

P1055 DEFINITIONS FOR GENE TECHNOLOGY AND NEW BREEDING TECHNIQUES

Second Call for Submissions

September 2024

10 September 2024

Dr Sandra Cuthbert
Chief Executive Officer
Food Standards Australia New Zealand

By email: submissions@foodstandards.gov.au

Dear Dr Cuthbert,

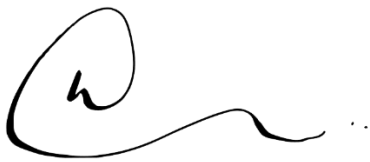
RE: Second Call for Submissions: P1055 Definitions for gene technology and new breeding techniques

Australia's billion-dollar seed industry is the very starting point of vast sectors of Australian agriculture. From direct horticulture and grains production, through to the pasture and feedstock that feeds our livestock industry – seed is an agricultural foundation.

The membership of the Australian Seed Federation covers the full seed supply chain and includes plant breeders, seed growers, seed processors and seed marketers. Some of our membership is involved in gene technology and new breeding techniques.

We welcome the opportunity to comment on the Second Call for Submissions: P1055 Definitions for gene technology and new breeding techniques,

Yours sincerely



Katherine Delbridge
Chief Executive Officer

In Australia, the seed industry is a vital link in the development of crops that are critical to the nation's agricultural productivity, sustainability, and food security. The ASF is providing this submission in the interest of developing a nationally and internationally consistent approach towards the regulation of food derived from gene technology, and to future-proof ASF members' ability to deliver the best seed and technology to farmers.

The Australian Seed Federation welcomes FSANZ's proposal. There has clearly been an acceptance of much of the feedback FSANZ received from the first call for submissions in 2021 and we welcome the shift from a process-based approach to a product-based one. This shift will greatly assist in modernising our regulatory framework and see that it aligns with international standards.

However, the definition of "Novel DNA" requires further refinement and/or clarification.

1. Genetically Modified Food Definition

ASF supports in principle the definition of "Genetically Modified Food". The updated definition provides a clear understanding of the distinction between genetically modified foods and foods that do not require a pre-market safety assessment.

What still requires clarification is what becomes of processed food products derived from organisms containing "Novel DNA" but lacking novel DNA or the resultant protein in the final refined product which is sold to consumers. ASF views getting this piece right as crucial as the proposal to capture processed food ingredients that do not contain novel DNA or novel protein as genetically modified food is contradictory to the outcomes-based approach sought by FSANZ.

ASF supports the exclusion of null segregants, however this definition could be strengthened by including a simple statement; Null segregants are the offspring of GMOs that do not inherit the GM component.

2. Novel DNA Definition

The proposed definition of novel DNA aims to capture DNA sequences that are not naturally occurring within the gene pool of a species or a sequence that could not be introduced through conventional breeding methods.

This definition could be strengthened to provide greater clarity and avoid potential overregulation in various locations:

- The use of the phrase "has not previously" in sections b(i) and b(ii) complicates the definition by introducing a temporal aspect to cross-compatible gene pools.
Suggested replacement: Replace "has not previously" with "that cannot be".
- The current phrasing of b(ii) appears to target intragenic modifications that result in novel proteins. However, it is unclear whether this also includes changes like promoter rearrangements that do not alter the protein-coding sequence.
Suggested replacement: Novel DNA should be defined as referring specifically to 'coding sequence'. This will align with FSANZ's stated objective of exempting molecular scars and codon optimisation.
- Intragenesis should not be included within the definition of novel DNA. Because, as a subset of cisgenesis, intragenesis can be achieved through conventional breeding. This should not be confused with transgenesis, which involves the insertion of DNA from different species or

species not sexually compatible with the target organism and cannot be achieved through conventional breeding.

Suggested replacement: Remove intragenesis from novel DNA definition.

2.1 Novel DNA Proposed Definition

The ASF would like to see the proposed definition for novel DNA revised to ensure:

- Novel DNA means DNA in the form of coding sequences that have been stably inserted into the genome and:
 - are from genetic sources outside of an organism’s cross-compatible gene pool; or
 - could not have been introduced using conventional breeding methods, or could not occur in nature; or
 - are not from an existing species.

In summary, for these definitions to be future-proof and assist in creating a modern regulatory framework that aids global harmonisation:

- The definition of “Genetically Modified Food” must not inadvertently capture foods that are presently exempt from classification as GMOs under the Food Standards Code; and
- The proposed definition of “Novel DNA” can be simplified to exclude foods derived from intragenic organisms where the outcome is the same as could have been obtained through conventional breeding.

A note on market access

Coexistence in Australian farming where different agricultural systems – such as genetically modified (GM), organic, and conventional farming – can operate side-by-side without cross-contamination and therefore preserving market access is now commonplace.

The Australian seed industry supplies markets with all subsets of seed, including organic and GM. The markets and supply chains exist to handle these diverse inputs and are therefore already prepared for the introduction of any new technologies.

This review of definitions for gene technology and new breeding techniques offers an opportunity to modernise the regulatory environment and ensure new innovations – like those in seed – can be accessed by those they have been developed for. Given the maturity of our supply chains, this can – and must – be achieved without diminishing market access for other segments of industry.