Workshop on the Regulatory Status of New Breeding Techniques

Summary & Outcomes

Summary of Workshop

FSANZ held a workshop with jurisdictions and other interested Australian and New Zealand government agencies on 31 August 2016 to discuss the regulatory status of new breeding techniques (NBTs) under Standard 1.5.2 Food produced using Gene Technology of the Food Standards Code.

NBTs refer to a variety of recently developed methods that are being used in plant and animal breeding. Crop plants and livestock developed using these methods are rapidly approaching commercialisation in Australia and New Zealand and some crops are already commercialised overseas. There is ongoing debate and uncertainty about whether these techniques are captured by current gene technology regulations, including Standard 1.5.2.

As part of its consideration of the regulatory issues surrounding NBTs, FSANZ is trying to establish which of the techniques (if any) are captured by the standard as currently drafted so that product developers can determine if they need to submit an application to FSANZ for pre-market approval. This is not straightforward because the definitions in the standard are ambiguous in relation to certain NBTs, such as gene editing.

The primary purpose of the workshop was to get some consensus and clarity around the regulatory status of NBTs, and in particular to discuss a technical framework for deciding which techniques could be captured by Standard 1.5.2. Once finalised, this framework could be used to provide greater certainty to product developers, without the need to amend the standard.

Outcomes

1. The framework presented by FSANZ (see attachment) which sets out a technical determination of the techniques that are either captured or not captured by Standard 1.5.2, was well received. There was a general level of comfort with the outcomes it would produce, specifically the exclusion of products derived from null segregants, as well as gene edited organisms with deletions or small nucleotide changes. Workshop attendees will take this information back for further discussion within jurisdictions.

2. From an international perspective, the outcomes sit reasonably well in terms of the decisions being made by other countries. FSANZ will continue to monitor developments in other countries, especially major trading partners.

3. FSANZ will prepare a more detailed outline of the proposed framework, which will include more technical consideration around GM rootstock grafting, and the use of gene editing to introduce small insertions. FSANZ will also consider undertaking targeted consultation with stakeholders on the technical framework being developed. This more detailed framework will be provided to jurisdictions.

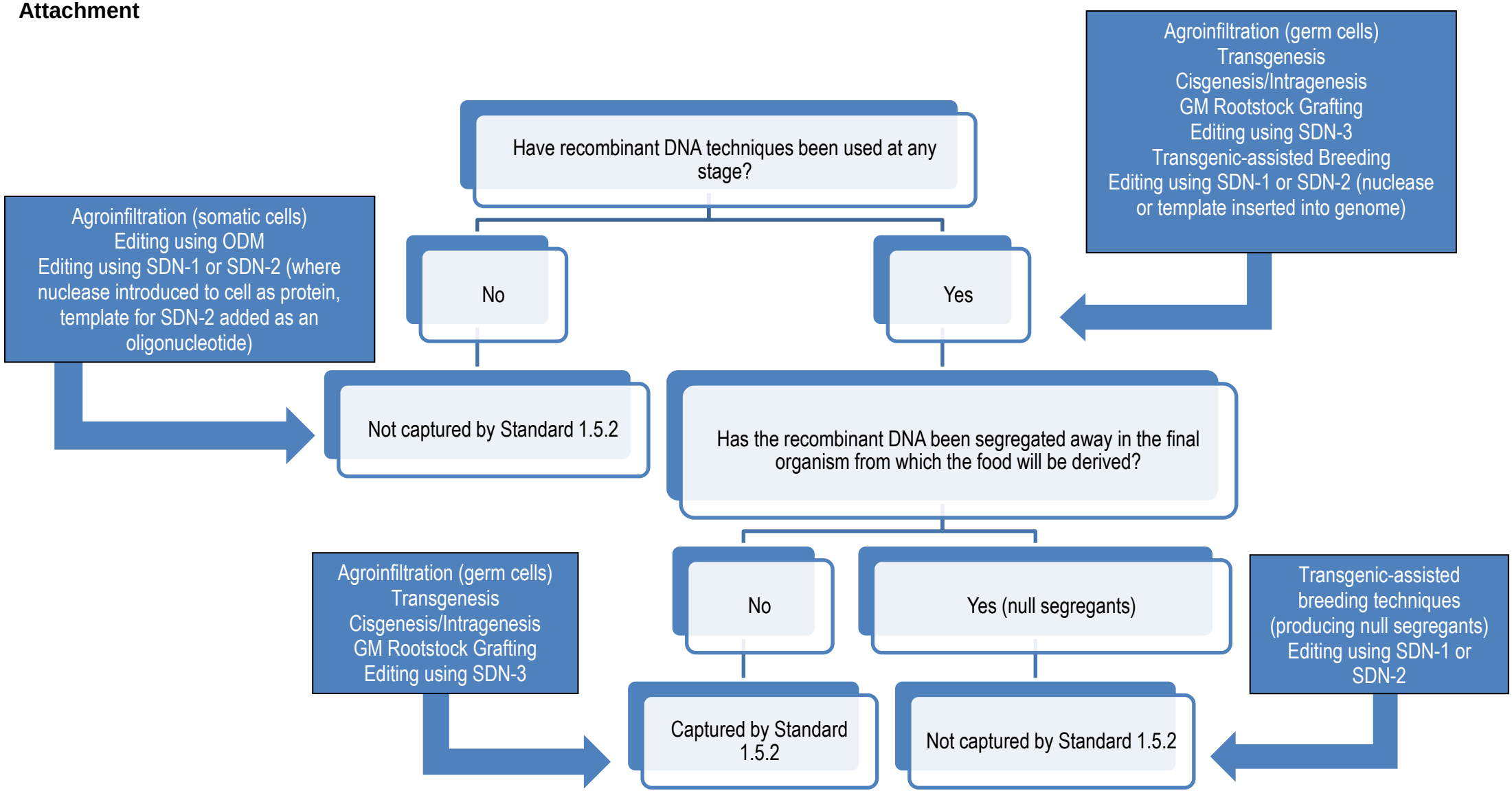
4. In terms of finalising the technical framework, it was proposed that FSANZ could discuss the preparation of a presentation for the Jurisdictional Meeting (March 2017) with the ISFR Senior Project Officer.

5. Once finalised, a possible mechanism for providing this information to stakeholders, especially product developers, would be through the FSANZ Application Handbook, where it could be included as technical guidance to help determine if an application is required. This would preclude the need for FSANZ to consider applications on a product by product basis.

6. Workshop participants also noted that the regulatory status of NBTs should be discussed in the broader context of enforceability, harmonisation of regulatory outcomes within Australia and New Zealand, and potential trade impacts.

7. FSANZ will continue discussing NBTs with the jurisdictions, and working together with other regulators to achieve a coordinated and consistent response where possible.

Attachment



SDN = site directed nuclease that introduces a double-stranded DNA break:

- Zinc finger nuclease (ZFN) – DNA targeting sequence is a protein
- Transcription activator-like effector nuclease (TALEN) – DNA targeting sequence is a protein
- Clustered regularly interspaced short palindromic repeats (CRISPR) coupled with Cas9 nuclease (CRISPR/Cas9) – DNA targeting sequence is RNA

DNA coding for a nuclease will involve recombinant DNA

- SDN-1 – deletions, point mutations, small insertions; the DNA break is repaired naturally
- SDN-2 – deletions, point mutations, small insertions; the DNA break is repaired by the addition of a template
- SDN-3 – involves a large insertion (e.g. a whole gene). The DNA break is repaired by the addition of a template