Latest perspectives on regulation of technologies for food crop improvement

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Background & context

Standard 1.5.2 – Food produced using gene technology

- Adopted in 1999.
- Establishes a pre-market assessment and approval system for GM foods & imposes mandatory food labelling requirements

Gene technology landscape
Original intent of Standard 1.5.2

- To ensure foods developed using recombinant DNA techniques are subject to pre-market assessment and approval
- To exclude products of “traditional breeding, mutagenic techniques etc” from this requirement

Why pre-market approval?

- Most food in our food supply has not been formally assessed
- This food has a presumption of safety - food is considered safe on the basis of human experience:
  - no history of adverse effects
  - adequate knowledge in community to address any hazards
- Some foods and substances added to foods do not have a presumption of safety
  - require a formal (pre-market) assessment to determine their risk to human health

No presumption of safety

Substances added to foods
- Food additives
- Processing aids
- Nutritive substances

Whole foods
- Novel foods
- GM foods
- Irradiated foods

Reasons for introducing Standard 1.5.2

- The community can be assured about the safety of GM foods for human consumption
- Industry can have a clear regulatory pathway for the commercialisation of products
- Consumers can have access to accurate information, including labelling
**Relevant definitions**

A food produced using gene technology means a food which has been derived or developed from an organism which has been modified by gene technology.

Gene technology means recombinant DNA techniques that alter the heritable genetic material of living cells or organisms.

**Effect of the standard**

Process-based distinction

- Conventional breeding
  - Traditional cross breeding & selection
  - Mutation breeding (plants)
  - Cell culture techniques

- Gene Technology
  - Recombinant DNA techniques
  - Transgenesis

**Current situation**

Emergence of new breeding techniques

- Conventional breeding
  - Traditional cross breeding and selection
  - Mutation breeding (plants)
  - Cell culture techniques

- Gene technology
  - Recombinant DNA techniques
  - Transgenesis

No pre-market approval

- Pre-market approval
The problem

- It's not clear whether food produced using NBTs are currently captured under relevant definitions for GM foods.
- There is ongoing debate about whether and to what extent they should be captured and subject to pre-market approval.
- A number of products are currently under development, and some crops have already been commercialised overseas.

Additional FSANZ-specific issues

- FSANZ is not a regulator
  - We are not responsible for enforcement of the Code or its application and interpretation.
  - Unable to give advice about whether a food comes within the scope of Standard 1.5.2.
- Potential applicants must seek their own legal advice about what they need to do to comply with the Code.

FSANZ activities on NBTs

- Started focusing on the issue in 2011.
- FSANZ held technical workshops on NBTs in 2012 and 2013 to:
  - Improve our understanding of the techniques.
  - Seek expert scientific opinion on whether derived foods were more similar to GM foods or conventional foods. [http://www.foodstandards.gov.au/consumer/gmfood/Pages/New-plant-breeding-techniques-in-the-spotlight.aspx](http://www.foodstandards.gov.au/consumer/gmfood/Pages/New-plant-breeding-techniques-in-the-spotlight.aspx)
- Monitor international developments in relation to NBTs.
- Consulting with jurisdictions regarding potential approaches to improve the legal clarity around NBTs.

FSANZ review

- FSANZ commenced a review in June 2017 to consider:
  - The extent to which food derived from various NBTs should be captured for pre-market approval under Standard 1.5.2, and whether the definitions for 'food produced using gene technology' and 'gene technology' should be changed to improve clarity about which foods require pre-market approval.
- An Expert Advisory Group on New Breeding Techniques (EAG NBT) has been established to assist with the review.
- There is no intent to review any other aspect of the standard or our approach to foods unambiguously captured by the standard.
**Issues to consider**

Where and how do we draw the line?

- The term “NBT” covers a diverse array of techniques
- A single technique may result in a variety of different outcomes
- Some products may warrant pre-market assessment, others may not

**NEED TO APPLY A RISK-BASED APPROACH**

**FOCUS SHOULD BE ON THE OUTCOME NOT SPECIFIC TECHNIQUES**

<table>
<thead>
<tr>
<th>1. DNA is inserted &amp; remains in final food producing line</th>
<th>2. No inserted DNA remains in final food producing line; changes to the existing genome</th>
<th>3. No inserted DNA remains in final food producing line; no genome changes in final food producing line</th>
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<tr>
<td>Examples include:</td>
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<tr>
<td>- Cisgenesis &amp; intragenesis</td>
<td>- SDN approaches</td>
<td>- Accelerated breeding using early flowering</td>
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<td>- GM rootstock grafting</td>
<td>- Oligo-directed mutagenesis (ODM)</td>
<td>- Pre-hatch sex determination in chickens</td>
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<tr>
<td>- Gene editing using site directed nucleases (SDN)</td>
<td>Changes introduced are substitutions (SDN &amp; ODM) or deletions (primarily SDN).</td>
<td>Use of an initial transgenic line. Final breeding step involves selection of progeny that have not inherited the inserted DNA. = “null segregants”</td>
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Although not classed as a NBT, transgenesis would also come under this group.
Questions to be considered

- Is the 'null segregant' category one that could be considered for exclusion from pre-market assessment?
- Would it be appropriate to capture foods from NBTs where the outcome resembles transgenesis?
  - Where does GM rootstock grafting fit?
- What approach should be taken to the genome editing category?
  - Would it be worthwhile investigating whether a distinction could be made between those edits leading to novel characteristics in the food versus those that simply reproduce existing variation without introducing novel characteristics into the food?
  - What do we know about the frequency of and potential risk arising from off target effects in comparison to changes that occur through random mutagenesis or spontaneous mutation?

Other relevant issues

- A number of broader issues are relevant to the discussion, e.g.
  - Enforcement & compliance
  - Consumer information
  - Harmonisation with trading partners
- These will be considered in the context of a Proposal, should FSANZ decide to proceed with an amendment to the Code

Where to get information

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