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10 September 2024

Food Standards Australia New Zealand
PO Box 5423
KINGSTON ACT 2604

By email only: submissions@foodstandards.gov.au

Dear Sir/Madam,

Re: Proposal P1055 – Definitions for gene technology and new breeding techniques

Thank you for the opportunity to provide comment on the proposal (the Proposal) to amend the definitions in the Australia New Zealand Food Standards Code (the Code) for 'food produced using gene technology' and 'gene technology.'

Animal Medicines Australia (AMA) is the peak industry association representing the registrants and approval holders of veterinary medicines and animal health products in Australia. They are the local divisions of global innovators, manufacturers, formulators and registrants that supply essential veterinary medicines and animal health products that are critical to supporting Australia's $34 billion livestock industry and the $33 billion pet industry. Our members represent more than 90% of registered veterinary medicine sales in Australia.

AMA and its members have a long-standing commitment to an animal health industry that is responsible and sustainable. Our members' products are essential tools that can help meet economic, environmental and social challenges.

AMA member companies play a vital role in Australia's food production, agricultural trade and biosecurity preparedness, as well as ensuring the health and wellbeing of our pets, wildlife and competition animals. AMA members develop, register and supply innovative new medicines including vaccines and anti-infection medicines to prevent and control outbreaks of animal disease, as well as medicines and treatments that enable good health and wellbeing, and the production of food and fibre products that are safe for human consumption and use. Healthy animals are much less susceptible to disease and infection, and good animal health is essential to good animal welfare.

Ensuring access to animal health products is vital to maintaining not only the health and wellbeing of the animals in our care, but also Australia's rigorous biosecurity systems, public health and access to safe, nutritious, affordable food.

Animal Medicines Australia is pleased to provide the following comments on the Proposal for consideration by Food Standards Australia New Zealand (FSANZ).

General comments

Next-generation breeding techniques (NBTs) products are becoming increasingly important tools in veterinary medicine, just as they are in human medicine. In the future, innovative new veterinary medicines developed using NBTs may be registered for use in Australia, such as antisera, vector vaccines, antivirals, immunoglobulins and monoclonal antibodies.

AMA supports the regulation of NBTs and genetically modified organisms (GMOs) in a way that reflects a true level of risk and is based on reliable scientific evidence. We support a science-based regulatory system that allows new technologies to be used to improve animal health and welfare, and protect public health, while preventing unacceptable risks to the health of animals, people or the environment.

AMA welcomes the adoption of an outcomes-based approach to regulation by FSANZ, which incorporates NBTs and, consequently, aligns more closely with international standards than the current, process-based regulatory approach.

Further refinement and clarification in some areas of the proposal are, however, necessary to fully modernise the regulatory approach taken by FSANZ and ensure harmonisation with international standards.

Additional guidance material that assists product developers, applicants etc. in determining whether their product requires pre-market assessment without additional input from FSANZ would be valuable. A series of examples in the form of worked solutions or flow diagrams based on existing products to determine the presence of novel DNA would facilitate greater stakeholder understanding.

Definitions

Genetically modified food

AMA supports the proposal to repeal the current definitions for ‘food produced using gene technology’ and ‘gene technology’ and replace them with a new outcomes-based definition for ‘genetically modified food.’ This revised approach to define genetically modified food according to the outcome of the genetic modification process, rather than the process itself without consideration of the outcome, is welcome.

This outcomes-based approach will enable the regulatory environment to keep pace with innovative NBTs and ensure a risk-based approach that is aligned with international standards to regulating foods derived from these processes. Many NBT-derived products are genetically identical to, and thus indistinguishable from, the same products developed using conventional breeding methods. For example, selective breeding through successive generations has traditionally been used to promote certain genetic traits, such as polled (hornless) cattle or particular fleece types in sheep. NBTs can achieve the same end point (i.e. a cow that lacks horn buds) relatively quickly, and with a much greater level of precision and control by targeting only the specific genes associated with the desired trait.

When a food derived using NBTs is equivalent in its characteristics to food derived from conventional breeding techniques, it is appropriate that it is regulated in an equivalent manner.

The proposed definition for ‘genetically modified food’ provides a clear distinction between genetically modified organisms (GMOs) and genetically modified derived food additives. AMA further supports the exclusion of null segregants (i.e. the offspring of GMOs that do not inherit the GM component) and recommends the inclusion of a precise definition of null segregants that provides clarity to industry and FSANZ and supports a risk-based approach to regulation.

The Proposal outlines an intent to base the revised definition of ‘genetically modified food’ on the presence of ‘novel DNA’ in the genome of an organism – specifically by the “insertion of novel DNA into the genome.” AMA supports the intent to base this definition on the presence of novel DNA in the

genome; however, further refinement of the definition of 'novel DNA' is required to more clearly outline the scope of what constitutes a genetically modified food product.

Novel DNA

AMA supports the intention of the proposed definition of 'novel DNA' to capture the insertion of DNA into a genome or cells that are not naturally occurring within a species' gene pool or could not be introduced through conventional breeding methods. Nevertheless, further refinement of the proposed definition is recommended to avoid overregulation.

AMA recommends excluding intragenesis from the definition of 'novel DNA'. Intragenesis involves the transfer of a combination of DNA from one or more individuals, or other areas within the genome, from the same or a sexually compatible species. Cisgenesis, which has been excluded from the definition, involves the transfer of a single continuous DNA sequence from the same or a sexually compatible species. Both of these processes can be achieved through conventional breeding techniques and differ from transgenesis, which involves the insertion of DNA from different species or species that are not sexually compatible with the target organism and which cannot be achieved through conventional breeding techniques. Consequently, as intragenesis can be achieved via conventional breeding techniques, the inclusion of intragenesis within the definition of 'novel DNA' does not reflect the intention of the proposed outcomes-based regulatory approach. Excluding intragenesis from the definition would provide greater alignment with existing standards in other equivalent countries (e.g. Canada).

AMA understands that any alterations to the genome achieved via techniques that did not involve "insertion" but instead, were the result of genome editing (e.g. deletions, inversions etc.) would be excluded from the definition of 'novel DNA.' It is unclear from the Proposal, however, whether changes including promotor rearrangements that do not alter the protein-coding sequence are included in the proposed definition of 'novel DNA'. Clarification that 'novel DNA' refers specifically to 'coding sequence' would ensure alignment with the intention of excluding molecular scars and codon optimisation from the definition of a genetically modified food. Further clarity is required as to whether these alterations would be instead by captured under FSANZ's Novel Food Standards.

For clarity, AMA recommends replacing the phrase "has not previously" with "could not have" in sections b(i) and b(ii) of the proposed definition of 'novel DNA' for greater clarity and to remove any potential temporal aspect to cross-compatible gene pools.

Replacing 'species' with 'gene pool' would more accurately capture the total range of cross-compatible germplasm available to a breeder for improvement of a particular species.

Finally, AMA recommends clarifying that the definition applies to novel DNA that has been *stably inserted* into the genome, to avoid any confusion regarding rapid degradation of inserted DNA.

AMA supports the amended definition as proposed by CropLife Australia that incorporates the above:

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

In Summary:

AMA supports:

- The proposal to adopt an outcomes-based approach to regulation.

AMA recommends:

- Further refinement of the definition of ‘novel DNA’ to exclude intragenesis to ensure alignment with the proposed outcomes-based regulatory approach and existing Health Canada standards.
- Clarification that ‘novel DNA’ refers specifically to ‘coding sequence’ to ensure alignment with the intention of excluding molecular scars and codon optimisation from the definition of a genetically modified food.
- Replacement of the phrase “has not previously” with “could not have” in sections b(i) and b(ii) of the proposed definition of ‘novel DNA’ for greater clarity and to remove any potential temporal aspect to cross-compatible gene pools.
- Replacing ‘species’ with ‘gene pool’ in part a) of the definition of ‘novel DNA’.
- Clarification that ‘novel DNA’ refers to DNA that has been stably inserted into the genome.

If we can provide further information at any time, please do not hesitate to contact me.

Yours Sincerely,

Dr Katie Asplin

Director, Animal Health Policy and Engagement