Australia's National
Science Agency

Definitions for 'food produced using gene technology' and 'gene technology'

Food Standards Australia New Zealand

CSIRO Submission 21/768

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[redacted]

Contents

Introduction

Thank you for the opportunity to comment on the FSANZ 1st Call for submissions – Proposal P1055.

Since the first commercial planting of GM crops in 1996, there have not been any reported incidents of harm to an individual or to the environment attributable to the genetic modification itself. In contrast, GM crops have contributed to sustainable agriculture and created significant economic value.

The societal benefits of this technology have been hampered by globally inconsistent GM regulatory frameworks. Lengthy and expensive process-based regulation, dissociated from pragmatic risk assessments, have further impeded realisation of the technology's potential benefits. This difficult regulatory landscape has concentrated use of the technology into the hands of just a few global players, stifling innovation and competition.

Despite these hurdles, CSIRO has successfully brought a number of GM products to market with its partners, notably omega-3 canola, high oleic safflower, and insect resistant cowpea. Each of these products have taken over 10 years to develop, and the list could have been many times longer if regulation was commensurate with risk.

We encourage FSANZ to reconsider the entire gene technology regulatory framework and move toward product-based regulation in proportion to risk; recognising that this may be a difficult, sensitive, and protracted process. CSIRO supports FSANZ in its aim to dissociate the regulation of GM foods from those produced using NBTs, through modifying the definition for 'gene technologies', and using a product-based regulatory framework. We see this as a reasonable first step in the right direction, protecting the economic opportunity provided by new breeding technology products that are indistinguishable from those developed through other breeding techniques.

CSIRO also continues to support harmonising approaches with other regulators, where achievable.

This submission has been prepared in consultation with CSIRO researchers in new breeding technologies across the fields of agriculture, food, livestock, aquaculture, health, and biosecurity.

Regulatory Approach to New Breeding Technologies

CSIRO supports the proposed hybrid approach to regulating food and food ingredients generated using new breeding techniques (NBTs) using a broad process criteria/definition to capture all potential NBT products and then a range of exclusions from pre-market safety assessment for specific products based on their "product characteristics" and similarity to foods and food ingredients that could be produced using conventional breeding methods, which are not currently subject to pre-market assessment.

This hybrid regulatory approach allows for regulation that is proportionate to risk and is in line with the role of FSANZ as a food safety regulator. The same approach extends to highly processed food ingredients derived from NBT sources.

This class of product is likely to form a large proportion of NBT products in the next few years, as there is already significant investment into developing NBT microorganisms and plants to produce novel or 'conventional equivalent' food ingredients. All such products would remain subject to all the normal general food safety requirements under the Code to ensure consumer safety. We expect the status quo would continue to apply to any novel foods requiring assessment regardless of how they were produced, i.e., that NBT process would not trigger novel food assessment just due to the modified process when the safety is equivalent to the conventional counterpart.

Regulatory Harmonisation

While global regulatory harmonisation is highly desirable, CSIRO understands this is a difficult long-term process that may take several years and could ultimately prove to be unachievable given divergent views and systems across jurisdictions. As new NBT foods are either here or imminent, FSANZ must proceed now with the interests of food safety for Australia and New Zealand at the forefront. CSIRO is concerned, that within our jurisdiction there is inconsistency between regulations for Gene technology R&D and GM Food safety, and that there is a disparity between what OGTR and FSANZ will define as GM once these changes to the Code are implemented. Clarity will be required from both Regulators in relation to how developers, producers, importers, and marketers will have to deal with products that fall into different categories within the two Australian regulatory systems. According to the OGTR, products produced by NBTs using different methods (e.g. SDN-1, SDN-2 and SDN-3) are considered GM or non-GM based on the particular process used to produce them, even if identical in outcome and potentially indistinguishable at the molecular level). The proposed changes to the Code would be agnostic to the NBT method used and would only be triggered if the product did not satisfy the exclusion criteria or was sufficiently novel to warrant detailed safety assessment. While this dichotomy is noted in the Consultation document it should be clarified further in the Guidance documents to inform developers or importers how they should treat such material.

Definition of Gene Technology

As the updated definition/s of gene technology have yet to be proposed by FSANZ, in principle CSIRO supports updating the definitions for both gene technology and food produced using gene technology. Clearly NBT and synthetic biology developments have rendered the existing definitions not fit for purpose. The inadequacy of the current definitions leads to regulatory uncertainty and ambiguity for developers of new foods and food ingredients using NBTs, and in time may erode public confidence in the food regulatory system.

A definition of 'gene technology' somewhat like that adopted by the USDA (Supporting document 3 - *Compilation of regulatory approaches and definitions*) could be considered as it also includes modified genomes and should capture novel foods or food products and food ingredients generated using synthetic biology approaches from potentially completely novel organisms. If terms like 'recombinant DNA', 'foreign DNA', 'conventional foods' etc. are used in the formal definitions, CSIRO would like to see those terms clearly and legally defined in the Code. Technological developments may still potentially render some terms outdated in the future.

The intent of these definitions is to capture genetic changes accompanied through molecular biology techniques, excluding conventional breeding and mutagenesis. An approach toward re-definition of gene technology could be:

Genetic changes, or creation of novel genomes, directed through application of molecular biology techniques, excluding those meeting the criteria listed in a schedule.

The above approach may introduce a need to then define terms such as molecular biology, similar to the need to define terms for other possible definitions.

The example regulatory approaches (Supporting document 3 - *Compilation of regulatory approaches and definitions*) show many definitions include elements such as "foreign genetic material" or in Argentina's case "novel combination of genetic material". Natural variation continually provides novel combinations of genetic material in all organisms and foreign DNA is likewise present through contamination. As noted in section 3.3 of the call for submissions document, FSANZ's risk assessment found that product characteristics are the key determinant of whether a pre-market safety assessment is required, not the types of genetic change occurring in a food organism or whether the changes were intended or unintended. The presence of novel or foreign genetic material is a poor proxy for risks posed by the food characteristics. Additionally, testing for presence introduces an uncertain target for industry if testing methodologies increase their sensitivity to lower-level presence.

Exclusions from Pre-Market Safety Assessment

The exclusion criteria for 'NBT foods' based on 'similarity to conventional food products with a history of safe use' or 'conventional foods' will need to be clearly expressed to allow efficient determination of a food's status. The measure of conventional equivalent foods, e.g. those available now with history of safe food use (similar to the concept of traditional foods in the novel food framework) or that could be developed by conventional breeding processes will need to be clarified. While this exclusion would exclude products if their characteristics fall within the current range of properties or composition already found in currently consumed foods that have arisen due to natural genetic variation or produced using conventional breeding techniques such as crossing or mutagenesis, it is unclear if this is intended to include foods that might fall outside of that existing range, such as 'BARLEYmax' or high amylose wheat, for example, that 'could' be produced using either conventional mutagenesis, or crossing, or generated using NBT. If these types of products were produced using NBTs, would they (as suggested in Table 1, pg. 16 of the Call For Submissions) always require pre-market safety assessment as GM foods? In this example they would have an amylose content well outside of the 'natural' range and may not have had a demonstrated history of safe use when first developed (BARLEYmax was put to the FSANZ Advisory Committee for Novel Foods and found 'not to be a novel food') or would they fall under 'conventional foods'? This really revolves around clarity of the definition of what 'conventional foods' really means and what product types FSANZ intends to capture for pre-market assessment. We note the USA allows for modifications that "could have been achieved through conventional breeding".

It is important that the new definition excludes food ingredients specifically next to foods in general, as the limitations on offering for retail sale of food and food ingredients that are not expressly permitted by a pre- market assessment process are addressed individually in Standard 1.1.1 of the Food Standards Code [regulations 1.1.1-10 (5) and 1.1.1-10 (6), respectively].

CSIRO agrees with:

1. The exclusion of GM rootstock grafting as requiring pre-market assessment, noting that use of the plants in horticulture would still require OGTR approval for commercial release of the rootstock into the environment.

2. Cisgenics being excluded provided there were no unintended effects on endogenous genes caused by the insertion process, but this is covered by Call For Submissions pg. 26 points (ii)-(iv).

3. Refined ingredients used as food ingredients, or processing aids should not be considered GM-foods if they meet the indicated exclusion criteria as these ingredients have the same risk profile as conventional products.

Call For Submissions pg. 26 point (ii) may need guidance around what are considered to be endogenous toxicants – some 'highly desirable components' of foods are in fact also toxic compounds (caffeine in tea and coffee products, theobromine in chocolate etc) – is it FSANZ's intention to require pre-market safety assessment of caffeine-free coffee or tea produced using NBTs when similar products produced using chemical treatments are not so regulated? Should the terminology not be 'modify', but specify the direction of the change i.e. 'substantially decrease key nutrients or substantially increase endogenous toxicants or anti-nutrients' or allow change within a safe range? Noting that some increases or reductions might be beneficial?

It is unclear why FSANZ would be concerned about safety implications of removing allergens from foods (pg. 26 dot point (v)) and specifying it as a criterion for triggering pre-market safety assessment. It is understandable that any increases in allergen content need to be evaluated and assessed, but removal of allergens or significant reductions in the allergenicity of foods should be encouraged. This is in fact, an ideal application for NBTs as it can use targeted knockouts of allergen-encoding genes, which could be achieved by mutagenesis or inter-crossing of natural mutations in those allergen genes. Perhaps section (v) should be '…has not been substantially increased as a result of gene technology', bearing in mind that there will be natural variation in the amount of such allergens in foods and some small increases may occur through natural variation. Any changes to alter allergenicity through modifying allergen protein sequences would be captured under dot point (iii) as it would generate a substance that is not present in existing conventional foods.

Guidance and Advisory Council

CSIRO endorses establishment of an Advisory Committee to provide non-binding advice to proponents on what is and isn't a GM food under the Code, akin to the existing Advisory Committee for Novel Foods, this will assist in providing certainty for developers encouraging innovation in the food industry. Provision of well-designed guidance documents is critical to support both developers and the public understand the scope of changes to the Code and its application to all organisms, not only plants. It will be very useful for food developers if the guidance documents, particularly in relation to the determination of whether the food is GM or an excluded NBT, include the criteria against which the food will be assessed and a wide range of example assessments.

It would be useful for food developers to have guidance and clarity on which methods they can use to:

1. demonstrate indistinguishability to conventional food (i.e. what authenticity methods), and

2. demonstrate absence of novel DNA or novel protein (i.e. what testing methods shall be used and what levels are acceptable, if any)

CSIRO agrees that Call For Submissions pg. 26 dot point (i) will require a legal definition of what constitutes 'foreign DNA' (or 'recombinant DNA' if that is used instead) and the guidance material should clarify whether it is intended to capture either/or both of cisgenic and intragenic derived foods etc. and to prevent getting into the quandary that the OGTR battled with in relation to using repair templates in gene editing using SDN-2 as that process is guided by a synthetic DNA molecule which could be considered 'foreign' even though it is the same sequence as occurs endogenously except for the desired base edit(s).

Clarification should be provided on the FSANZ's view of trait stacking, i.e. whether it is acceptable for multiple changes generated using NBTs to be combined within a single organism or plant or when NBT foods are produced by crosses with organisms producing existing approved GM-derived food products. For example, if an exempt NBT generated trait for say disease resistance or altered seed oil composition were introduced into an already approved GM cotton plant, would the seed or linters require a review of the food safety assessment previously carried out for that GM-product before stacking?

Additional Feedback

Most of the examples given in the supporting documentation are for crop plants but NBTs are going to be applied to food related and industrial microbes, domestic animals, and aquaculture. FSANZ should broaden their documentation to include some examples in the different categories e.g. foods, food ingredients, food additives, processing aids and nutritive substances.

As noted in section 3.3 of the Call For Submissions document, the risk assessment found the product characteristics are the key determinant of whether a pre-market safety assessment is required not the types of genetic change occurring in a food organism or whether the changes were intended or unintended. A similar hybrid approach being proposed for NBT foods could equally be considered for wider application to older GM technologies which have generally been subject to pre-market safety assessment. Many currently approved GM foods already pose no greater risk to food safety than conventional foods. Individual whole or processed GM foods could be exempt from pre-market safety assessment based purely on their product characteristics rather than the presence of "foreign DNA" which is itself non-toxic. CSIRO appreciates that this will require consideration of public attitudes and acceptance, but the current regulations are imposing a considerable and unnecessary regulatory burden on innovation in the food industry.

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