Workshop on the Regulatory Status of New Breeding Techniques

TALKING POINTS

Agenda Item 1 – Welcome and introduction from the Chair

Refer to the power point presentation

Agenda Item 2 – Overview of techniques – FSANZ presentation

- In terms of the conclusions from the two workshops, the expert panel considered the techniques from a purely scientific and product-based perspective. Their conclusions therefore are not an interpretation of the standard, but rather are based on their scientific understanding of what is GM.

- One of the important conclusions from the workshops is that techniques resulting in null segregants, and certain applications of gene editing, do not present a greater food safety concern than techniques currently used in conventional breeding (e.g. chemical mutagenesis).

- From a scientific and safety perspective, we are quite comfortable with foods derived from those types of techniques not having to undergo premarket assessment and approval, given their similarity to conventional food products.

- But whether they are actually captured by Standard 1.5.2 is another issue altogether.

- We have tried to avoid making any statements about this that could be construed as a legal determination but what we did say when we released the workshop reports is that we would have regard to the scientific conclusions when considering applications to amend Standard 1.5.2.

- Since the workshops, we have done quite a bit of work in-house on the regulatory issues, as well as keeping in close contact with other regulators, especially the OGTR and the NZ EPA. We have used this time to gradually develop a FSANZ position on NBTs and this is what Lisa will take you through after the coffee break

Agenda Item 3 – Regulatory issues – FSANZ presentation

- The definitions are technical definitions so in our view it's both a scientific as well as a legal question as to how they should be interpreted. We've also tried to have to regard to the original intent of the Standard. Fortunately for us, Lisa was the project manager of that Proposal that lead to the development of the standard so she is well placed to comment on the original intent.

- There are other considerations that are influential in terms of getting outcomes that make sense from a regulatory perspective. The first is enforcement. Null segregants will basically be indistinguishable from conventionally bred organisms. The other issue is that if the end products are essentially no different to food derived through conventional breeding, what is the purpose of subjecting them to pre-market safety assessment.

Agenda Item 4 – Roundtable discussion

- The plan with this session is to break it up into two parts. The first part will be to discuss the interpretation issue and see if we can reach some form of consensus. For the second part of the discussion, we'd like to focus on some of the broader considerations, and this will likely be influenced by how the first part of the discussion has gone.

- So in terms of the first part of the discussion, we've gone over the issues with some of the wording in the definitions and how this is creating interpretation problems for some of the techniques and we've also presented our view on interpretation.

- What do the jurisdictions think about what we have proposed?
    - Is it a reasonable interpretation?
    - Do you see any problems with our interpretation?
    - Are there alternative views around the table?

- While its tempting to bring some of the broader considerations into this discussion, its important to not let that influence the interpretation. The broader issues become relevant once we have decided what is or is not captured by the standard, and whether we think that is appropriate from a safety/risk perspective and also in terms of community expectations.

- One of the important considerations is the harmonisation of regulatory outcomes between food products and GMOs in Australia and New Zealand. FSANZ has been liaising with the OGTR and relevant NZ government agencies for a while now and we thought it would be useful to get an update from them about the work they have been doing in this space.

- International harmonisation and potential trade impacts is another important issue, especially if Australia and New Zealand are out of step with how the rest of the world are regulating these techniques. There is no international consensus on this however, although it seems fairly clear that most jurisdictions around the world are not interested in regulating the null segregants. It's a little less clear in relation to gene editing.

Agenda Item 5 – Agreed outcomes and next steps

- One of the objectives of the workshop today was to see if we could reach some kind of consensus on how Standard 1.5.2 should be interpreted. So first we need to decide what we can agree on, and also what we have been unable to reach agreement on.

- The other thing we need to decide is how to proceed from here, which of course may depend on what we can agree on.

- Questions to get feedback on from the jurisdictions:

    - How should we report the outcomes of this workshop?
    - If we can agree on how to interpret the standard with respect to certain techniques how should we communicate that decision?
    - Do we need to undertake community consultation?
    - What further role do jurisdictions want to play in this?