

Board Meeting FSANZ68, December 2016 – AGENDA ITEM D5

New Breeding Techniques - Update

TALKING POINTS

- We last updated the Board on new breeding techniques or NBTs in March 2014 (FSANZ57). Since then there have been a number of developments which has prompted further work on the issue.
- The main issue for us and stakeholders is uncertainty about whether foods produced using NBTs come within the scope of Standard 1.5.2 Food produced using gene technology. This issue is not unique to FSANZ. It affects gene technology regulations all around the world.
- This uncertainty arises because most definitions for gene technology were developed over 15 years ago when the methods, collectively referred to as NBTs, had not yet been developed.
- When this issue first came to our attention in 2011 we responded by convening two technical workshops on NBTs (in 2012 and 2013) to improve our knowledge and understanding of the techniques and types of food products that would be produced. The reports from both workshops are available on our website and were well received by the scientific community.
- In our report to the Board following the first workshop (December 2012), we noted it was unclear whether some of the techniques would be captured by definitions in Standard 1.5.2. This is because the definition for gene technology in the standard is centred around the introduction of DNA from another source, resulting in a recombinant organism. All the GM foods approved to date are derived from recombinant organisms, whereas some of the new techniques do not result in recombinant organisms.
 - The technique causing the most uncertainty is gene editing. Gene editing is often used to make the same sort of changes as conventional breeding methods. Gene editing is often preferred over these methods because it's quicker and more precise. Food from gene edited plants and animals is often very similar to conventional food.
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 - A variety of NBTs also result in what are called null segregants. Null segregants are descended from a GM line but have not inherited the genetic modification present in that GM line. Food products from null segregants are indistinguishable from conventional foods.
- The uncertainty is complicated by the fact that FSANZ does not have interpretive power when it comes to the Code, so we are unable to provide advice to product developers about whether an application is required under Standard 1.5.2.
- As a consequence, several approaches have been made to us regarding possible applications to trigger an assessment of the regulatory status of specific products, or to apply for an exemption for a specific technique.
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- Given these developments it was considered prudent to raise this matter with jurisdictions and try to develop some consensus around what techniques (and their products) come within the scope of Standard 1.5.2.
- We subsequently held a workshop with jurisdictions at the end of August during which we presented a draft technical framework for determining which techniques may be captured by Standard 1.5.2. The framework was well received by the attending jurisdictions and there was support for FSANZ undertaking more technical work to develop it further.
- The attending jurisdictions were also comfortable with the idea that, under the technical framework being proposed, null segregants, and certain uses of gene editing, may fall outside the scope of the standard.
- We are now engaged in a process to further develop the technical framework. S22

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