

Proposal 1055

Definitions of gene technology and new breeding techniques

1st Call for Submissions

Summary

NSW appreciates the opportunity to comment on Proposal 1055 – Definitions of gene technology and new breeding techniques.

NSW applauds the rigour FSANZ has applied to the documents released in the 1st call for submissions to facilitate a constructive discussion on where to position regulatory scrutiny for new breeding technologies (NBT) applied to food.

In principle, NSW supports:

- FSANZ taking a hybrid definitional approach
- The proposed broadening of the process-based definition for ‘gene technology’
- The inclusion of product-based exclusion criteria in defining ‘food produced using gene technology’.

NSW supports an open and constructive dialogue with all stakeholders in this area so industry may be provided certainty in research and development planning and pathways to market, and consumers adequately assured of food safety and appropriately informed on new technologies applied to food.

NSW concurs with FSANZ’s proposed safety assessment principles in reviewing safety risk in NBT applied to food.

Further explanation of these comments is provided below.

Adjusting food derived from gene technology definition for NBT requires a balance of science with informed choice.

NSW concurs with FSANZ’s assessment that the language in the gene technology definition in the Australia New Zealand Food Standards Code (the Code) has fallen out of step with industry innovation, especially NBT. NSW further agrees with the principle of ‘widening the net’ (SD2) so that all types of gene technology are captured by the new definition, rather than limited by ‘*recombinant DNA*’.

NSW supports in principle the definition proposed for ‘*gene technology*’ - techniques that use recombinant, synthesised or amplified nucleic acid to modify or create a genome (page 24 of the 1st Call for Submissions). This appears to capture known and relevant, intentional genetic modification techniques applied to food for human

consumption or immediate pre-cursors to food for human consumption. This widening provides a means to align regulatory scrutiny of *'food produced using gene technology'* with a risk proportionate lens.

To continue to maintain public confidence in the Australian food supply, the difference between *'food produced using gene technology'*, *'conventional breeding'* and *'conventional food'* must be clear. NSW favours retaining the definition of *'conventional breeding'* and suggests further consideration is given to the merits of a *'conventional food'* definition.

NSW notes that current Code provisions (application and mandatory pre-market safety assessment) creates a visible trail of all GMOs deployed in Australian food production. This transparency makes Code listings in Schedule 26 easy to compare with the OGTR register, promoting traceability and synergy between the 2 relevant regulatory systems. An example is [herbicide tolerant GT73](#) listed in [Schedule 26](#) of the code. This was passed into the Code by Application 363. This compares with the OGTR register where [GT73 Canola](#) is a currently listed approval for agricultural use, with the applicant possessing a [risk assessment and risk management plan](#).

NSW supports preserving the [register](#) on the FSANZ website currently in place for pre-market approved genetically modified food.

Guidance material to support use of revised definitions

NSW agrees that guidance material will be required to support an amended Standard 1.5.2 in the Code. This Guidance should provide innovating businesses with interests in gene technology adequate clarity on when it is necessary to seek pre-market safety assessment advice from FSANZ (i.e. what is required to enable FSANZ to undertake pre-market safety assessment, what is required as an information declaration, how can that declaration be made - a label declaration or disclosed in another way).

Advisory Committee for Gene technology – OGTR and TGA membership

NSW supports in principle an advisory committee for gene technology and suggests its membership extends to the Office of the Gene Technology Regulator (OGTR) and the Therapeutic Goods Administration (TGA). Inclusion of the OGTR allows for early detection of submissions that should have also have OGTR approval. Inclusion of the TGA would assist determining whether the purpose of genetic modification is best regulated as a food or therapeutic.

It is possible that some referrals to ACGT could result in future applications to FSANZ to amend Schedules 26 (gene technology), 15 (food additives) or 18 (processing aids). Intention of addition should be determined as either nutritional (nutritive purpose) or technological (food additive or processing aid). If the line between these areas becomes difficult to practically navigate it may become necessary to develop a tool to assist in applying a consistent assessment process in making a decision whether food for sale requires pre-market safety assessment.

2nd call for submissions

To allow for targeted feedback in the 2nd Call for submissions, NSW suggests the following:

- New definitions for *gene technology*, *food produced using gene technology*, *conventional food*, retaining *conventional breeding*. There may also be merit in considering a definition for '*amended characteristic*' so users of the standard may unambiguously determine the degree of difference required in a particular trait of a food to trigger mandatory pre-market safety assessment.
- A membership model and process flow of operations for the proposed Advisory Committee for Gene Technology (ACGT). NSW suggests that OGTR and TGA are invited to participate as well as FSANZ and the jurisdictions.
- The drafting in the 2nd Call for Submissions should clearly describe the regulatory pathway required for all *food produced using gene technology* and offer a risk-based, tiered approach whereby pre-market safety assessment is only required where the resultant food for human consumption contains *novel DNA*, *novel protein* or has an *amended characteristic* compared to the *conventional food* counterpart.
- Clarity on when a declaration requirement applies and appropriate disclosure methods.
- Some form of a centralised register is required to preserve the very high of transparency that exists for the use of gene technology. NSW supports the continuation of this register.

ENDS

The views expressed in this submission may or may not accord with those of other NSW Government agencies. The NSW Food Authority has a policy which encourages the full range of NSW agency views to be submitted during the standards development stages before final assessment. Other relevant NSW Government agencies are aware of and agree with this policy.