By email:

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Australian Academy of Science and Australian Academy of Technology and Engineering joint submission to the Food Standards Australia and New Zealand consultation on Proposal P1055: Definitions for gene technology and new breeding techniques

The Australian Academy of Science and the Australian Academy of Technology and Engineering (jointly, the Academies) welcome the opportunity to contribute to the consultation on the Food Standards Australia and New Zealand definitions for gene technology and new breeding techniques.

The Academies support the responsible and ethical use of biotechnology, including gene technologies, to produce genetically modified plants and animals for use in Australian agriculture and medicine. The Academies continue to support a regulatory scheme for gene technology that is proportional to the risk being managed, and which provides benefits that outweigh the costs of regulation.

The Academies are broadly supportive of FSANZ's preferred option in the *Call for Submissions*, Option 3, and support the proposed approach to defining genetically modified food. However, the nuance of the definition and consequent exemptions will need to be carefully managed to not stifle innovation in the field of gene modification while ensuring safety.

The Academies acknowledge that Option 3 would require amended definitions in the Food Standards Code, and recognise the strengths of this approach to capture current and future developments in the gene technology field. This option involves revising (and broadening) the process-based definition for 'gene technology' to capture products developed using New Breeding Technologies (NBTs). Product-based criteria will then be used to exclude certain NBT foods that are substantially equivalent to conventionally produced foods from the pre-market safety assessment required of genetically modified foods. Within the constraints for the current system, this appears to be a pragmatic approach that will meet the need for food safety going forwards without severely restricting research. The Academies therefore support this approach.

The Academies continue to prefer a purely product-based system that focusses on the risks posed by the final product rather than the technology used to create it, but acknowledge the constraints that make such a system impractical at the current juncture in Australia and New Zealand.

The definition of genetically modified food.

While no exact definitional changes have been finalised, FSANZ proposes adopting a definition similar to that used by the United States Department of Agriculture as their definition for 'genetic engineering':

> "[T]echniques that use recombinant, synthesised or amplified nucleic acid to modify or create a genome."

This is a broad definition that captures what is currently considered "genetic modification". Such a definition would cover potential new foods or food ingredients derived from novel organisms generated through gene editing and Synthetic Biology approaches. It would also capture epigenetic changes, which can be stably inherited for a few generations without changing the gene sequence. Broadening the definition carries the risk that inappropriate techniques will be captured, but this risk is ameliorated by the product-based exclusions. The Academies support this approach.

The proposed definitional and exclusion changes would, however, lead to a disparity in what is designated as a GM food by FSANZ, and the narrower definition of gene editing used by the Office of the Gene Technology Regulator. While this is discussed in the Consultation documents, it may be pertinent to make an explicit statement in the Code or the Guidance documents that food products need to satisfy *all* relevant regulations before they can be used for human consumption. The situation might arise, for example, where a grafted organism with a non-GM scion and food derived from it would not be regulated by FSANZ, but its GM-rootstock would still be subject to regulation by the OGTR as it requires the release of a GM organism into the environment.

The Academies trust that the Australian regulators of gene technology and products derived from gene technology will work towards a harmonisation of their definitions to prevent uncertainty and confusion by researchers, product developers and importers.

Null segregants

FSANZ proposes to explicitly exclude null segregants from the definition of GM food. This is scientifically appropriate and in accord with the recent changes to the definitions in the Gene Technology Act.

NBT food that is the same as conventional food

Any new foods produced using NBTs that are biologically and biochemically indistinguishable from unmodified foods generated by conventional breeding techniques present no greater risks to human health than the corresponding unmodified foods, and the Academies believe that it is therefore appropriate to exclude such foods from pre-market safety testing.

Care would need to be taken with the definitions and wording of the exclusions to avoid unintended and perverse outcomes. For example, the criteria as described would mean an organism engineered to remove an allergen would be subject to a safety assessment by "modifying the endogenous allergen content", even if the only change was a single nucleotide alteration to a gene and loss of production of its allergen component. Such an outcome could also be achieved, perhaps more slowly, by traditional approaches such as random mutagenesis. Under the proposed changes to the Code, one product would require safety assessment and the other would not, even though they may be identical in genome sequence and product composition.

Similarly, greater clarity is needed in the definition of "conventional foods" and the range of properties displayed by those foods. High amylose wheat, for example, would have many health benefits from its resistant starch, but under the proposed exemption categories foods containing whole grains of high amylose cereals generated by NBTs would require safety assessment as the amylose levels would fall outside the natural range for that form of starch. An identical product produced by crossing together natural mutant alleles of the appropriate enzymes would not require assessment. Should the exemption be on the basis of comparisons of what *could* be achieved by

conventional breeding rather than just “outside of the *documented* range for an equivalent conventional food”? Greater clarity will be needed so as not to inhibit innovation in the field, and the Academies support the development of an advisory body within FSANZ, similar to the current Novel Foods Committee, to help product developers navigate the proposed changes to the Code. It will be critical to have well-considered guidance materials for product developers and importers if Australia and New Zealand are not to miss out on the benefits that these new advances in NBTs will bring to agriculture and nutrition.

The Academies concur with the safety assessment that cisgenic organisms (involving the transfer of whole genes from the same or closely related species) are equivalent in risk to those created through crossbreeding and other traditional breeding methods, such as mutagenesis. While the process of transformation itself may lead to some unintended mutational changes or chromosomal rearrangements within the cisgenic organism, these would be no different to those that result from chemical or radiation induced mutagenesis, interspecific crosses with embryo rescue or protoplast fusion. Poorly performing cisgenic individuals would be removed from breeding populations through standard selection regimes and so do not require the level of scrutiny given to GM organisms where novel traits are being introduced. Intragenesis may fall between these two categories as there is the potential for assembling novel combinations of domains within genes from the same organism that may lead to unexpected outcomes so may require case-by-case assessment. For that reason, presence of “foreign DNA” should be the determinant of genetically modified status rather than the catchall of “recombinant DNA” - but the definitions will need to be couched in such a way as to capture only the intended products.

Refined ingredients

The Academies support FSANZ’s reasoning and conclusion with respect to refined ingredients that are chemically equivalent to ingredients derived from current agricultural and industrial sources. The proposed exclusion criteria are appropriate.

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