of introduced DNA in the genome
- interruptions, deletions, duplications or rearrangements of the genome caused by random insertion of DNA
- increased metabolic burden due to expression of the proteins encoded by the introduced genes
- novel traits arising from interactions of the protein encoded by the introduced gene product with endogenous non-target molecules and
- secondary effects arising from altered substrate or product levels or change in substrate specificity in the biochemical pathway incorporating the protein encoded by the introduced gene.

Risk considerations

Unintended effects might result in adverse outcomes such as toxicity, allergenicity, weediness, and altered pest or disease burden compared to the parent organism.

However, these types of effects also occur spontaneously and in plants generated by conventional breeding (Ladics et al., 2015; Schnell et al., 2015). Accepted conventional breeding techniques such as hybridisation, mutagenesis and somaclonal variation can have a much larger impact on the plant genome than genetic engineering (Herman and Price, 2013; Schnell et al., 2015; Anderson et al., 2016).

Plants generated by conventional breeding have a long history of safe use, with few documented cases where conventional breeding has resulted in an unacceptable level of a metabolite in a crop (Berkley et al., 1986; Seligman et al., 1987). There are no documented cases where conventional breeding has resulted in the production of a novel toxin or allergen in a crop (Steiner et al., 2013). Current practices identify and remove harmful non-GM plants to protect domesticated animals and people (Steiner et al., 2013).

Unintended effects in GM plants are identified by comparing the GMO to the corresponding conventional plant. Substantially equivalent characteristics and composition indicate that the GM plant is as safe as the conventional (non-GM) plant (Fernandez and Paoletti, 2018). The accumulated experience with genetic modification of plants indicates that, as for non-GM breeding programs, the process has little potential for unexpected outcomes that are not detected and eliminated during the early stage of selecting plants with new properties (Bradford et al., 2005). This means that there is low likelihood of such changes leading to harm as a result of a commercial/general release in the long term.

In the event that unintended effects occur as a result of genetic modification, licence holders are required by Section 65 of the *Gene Technology Act 2000* (the Act) to report any information about risks

or unintended effects of the dealing to the Regulator on becoming aware of them. All licences are subject to this condition prescribed in the Act. There have been no credible reports of adverse unintended effects to date.

Conclusion

There have been no reports of adverse effects on human health and safety or the environment as a result of unintended effects associated with GM plants. Nevertheless, the potential for adverse unintended effects as a result of gene technology is assessed on a case-by-case basis, in the context of any proposed dealings, in each risk assessment for release of a GM plant.

References

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