



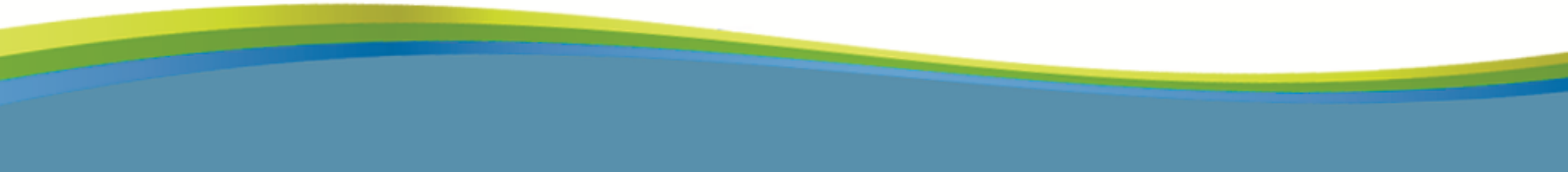
New Breeding Techniques: Regulatory Issues

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Workshop on the Regulatory Status of New Breeding Techniques
31 August 2016, Canberra

Overview

1. **Background & history to GM food standard**
2. **Relevant definitions**
3. **The regulatory problem**
4. **FSANZ view**



Today's Discussion

Main objective

- To reach consensus on how the GM food standard should be interpreted with respect to NBTs
 - To agree on what NBTs would be captured according to that interpretation

Broader considerations

- harmonisation of regulatory outcomes within ANZ
- community expectations
- third party trade/international harmonisation

Standard 1.5.2 – History

- **Standard 1.5.2 came into effect in 1999 (Proposal P97)**
- **The standard was introduced so that**
 - 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

GM Food Regulation

Two separate legislative instruments for GM foods

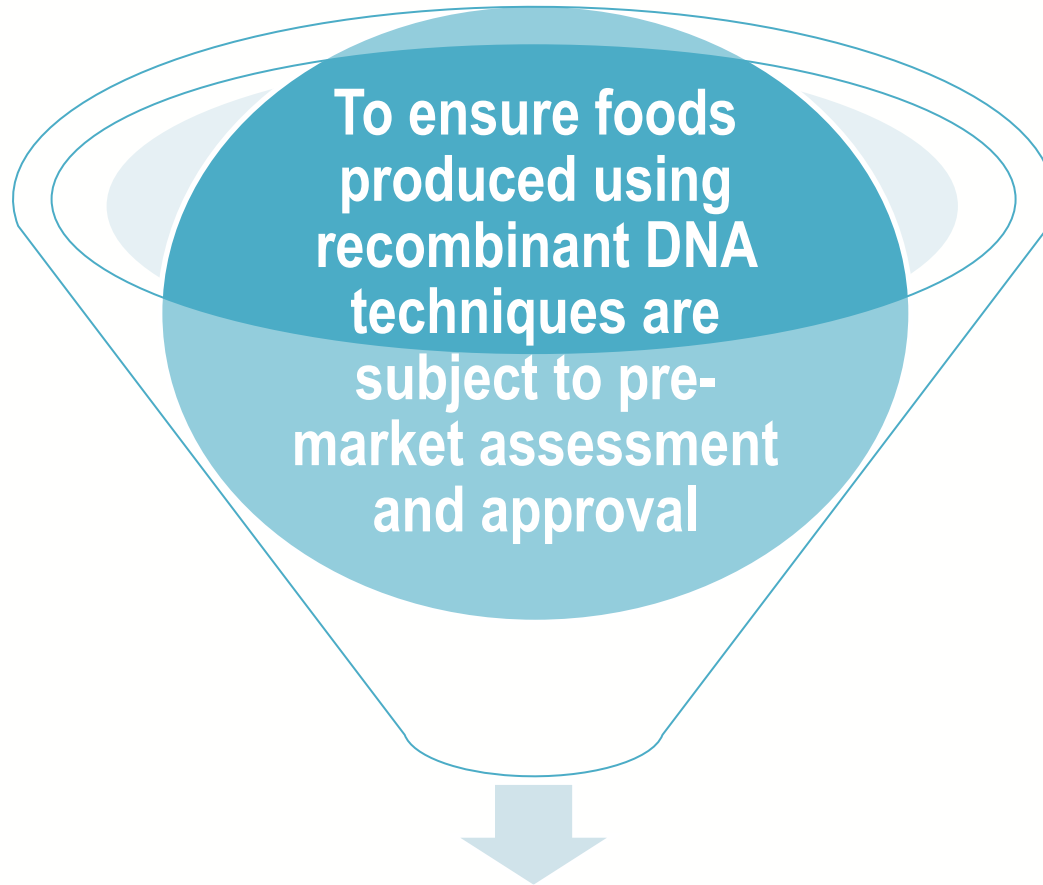
Standard 1.5.2 – Food produced using gene technology

Provides definitions, conditions for the sale of food produced using gene technology, labelling requirements (including relevant definitions)

Schedule 26 – Food produced using gene technology

Provides a list of permitted foods produced using gene technology, additional definitions

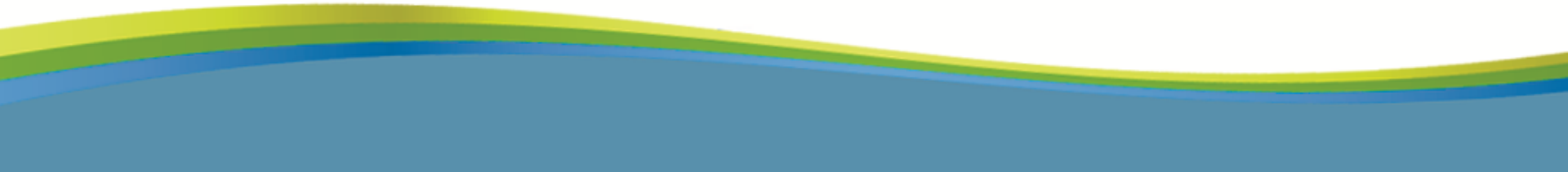
Original Intent of Standard 1.5.2



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



Regulatory Problem

The definitions in Standard 1.5.2 are nearly 20 years old.

- all GM foods approved under Standard 1.5.2 are derived from transgenic organisms (plants)

Some NBTs do not result in transgenic organisms as a final food-producing line

- Its not clear whether foods derived from these lines are currently captured under Standard 1.5.2

A number of products are close to commercialisation yet their regulatory status is uncertain

- Some product developers have indicated they intend to submit applications to FSANZ to trigger a decision

What Techniques are causing Uncertainty?

? Gene editing – small nucleotide changes

✓ Gene editing – gene addition/replacement

✓ Cisgenesis and Intragenesis

✓ RNA interference/RdDM

✓ GM Rootstock Grafting

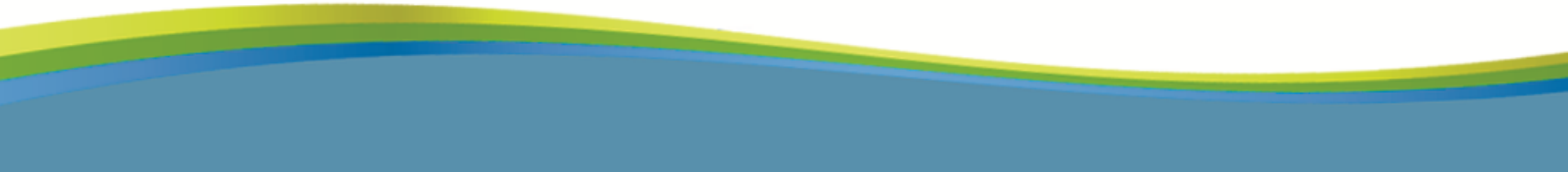
X Agroinfiltration – somatic cells

? Transgenic-assisted breeding techniques – null segregants

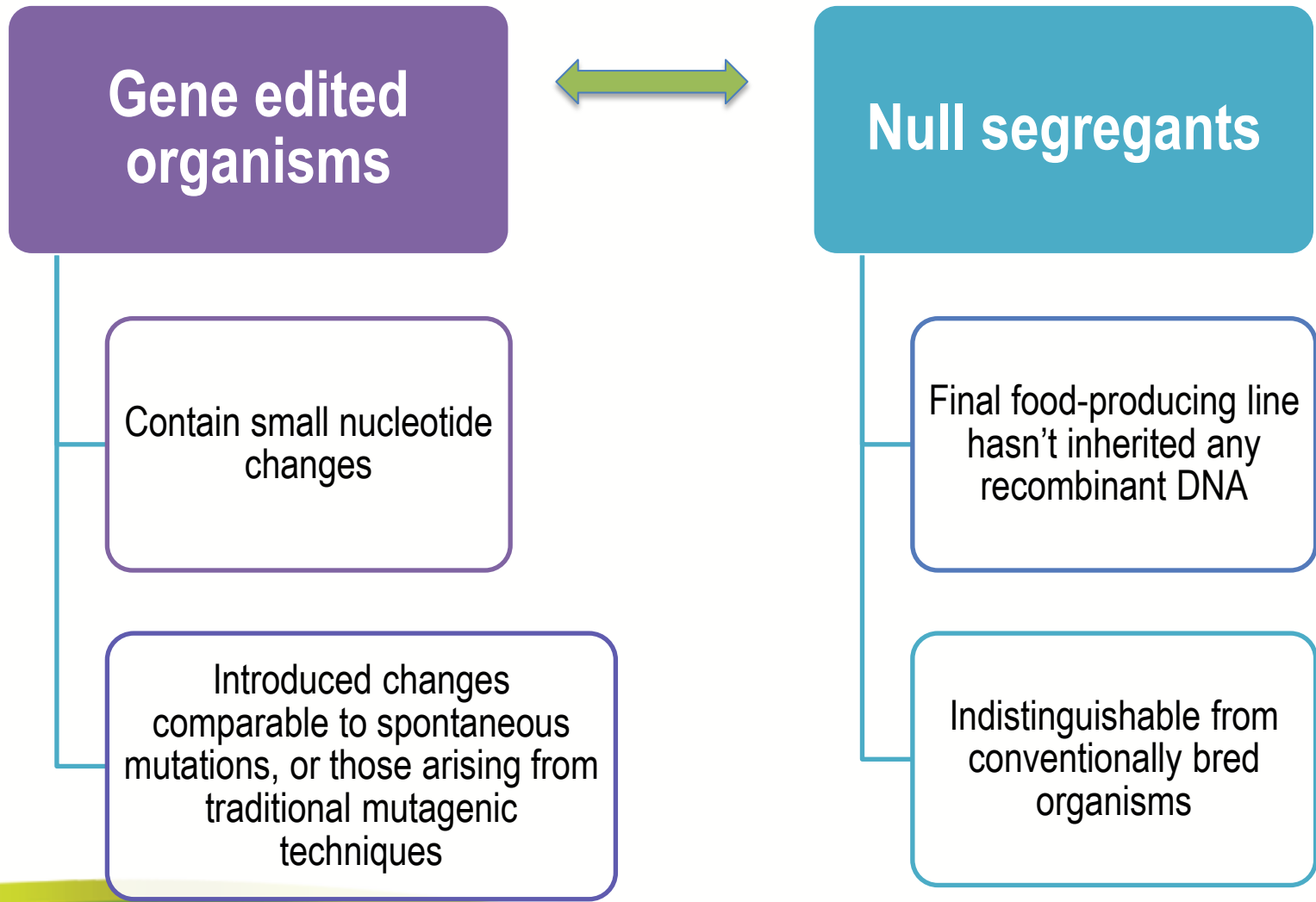
Source of Uncertainty

- **Ambiguous wording in the definitions**
- **Certain key words are not defined**

May make interpretation difficult for those techniques resulting in null segregants, and certain applications of gene editing



NBT Products



Ambiguous and Undefined Wording

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

Important for null segregants

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

Important for gene edited organisms

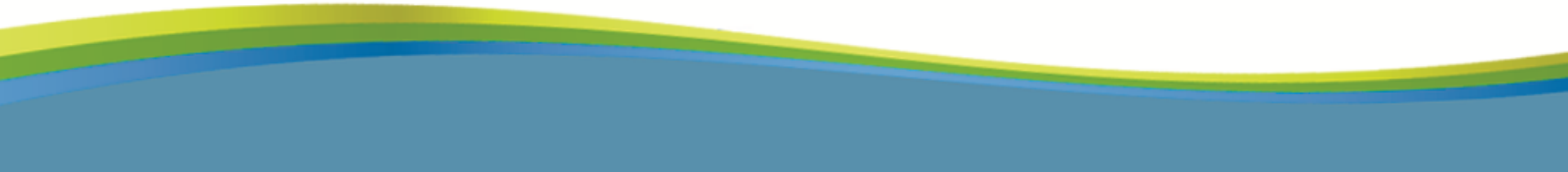
“...derived or developed from....”

How may we interpret this with respect to null segregants?

- Final food producing line has not inherited the genetic modification although one or more of the breeding parents have been “modified using gene technology”

What do we know about the intent of this wording?

- There were several iterations of the definition
 - “....obtained from an organism....”
 - “derived from an organism.....”
 - “....derived directly from an organism....”



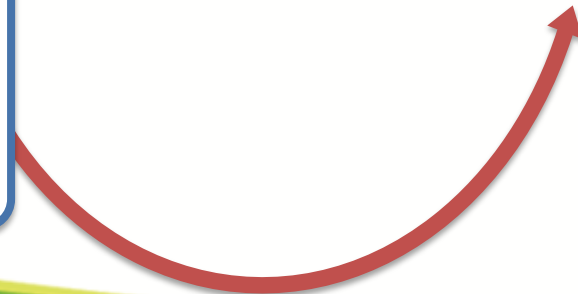
Option 1

- “derived” means “originate” and “come from a source or origin”
- “developed” means to “generate; evolve” and “gradually come into existence”
- the wording does not restrict the food to being *immediately* or *directly* derived or developed from an organism which has been modified by gene technology

Apply a literal, dictionary definition interpretation

Outcome

- Null segregants captured because they are descended from an organism that has been modified using gene technology



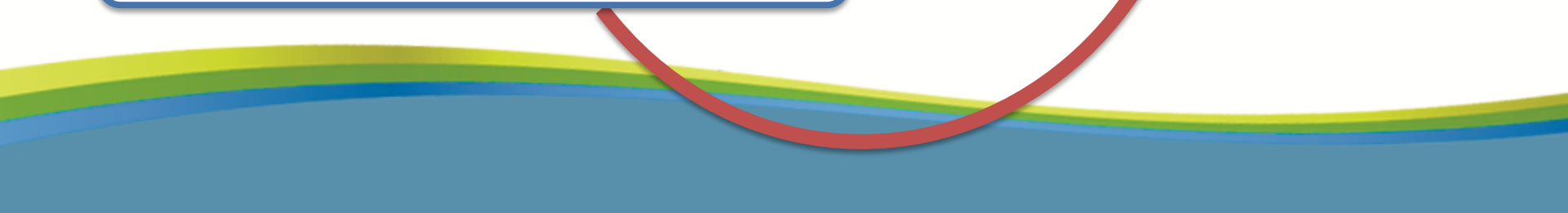
Option 2

- “derived or developed from” appear in a specific context – using recombinant DNA techniques to alter the heritable genetic material of living cells or organisms
- Could reasonably argue the words are concerned with the inheritance of altered genetic material

Have regard to the meaning within the context of Standard 1.5.2 as a whole

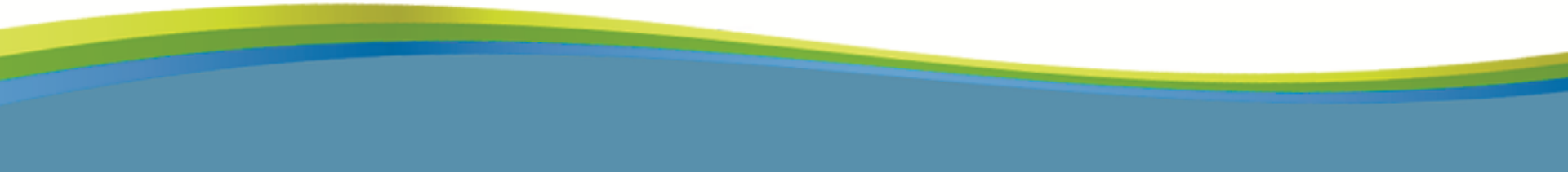
Outcome

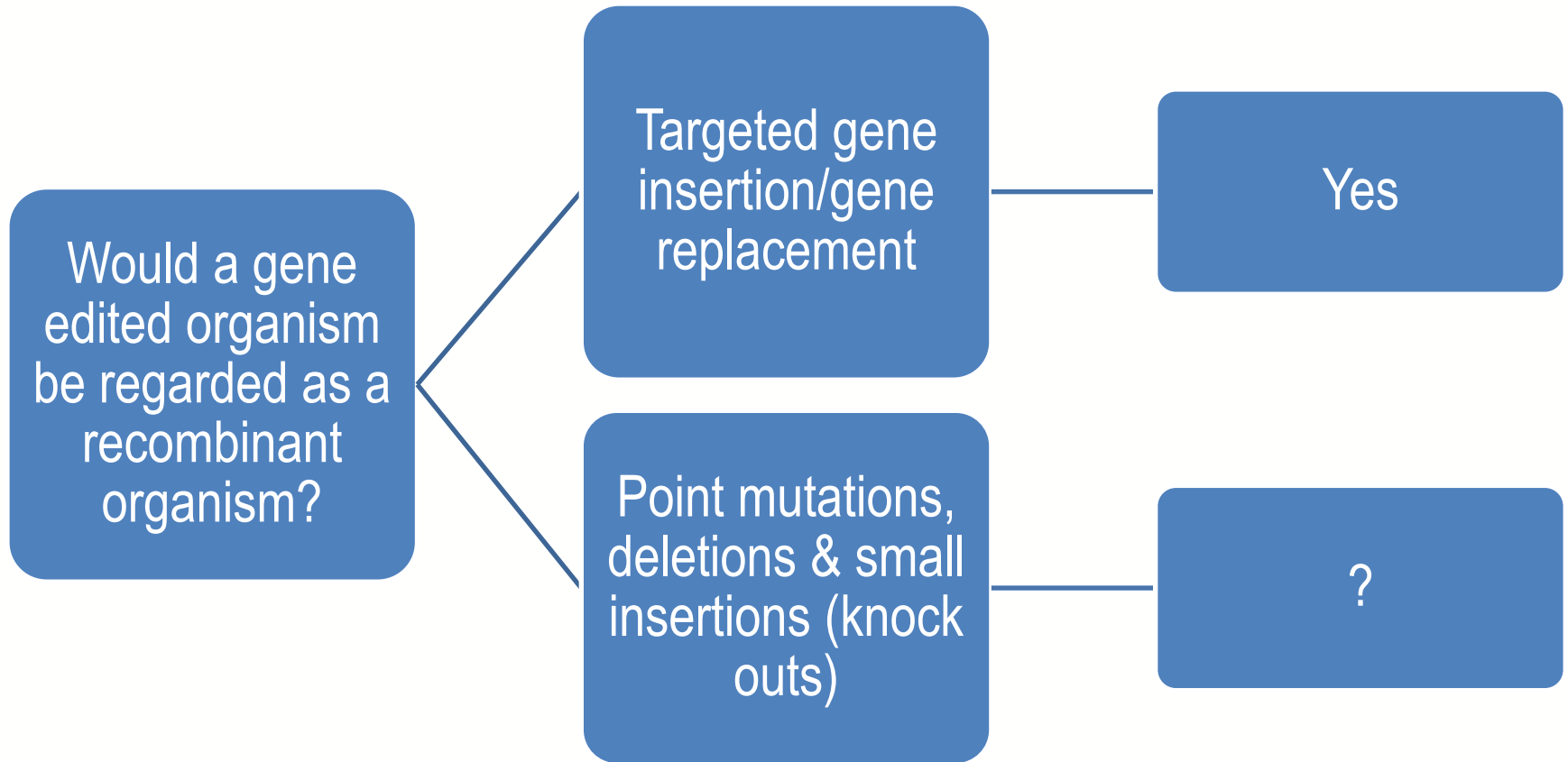
- Null segregants excluded because they are not themselves modified using gene technology, nor have they inherited a genetic modification introduced using gene technology



“recombinant DNA techniques”

- **Not defined in the standard**
 - Commonly understood to mean techniques that combine DNA from two or more sources (may or may not be different species)
- **Its meaning should be considered in the context of the rest of the definition**
 - “.....used to alter the heritable genetic material of living cells or organisms”
- **Could reasonably argue this refers to techniques that result in the presence of recombinant DNA in the genome of an organism = a recombinant organism**





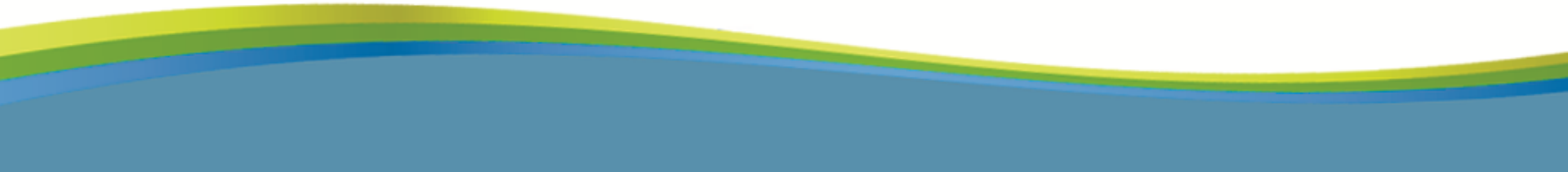
FSANZ View

‘derived or developed from’

- The genetic modification that was introduced using gene technology should be present in the organism that produces the food

‘recombinant DNA techniques’

- Means recombinant DNA should be present in the organism
- Organisms with small nucleotide changes or deletions introduced using gene editing techniques are not recombinant organisms

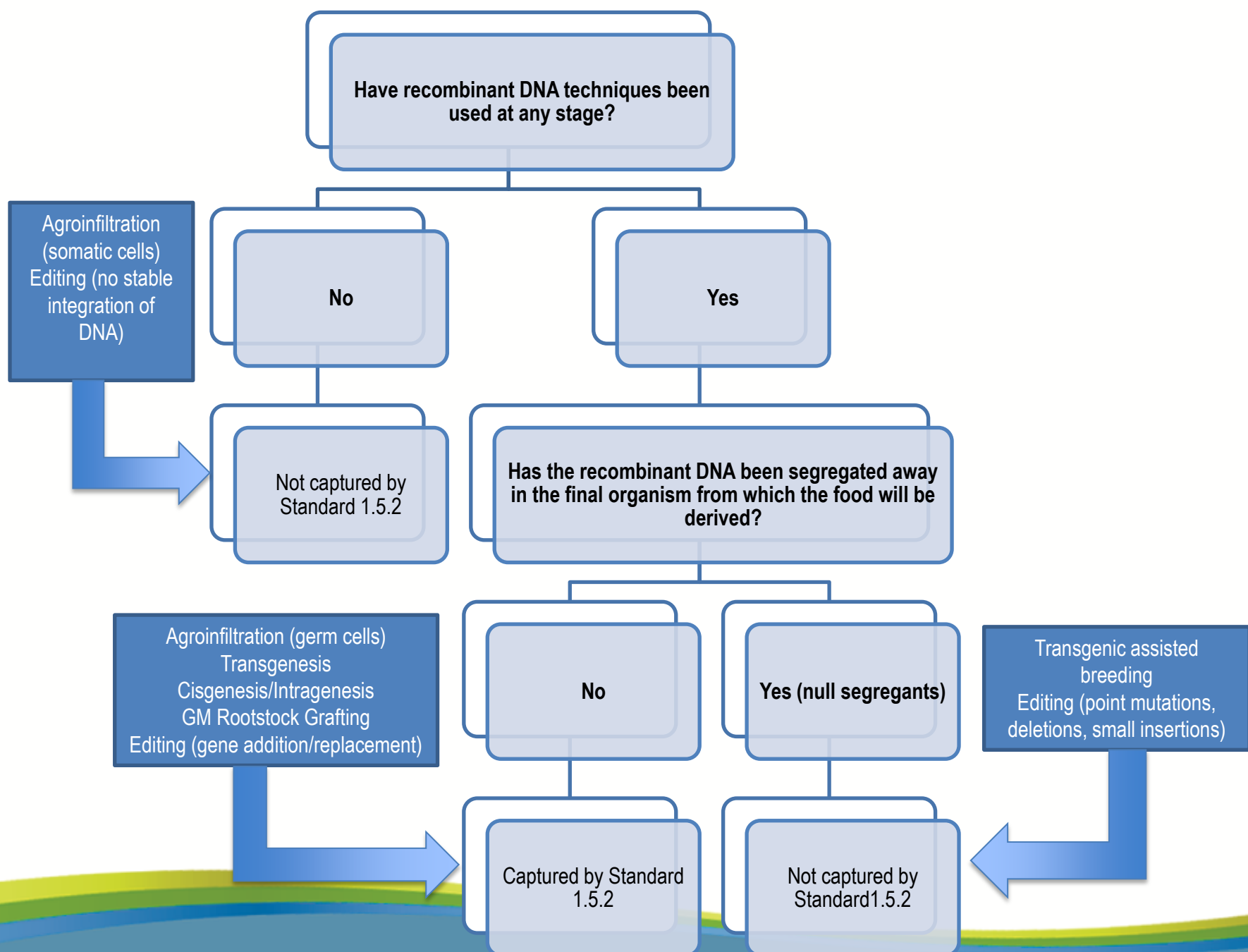


In other words.....

Only food obtained from recombinant organisms (organisms having recombinant DNA in their genome) is captured by current definitions in Standard 1.5.2

This would have the effect of excluding all null segregants, including gene edited organisms with small nucleotide changes, or deletions







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FSANZ 25th birthday cake - August 2016

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