Perspectives on regulation of technologies for food crop improvement
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Two GM regulatory agencies in Australia
- Office of the Gene Technology Regulator (OGTR) – licences GM releases to the environment in Australia
- Food Standards Australia New Zealand (FSANZ) approves GM food in Australia & New Zealand

FSANZ offices in Canberra and Wellington
- Approx. 100 staff in Canberra
- Approx. 11 staff in Wellington

Dr Lisa Kelly, GM Team Leader
3 people in the GM Team
What I’m going to talk about

• GM (Transgenic) Food Regulation
  • The Regulation of Breeding Stacks
  • The Regulation of New Breeding Techniques

No matter how a food is produced or what the food is, there are generic regulations that must ensure it is safe
Chapter 1
General Food Standards

PART 1.1 Labelling and other Information Requirements
PART 1.3 Substances Added to Food
PART 1.4 Contaminants and Residues
PART 1.5 Foods Requiring Pre-Market Clearance
PART 1.6 Microbiological and Processing Requirements

GM (Transgenic)
Food Regulation

Why is GM regulated?

- no history of safe use/unintended effects – precautionary approach
- provides assurance to developers – clear path to market for approved products
- public confidence
- “the more the… public has tended to worry about a particular risk, the more strictly…. policy-makers are likely to regulate it”


“We shouldn’t forget that there are also other promising novel… breeding technologies, post-GM, and we shouldn’t make the mistake of regulating them to death as we have done with GM.” – Prof. Anne Glover (2013): [then] Chief Scientific Adviser to the President of the European Commission
On the basis of its detailed examination of comparisons between currently commercialized GE and non-GE foods in compositional analysis, acute and chronic animal toxicity tests, long-term data on health of livestock fed GE foods, and epidemiological data, the committee concluded that no differences have been found that indicate a heightened risk to human health from these GE foods than from their non-GE counterparts.

There are two separate legislative instruments in the Code that are relevant to GM food.

**Standard 1.5.2 – Food produced using gene technology**

- **Note:** This standard is a standard made under the Food Standards Australia New Zealand Act 1991 (Cth). The standards together make up the Australia New Zealand Food Standards Code. See also sections 1.1.1.3 and 1.1.1.4.

This provides definitions and labelling requirements for regulation.

**Schedule 26 – Food produced using gene technology**

- Since 2000, 69 approvals covering 88 lines: canola (11), corn (26), cotton (17), lucerne (3), potato (11), rice (1), soybean (17), sugarbeet (2) – all plants.
- Most of these foods are imported.

**FSANZ regulation of GM foods: Standard 1.5.2 – Food produced using Gene Technology**

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.
The Regulation of Breeding Stacks

Stacked events obtained by breeding

- FSANZ does not separately assess food from breeding stacks where food from the GM parents has already been approved.
- Schedule 26 states:

> Stacked events obtained by breeding means:
> • a plant, the genetic material of which includes a transformation event or events; or
> • any plant descended from the plant referred to in paragraph (a), that is the result of conventional breeding of that plant with:
>   • any other plant that does not contain a transformation event or events; or
>   • any other plant that contains a transformation event or events, whether expressed as a line or event, that is listed in the table to Schedule 26.
>   
>   But shall not be taken to mean any plant derived solely as a result of conventional breeding.

Why doesn’t FSANZ assess food from stacked lines in which food from the parents has already been approved?

Crossing two or more approved GM plant lines is not likely to pose any additional hazards over and above what would have already been considered when food from each of the parental GM lines was assessed for safety.

What we know

- Many modern non-GM crop varieties are already stacks obtained by breeding – along with all of its imprecisions
- The likelihood of formation of unexpected, unknown, unpredictable toxins/allergens unrelated to the genotype of the parents is negligible – for both non-GM and GM stacks.
New Breeding Techniques

What are New Breeding Techniques?

- Cisgenesis/Intragenesis
- GM Rootstock Grafting
- RNA dependent DNA methylation/RNA interference
- Agro-infiltration (including non-germline and germline tissue)
- Accelerated breeding following early flowering
- Reverse Breeding
- Seed Production Technology (SPT) – a proprietary technique developed by Pioneer Hi-Bred
- Oligo-directed mutagenesis (ODM)
- Site-directed nucleases – ZFN, TALEN, CRISPR/Cas9

Are/should these NBTs be covered by current regulations?

All our food is ‘genetically modified’ in some way – where do you draw the line?
..‘regulators are struggling..’

Breeding controls

Scientists must help to inform regulators wrestling with how to handle the next generation of genetically engineered crops.

On 9 April, activists gathered in Paris to protest against an emerging class of geneticaly altered crops. Regulators often classify them in the product of ‘new breeding techniques’ (NBTs), but are sometimes distinct from classical — and historically controversial — genetically modified (GM) varieties. But some politicians, such as those who issued the Panel of the French Agrobios- mation in Paris last week, are unconvinced by that argument. They call the new plants ‘golden GMOS’.

“There is room for healthy debate on how these crops are regulated.”

FSANZ Workshops on NBTs

FSANZ hosted two technical workshops to discuss various new breeding techniques with a panel of invited experts in the fields of plant breeding and plant biotechnology.

The aims of the workshops were to:

- Improve FSANZ’s understanding and knowledge of certain new plant breeding techniques.
- Provide advice to FSANZ on whether there are safety concerns with food derived using certain new plant breeding techniques.

The workshops were held on 11 May 2012 and 6 August 2013.

Workshop Reports


Current constraints for FSANZ

- FSANZ is not a policy-setting agency and therefore cannot change the scope of Standard 1.5.2.
- FSANZ is not an enforcement agency and therefore is unable to provide interpretive or enforcement advice in relation to Standard 1.5.2.
  - This means FSANZ is unable to advise developers if an application for pre-market approval under Standard 1.5.2 is necessary.
**SCIENTIFIC**
- Science/evidence-based decision-making
- Knowledge of the techniques/products – do they pose unique risks?
- Detectable? Identifiable?

**LEGAL**
- Want to avoid regulatory uncertainty
- Is the technique/product captured by current regulations?
- Ambiguous definitions open to interpretation
- Courts as ultimate decision-maker

**POLICY**
- Appetite for change
- Balance between the science and public opinion
- The balance between risk and regulation should be commensurate
- Regulatory harmonisation

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**A tangled web…**

**GOOD REGULATION SHOULD…**

- Be science-based
- Be transparent
- Assure the public
- Fulfil legitimate objectives
- Assess risk relative to what is already regarded as safe
- Be harmonised as much as possible
- Be open to update
- Provide timely guidance to developers

**NOT…**

- Stifle innovation
- Be cost prohibitive
- Be inconsistent
- Stigmatise new technologies
- Create trade barriers
- Ask for data that are not relevant for decision-making

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