

Stakeholder Feedback

Summary Report

Proposal P1055 – Definitions for gene technology and new breeding techniques



Contents

About this report					
	Acknowledgement				
Executive summary					
1. Background					
	1.1	Purpose of Proposal	6		
	1.2	Public consultation	7		
2. Key themes 8					
	2.1	Risk and safety	8		
	2.2	Regulatory Issues	9		
	2.2.1	Options	9		
	2.2.2	Preferred approach under Option 3	_ 10		
	2.2.3	Clarity in definitional criteria	_ 11		
	2.3	Non-regulatory Issues	_ 12		
	2.3.1	Industry guidance material	_ 12		
	2.3.2	Advisory committee	_ 13		
	2.4	Government oversight	_ 13		
	2.5	Other relevant issues	_ 14		
	2.5.1	Labelling and consumer choice	_ 14		
	2.5.2	Regulatory harmonisation	_ 15		
	2.5.3	Environmental and sustainability benefits	_ 16		
	2.5.4	Traceability and enforcement	_ 16		
3.	Ne	xt steps	_ 17		
Appendix 1: Submitters to P1055 1st Call for Submissions 18					

About this report

This report provides a summary of views expressed by submitters in response to the first call for submissions for Proposal P1055 – Definitions for gene technology and new breeding techniques.

Selected quotes from some submissions are included to reflect the range of views expressed. All submissions are available on our <u>website</u>.

Acknowledgement

FSANZ wishes to acknowledge the time and effort that submitters have put into preparing their submissions.

Executive summary

FSANZ commenced Proposal P1055 in February 2020. The purpose of the proposal is to revise and update the definitions in the Australia New Zealand Food Standards Code (the Code) for 'food produced using gene technology' and 'gene technology' to make them clearer and better reflect existing and emerging genetic technologies, including new breeding techniques (NBTs).

The <u>first call for submission</u> (CFS) was released for public consultation between October and December 2021. The CFS included a detailed safety assessment, FSANZ's preferred approach to amending the definitions, and suggested criteria for use in revised definitions.

A total of 1734 submissions were received from stakeholders (<u>Appendix 1</u>). The submissions reflect diverse views and provide a wide range of comments on issues, some of which have been previously considered by FSANZ as part of the <u>NBT review</u> which preceded P1055. Some submissions provide detailed feedback and suggestions on FSANZ's preferred approach and definitional criteria.

The key outcomes from the feedback received are summarised as follows:

Outcome 1: Views are divided on the risks or safety of NBT foods and the merits of excluding some NBT foods from pre-market safety assessment.

Outcome 2: The majority of submitters support revising the current definitions in the Code for 'gene technology' and 'food produced using gene technology'. However, views are divided on how the definitions should be revised, including whether the 'gene technology' definition should be expanded.

Outcome 3: A number of concerns were raised by submitters about the lack of clarity in the proposed definitional criteria for the '*gene technology*' definition and product-based exclusion criteria.

Outcome 4: Submitters generally supported the development of industry guidance material, but many expressed reservations and questioned the value of an advisory committee, including concerns that it would increase the regulatory burden.

Outcome 5: Views are divided on the need for government oversight of all NBT foods and the potential economic and other benefits of excluding some NBT foods from pre-market safety assessment.

Outcome 6: Labelling of GM foods continues to be an important issue for certain submitters who wish to exercise purchasing choice. These submitters also want GM labelling applied to food derived using NBTs.

Outcome 7: Many submitters continued to stress the importance of regulatory harmonisation both domestically and internationally to ensure Australia's agriculture industry remains globally competitive and allows for trade continuity.

Outcome 8: Views are divided about the benefits and risks of traceability in terms of compliance and enforcement.

This feedback will inform the further development of definitional criteria and the drafting of revised definitions for '*food produced using gene technology*' and '*gene technology*'. Revised definitions will be available for public comment during the second CFS.

1. Background

1.1 Purpose of Proposal

Food Standards Australia New Zealand (FSANZ) commenced Proposal P1055 to revise and update the definitions in the Australia New Zealand Food Standards Code (the Code) for *'food produced using gene technology'*¹ and *'gene technology'*². These definitions determine what foods require pre-market safety assessment and approval as genetically modified (GM) food. The proposal was initiated after a previous review by FSANZ, completed in 2019, found the current definitions in the Code are unclear and outdated³.

A key component of the proposal was to undertake a safety assessment of new breeding techniques (NBTs) compared to other methods of genetic modification. In particular, the assessment considered whether there is a risk justification for subjecting foods derived from NBTs (NBT food) to pre-market safety assessment, similar to GM foods. It was concluded that NBT food and refined ingredients should not be GM food for Code purposes (i.e. not require an application to FSANZ for pre-market approval as GM foods) if they are equivalent in characteristics and risk to conventional food with a history of safe use.

Based on this assessment, FSANZ proposed:

- expanding the existing process-based definition for 'gene technology' to capture all methods for genetic modification other than conventional breeding, and
- revising the definition for 'food produced using gene technology' to exclude foods that are equivalent in risk to conventional food from pre-market safety assessment and approval as GM food. Exclusions would be based on specific product-based criteria. Food not meeting all exclusion criteria would require an application to FSANZ for approval as a GM food.

In addition to changes to definitions, FSANZ proposed non-regulatory measures including the development of industry guidance material, consumer education and the establishment of an advisory committee on NBT foods. These measures were proposed to assist product developers to interpret and comply with the new definitions, provide useful information to consumers on why changes to the Code are required and what those changes mean, and help facilitate the implementation of revised definitions by jurisdictions.

No changes to the current labelling requirements for GM foods were proposed. Foods that meet the definitions for '*food produced using gene technology*' and '*gene technology*', either in their current form or future revised definitions, will be subject to the mandatory GM labelling requirements in the Code.

¹ food produced using gene technology means a food which has been derived or developed from an organism which has been modified by gene technology.

² gene technology means recombinant DNA techniques that alter the heritable genetic material of living cells or organisms.

³ <u>https://www.foodstandards.gov.au/consumer/gmfood/Pages/Review-of-new-breeding-technologies-.aspx</u>

1.2 Public consultation

The first CFS was released for an 8 week consultation period between 7 October and 3 December 2021. The CFS included a detailed safety assessment, FSANZ's preferred approach to amending the definitions, suggested criteria for excluding certain foods from revised definitions, and a preliminary cost benefit analysis.

In response FSANZ received 1734 submissions from a broad range of stakeholders (<u>Appendix 1</u>).

2. Key themes

Submitters to the first CFS expressed diverse views across a range of issues. The issues raised were grouped by FSANZ into five major themes (Figure 1). Submitter views in relation to each of these themes are summarised in more detail below.



Figure 1: Themes that emerged from the first public consultation

2.1 Risk and safety

Many submitters expressed general concerns about the safety of GM foods, and were opposed to excluding NBT foods from pre-market safety assessment. These submitters disagree that some NBT food is equivalent to conventional food in terms of risk. Rather, they believe the risks of NBT food are similar to those of GM food.

Some of these submitters consider that NBT foods pose new and unassessed risks, citing 'off-target effects' from genome editing, and therefore should be subjected to pre-market safety assessment regardless of similarity to conventionally produced food. These submitters stated that foods derived from NBTs lack a history of safe use and therefore should be subjected to more rigorous assessments i.e. animal/human feeding studies and whole genome sequencing analysis, before being approved as safe.

In contrast, other submitters point to the safety record of GM foods, arguing that the current pre-market safety assessment approach is not risk proportionate. These submitters noted that GM foods have been in the food supply for 25 years and have been rigorously evaluated for risks to human health and safety by technology developers and regulatory agencies worldwide, with no safety risks identified so far.

"Scientific evidence clearly shows that new GM techniques such as CRISPR pose risks that require expert assessment and management. It's vital that gene edited organisms are independently assessed for safety before being released into our environment and supermarkets." – Private individual SH

"Use of NBT processes should trigger safety oversight of all Gene Editing products, including those superficially similar to conventional breeding." – Buy Pure New Zealand

"There is ample evidence in the literature to see that there are numerous studies from around the world that have found these NBTs are not specific and can cause unintended effects. It is therefore essential that all such applications should be considered on a case-by-case basis. Consumers SA calls on FSANZ to take a more precautionary approach to deregulation." – Consumers' Association of South Australia Inc.

"Over 3,500 independent regulatory agency reviews have reached positive conclusions on the safety of GM plants used for food and feed. The approvals have unanimously found in each case that the GM plant in question was as safe as its conventional counterpart, and there remains no credible evidence to the contrary." – Australian Seed Federation

"The idea that the introduction of foreign DNA into food should warrant a risk/safety assessment may have been relevant in the late 1990's and early 2000's and was based on a cautionary approach driven mostly by uncertainty at the time and a great deal of politics. But to my knowledge, after hundreds and hundreds of safety assessments completed around the world by just about every food regulatory agency across the globe, often {mostly} on the same GM food products and using the same datasets, we have a situation where there has never been any risk to human health and safety identified by all the safety assessments combined." – Private individual PB

Outcome 1: Views are divided on the risks or safety of NBT foods and the merits of excluding some NBT foods from pre-market safety assessment.

2.2 Regulatory Issues

2.2.1 Options

A majority of submitters supported FSANZ's preferred **Option 3 – to amend the definitions** *in the Code*⁴. These submitters agree the current definitions require greater clarity with respect to existing and emerging genetic technologies. A few submitters preferred the status quo (**Option 1**), believing the current definitions are able to capture NBT foods for pre-market safety assessment. In their view, all food derived from NBTs should be regulated as GM foods and they were opposed to any changes that would exclude specific NBT foods from pre-market safety assessment.

"MPI supports Option 3: Amend the definitions in the Code to revise the process-based definition for 'gene technology' to capture all methods for genetic modification other than conventional breeding, and to revise the definition for 'food produced using gene technology' to include specific productbased criteria for excluding certain foods from pre-market safety assessment and approval as GM food." – New Zealand Ministry for Primary Industries

"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." – Joint submission from Australian Academy of Science and Australian Academy of Technology and Engineering

⁴ FSANZ considered three options for improving the definitions for 'food produced using gene technology' and 'gene technology' in the Code: Option 1 – Status quo; Option 2 – Status quo combined with non-regulatory approaches; Option 3 – Amend the definitions in the Code

"We agree with the FSANZ Option 3 risk management approach to amend Code 'food produced using gene technology' and 'gene technology' definitions to clarify and better accommodate existing and emerging genetic technologies." – Queensland Health

"AOL is strongly against the update of 'food produced using gene technology' and gene technology within the FSANZ Code where new breeding techniques are deregulated." – Australian Organic Limited

"There is no evidence presented that the existing rules lack clarity, and the opaque phrase "better reflect existing and emerging genetic technologies" provides no objective basis for reassessment of, or rationale for a change to, the definition." – Sustainability Council of New Zealand

2.2.2 Preferred approach under Option 3

A number of submitters supported FSANZ's proposed hybrid approach, which involves broadening the process-based definition for 'gene technology' and including product-based exclusion criteria for the 'food produced using gene technology' definition. Other submitters however did not agree with the hybrid approach, with some preferring the definitions be process-based only, while others favoured a fully product-based approach.

Many submitters supported broadening the 'gene technology' definition because they want all GM and NBT foods regulated irrespective of their equivalence to conventional products. These submitters have concerns that all GM and NBT foods pose undue risks to consumers and do not agree there should be any product-based exclusions.

In contrast, some submitters who support the exclusion of certain foods from the scope of a revised definition are concerned that broadening the 'gene technology' definition extends FSANZ's regulatory ambit and will disproportionately increase the regulatory burden on industry. In their view, such an approach is not scientifically supported, and goes beyond current policy.

"In principle, NSW supports FSANZ taking a hybrid definitional approach." – New South Wales Food Authority

"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 premarket assessment." – Commonwealth Scientific and Industrial Research Organisation

"We support expanding FSANZ's definition for 'gene technology' so FSANZ continues to assess and regulate food products derived from all techniques and methods of genetic modification, other than conventional breeding." – Joint submission from Friends of the Earth and Gene Ethics

"We do not support "Product-based pre-market safety assessment exclusions for certain foods" based on exclusion criteria focussed on food characteristics alone. We do not believe that the proposed nonregulatory approaches are a satisfactory way to mitigate risk." – Institute of Health and Environmental Research "The proposal for an all-encompassing definition of gene technology and risk that this extends the regulatory ambit of FSANZ, is not risk-proportionate, scientifically justified, nor consistent with the policy to regulate GM foods." – Grain Trade Australia

2.2.3 Clarity in definitional criteria

Many submitters stated that the use of overly technical terms in the proposed definitional criteria for a revised '*gene technology*' definition will mean that additional definitions may be required, potentially increasing complexity and misinterpretation of a revised definition. A number of these submitters provided constructive suggestions on how the definition could be revised to provide better clarity.

While many submitters supported the product-based exclusions, there were concerns the proposed exclusion criteria are unclear, open to misinterpretation and burdensome in terms of demonstrating compliance. More specifically, submitters argued that as drafted the exclusion criteria could impose a significant regulatory burden on developers to generate data sets for excluded products of equivalent scale to data sets required for an application to FSANZ.

A number of submitters raised concerns about the lack of clarity in technical concepts associated with the definitions. These submitters were concerned it could lead to definitions being applied and interpreted inconsistently, resulting in two identical food products being regulated differently.

Several submitters made very specific suggestions about how the proposed exclusion criteria and associated definitions could be revised to provide greater clarity. These submitters stated they would like to be consulted in the process of any revision to the proposed exclusion criteria before the second CFS.

"We are concerned that the definition proposed in the consultation documents introduces several new, technical terms, not currently in the Code that would need to be defined – 'recombinant', 'synthesised', 'amplified', 'modified' and 'create'." – Australian Seed Federation

"Exclusion criteria throughout the proposal refer to 'novel DNA' but this term is not defined. Would products that have small changes to the genome that have not been observed in nature in the species or a closely related species be considered to contain "novel DNA?" Depending on how this concept is interpreted, a wider variety of products may be captured under the new definitions than is intended. We encourage FSANZ to clarify what it means when referring to 'novel DNA'." – U.S Embassy Canberra

"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 or that could be developed by conventional breeding processes (e.g. BARLEYmax or high amylose wheat) will need to be clarified. If these types of products were produced using NBTs, would they always require pre-market safety assessment as GM foods?" – Commonwealth Scientific and Industrial Research Organisation

"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"?" – Joint submission from Australian Academy of Science and Australian Academy of Technology and Engineering

"InterGrain is of the view that there is a requirement for exclusion criteria. However, we found that the criteria were vague if not confusing." – InterGrain

Outcome 2: The majority of submitters support revising the current definitions in the Code for 'gene technology' and 'food produced using gene technology'. However, views are divided on how the definitions should be revised, including whether the 'gene technology' definition should be expanded.

Outcome 3: A number of concerns were raised by submitters about the lack of clarity in the proposed definitional criteria for a revised '*gene technology*' definition and the product based exclusion criteria.

2.3 Non-regulatory Issues

2.3.1 Industry guidance material

A number of government, research organisation and industry submitters supported the development of guidance material. Various suggestions were received as to what should be included in the guidance material i.e. scenarios, decision trees, scientific rationale for exclusion, requirements for compliance etc. Some of these submitters stated that clear and detailed guidance material will enable food producers to determine compliance of their products without the need to consult with FSANZ or the advisory committee. Several submitters also suggested to include details on the assessment process, testing and disclosure methods for pre-market safety assessment in the guidance material. It was also suggested that such material be prepared in consultation with industry stakeholders and made available for comments during the second CFS.

"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." – Commonwealth Scientific and Industrial Research Organisation

"For guidance material, clarity on when a declaration requirement applies and appropriate disclosure methods." – New South Wales Food Authority

"Any guidance material must be clear and detailed enough for applicants to be able to assess their products themselves, without necessitating advice from FSANZ or the proposed AC. Further, clear guidance materials would eliminate the need for an AC." – BASF

"We suggest that the guidance materials should present example scenarios to provide developers with further clarity. It may also be beneficial for the guidance materials to present the scientific rationale for the exclusion of some NBT foods from premarket assessment and highlight the riskproportionate and product-based assessment process." – CropLife Australia

"Guidance documents should be developed in consultation with industry to ensure they are fit for purpose." – Fonterra Co-operative Group Limited

2.3.2 Advisory committee

The establishment of an advisory committee received mixed views from government, research organisation and industry submitters. A number of government and research organisations were in favour of the advisory committee but did not provide further comments.

Some industry submitters however were concerned the advisory committee would contribute to an increased regulatory burden. The legal standing of the advisory group's decisions, funding and management of confidential information are just some of the concerns put forth by these submitters. These submitters also noted that consultation with the advisory committee should be voluntary and they would prefer an informal consultation with FSANZ. Overall, industry submitters felt the advisory committee will impose an increased regulatory burden without necessarily providing additional certainty.

"Agcarm does not see a clear need for an advisory committee (AC) as outlined in the proposal (p 23; Non-regulatory measures) and notes that very few details are provided on this in the proposal. We note the proposed purpose of "being a point of enquiry in situations where a developer remains uncertain about whether application to FSANZ may be required" however, it is not clear why the proposed advisory committee would be a preferable avenue to a general consultation with FSANZ." – Agcarm

"This committee in our view would contribute to further red tape. We would rather see that the potential purpose of the advisory committee be undertaken by FSANZ itself." – InterGrain

"Should an advisory committee be set up that consultation with it would be voluntary. Compulsory consultation would be onerous and risks capturing many conventional foods, adding to the bureaucratic burden." – Life Science Network

"As an alternative to an Advisory Committee, the ASF would prefer to see FSANZ have the power to directly provide clear and consistent advice, in writing, to applicants concerning whether a product meets the criteria for a pre-market safety assessment as a GM food." – Australian Seed Federation

Outcome 4: Submitters generally supported the development of industry guidance material, but many expressed reservations and questioned the value of an advisory committee, including concerns that it would increase the regulatory burden.

2.4 Government oversight

A number of submitters expressed dissatisfaction over what they consider to be a lack of government oversight of NBT products associated with the proposed approach. One of the concerns expressed was that reduced government oversight may pose a risk to the safety of the food supply. These submitters were concerned that allowing biotech companies to self-determine the regulatory status of their products is a conflict of interest and will reduce confidence in the Australia and New Zealand food regulatory system.

A common issue raised by some submitters was the perceived monopoly of the food industry by big biotech companies and consequent negative impact on farmers. Submitters in this group questioned FSANZ's motivation in consulting with biotech companies and scientists that have conflicts of interest, and they reiterated the need to prioritise consumer needs ahead of any regulatory changes.

In contrast, other submitters stated that the proposed definitions will reduce red tape and help farmers and consumers access safe NBT products and their benefits more quickly. This group also added that the proposed approach will enable innovation to promote sustainable agriculture production and provide economic benefits. Some submitters stated that enabling NBTs will boost food security by allowing for more efficient and innovative food production compared to conventional breeding.

"What is surprising is the fact that FSANZ is considering both deregulating GMOs and allowing them to be released into our food system and environment without oversight, rigorous testing, or labels on all GM foods or organisms. That is an abrogation of duty to protect the food chain and human and environmental health." – Sustainable Agriculture and Communities Alliance

"GM crops are covered by patents which monopolise the seed market and can have negative economic consequences in the agricultural sector." – Australian Organic Limited

"Newer methods, including genome editing, can be used to develop enhanced crops at a faster rate, allowing farmers and consumers to access these products and their benefits more quickly." – U.S Embassy Canberra

"The LTIBC recommends that the regulation of gene technology should be considered in accordance with the Australian Government's Regulatory Reform Agenda that focuses on enhancing innovation, competitiveness, productivity and economic growth, as well as reducing regulatory burden." – La Trobe Institutional Biosafety Committee

"Access to new breeding technologies is critical for researchers and breeders to continue to explore and develop world class barley varieties, that will be globally competitive and provide value to Australian growers and right through the supply chain to our customers, both domestic and international." – Barley Australia

Outcome 5: Views are divided on the need for government oversight of all NBT foods and the potential economic and other benefits of excluding some NBT foods from pre-market safety assessment.

2.5 Other relevant issues

2.5.1 Labelling and consumer choice

GM food labelling was a major concern for many submitters. These submitters wanted foods produced using NBTs to be clearly labelled so that consumers could make an informed choice once such foods enter the food supply. Several submitters stated that clear labelling will ensure public trust and transparency in the food regulatory system. Other submitters noted that capturing NBT foods for pre-market safety assessment also ensures such foods are subject to the mandatory labelling requirements for GM foods.

Several submitters expressed concern that lack of labelling could cause cross-contamination of NBT products with other non-NBT products i.e. conventional and organic products. They were concerned that this may affect consumers' freedom of choice and lead to issues with exporting non-NBT products to countries where NBT products are regulated.

Other submitters stated that more clarity is needed regarding labelling requirements for NBT foods. Some submitters suggested that NBT foods exempted from pre-market safety assessment should not require GM labelling.

"The departments consider that there would be benefits to foods produced by new breeding techniques to continue to be labelled to inform that choice." – Joint submission from Victorian Department of Health and the Victorian Department of Jobs, Precincts and Regions

"As the organic industry continues to grow, the issue around truth in labelling is a concern for consumers of organic products across Australia. FSANZ's proposal to revise the definition not to include certain gene technology like NBTs complicates an action concerning false organic claims." – Australian Organic Limited

"As a consumer I would like to know complete details about the content and origin of all food I eat. This right to know includes genetically modified input into the food. More detailed labelling is required and not less." – Private individual IL

"It must be made clear that if a food does not require pre-market approval, it does not require GM labelling." – CropLife Australia

"Wider issues including the labelling of GM have been considered previously and should remain out of scope of P1055. This will ensure questions about needs of food safety and risk assessment are addressed as needed." – New Zealand Ministry for Primary Industries

2.5.2 Regulatory harmonisation

Many submitters stressed the importance of greater consistency and harmonisation of definitions. Some of these submitters emphasised the potential impact on trade and market access due to definitional differences between jurisdictions. Others expressed concern over the need for consistency with regulations between Australia and New Zealand. On the other hand, some submitters argue that New Zealand's stance on NBTs should not stifle the progress of the Australian food production industries.

Several submitters stated that there should be an alignment of definitions between the *Gene Technology Act* and the Code to avoid inconsistencies between what is regulated as a genetically modified organism (GMO) and what is regulated as a GM food. They added that the lack of alignment of definitions has serious implications for industries dealing with products that may be classified as GM under the Code but not by the *Gene Technology Act*. They emphasised the need for greater clarity on what constitutes GM food and GMO.

"A major challenge for the global grain trade is the lack of consistency in regulations regarding gene technology regulation globally. GTA supports the harmonisation of regulation and encourages Australia to remain involved and where appropriate take leadership in international forums on gene technology related issues." – Grain Trade Australia

"LSN is strongly opposed to specific 'carve outs' for New Zealand. It is critical that a collective FSANZ approach is continued which is evidence-based and relies on scientific objectivity." – Life Science Network

"Given New Zealand's stance on GE crops, it is important that this does not drag Australia backwards so that the remarkable benefits GE technologies have to offer are not lost." – Murdoch University

"The departments would appreciate a more considered assessment of any potential risk related to this non-alignment, such as implications for industry where segregation of ingredients or products that may be defined as genetically modified under the Code but not by the Office of the Gene Technology Regulator (OGTR), becomes necessary." – Joint submission from Victorian Department of Health and the Victorian Department of Jobs, Precincts and Regions

"We feel that it is important to have harmonisation between OGTR and FSANZ regulations and that there is transparency in this process of developing appropriate definitions." – Barley Australia

2.5.3 Environmental and sustainability benefits

A number of submitters questioned whether the use of GM crops in agriculture provided the claimed environmental and sustainability benefits. They insist that there are better ways to deal with food sustainability and the climate change crisis.

In contrast, other submitters highlighted the economic value and contribution of GM crops towards sustainability and food security. Several submitters claimed that inefficient regulatory processes have impeded the realisation of potential benefits from gene technology. Others emphasised the importance of biotechnology innovations in helping Australian farmers remain globally competitive while also being environmentally sustainable.

"GM crops have been promoted as reducing pesticide (e.g., herbicides, insecticides and fungicides). Yet weed resistance to herbicides is most closely associated with herbicide tolerant GM crops. In response, farmers have increased herbicide application rates, increased the number of applications, and have added additional herbicides. Increasing herbicides and a return to tillage jeopardises the original cost and environmental benefits provided by herbicide resistant crops." – Private individual SF

"Claiming GMO foods is to combat climate change is categorically false. The impact GMO crops have on pollinators, which are vital to the delicate balance of all ecosystems, has been strongly and repeatedly shown to be detrimental. Combating climate change, needs to see the introduction of policies that protect, not threaten this delicate balance." – Private individual AM

"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 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." – Commonwealth Scientific and Industrial Research Organisation

"The plant science industry contributes to the nation's agricultural productivity, sustainability and food security through innovation in plant breeding and pesticides that protect crops against pests, weeds and diseases. The plant science industry is worth more than \$17.6 billion a year to the Australian economy and directly employs thousands of people across the country." – CropLife Australia

2.5.4 Traceability and enforcement

Some submitters raised the need to be able to trace or distinguish NBT foods from other food products. A number of submitters highlighted the challenges faced in regard to compliance and enforcement of NBT foods when some NBT foods are identical to foods produced via conventional breeding techniques. Some submitters were optimistic that advancements in traceability systems will be able to support effective enforcement in the future, and others emphasised that deregulation of NBT foods could assist with effective enforcement.

"GM foods should be labelled as GM, and be traceable so farmers, food producers, retailers, and shoppers and myself to avoid them." – Private individual GJ

"The claim has been made that as some of the products of new breeding techniques will be no different to those that could be produced using conventional techniques, and these will not be able to be detected, or at least not detected as having had a GMO technique applied in their production. However, recent research has shown that reliable detection tests for even the most minor of changes in genetic structure can be independently produced. And even if such tests do not show a fingerprint of which technique was used, other methods for identifying the GM technique used are available. As noted above, food retail gatekeepers increasingly require information about the process used to make a food in declarations provided." – Sustainability Council of New Zealand

"MPI notes significant benefits to the enforceability of the standard with the exclusion of GM-sourced foods that are otherwise indistinguishable from conventional foods." – Ministry for Primary Industries

"The departments note that FSANZ considers that enforcement may be difficult when NBT foods are identical to those produced by conventional breeding techniques, and that view is informed by a recent EU analysis of enforcement issues with these foods. While that analysis suggested that the use of traceability systems to manage enforcement is too onerous and costly, the departments note that rapid developments in traceability systems can support effective enforcement."- Joint submission from Victorian Department of Health and the Victorian Department of Jobs, Precincts and Regions

Outcome 6: Labelling of GM foods continues to be an important issue for certain submitters who wish to exercise purchasing choice. These submitters also want GM labelling applied to food derived using NBTs.

Outcome 7: Many submitters continued to stress the importance of regulatory harmonisation both domestically and internationally to ensure Australia's agriculture industry remains globally competitive and allows for trade continuity.

Outcome 8: Views are divided about the benefits and risks of traceability in terms of compliance and enforcement.

3. Next steps

FSANZ is currently preparing the second CFS which is anticipated to be released for comment in the first quarter of 2023. The second CFS will contain the proposed draft amendment to the Code, including revised definitions, and detailed response to all the issues raised in submissions.

Appendix 1: Submitters to P1055 1st Call for Submissions

Sector	Name			
Government (5)	New South Wales Food Authority			
	New Zealand Ministry for Primary Industries			
	Queensland Health			
	United States Government			
	Victorian Department of Health and the Victorian Department of Jobs, Precincts and Regions (joint submission)			
Community and NGOs	Auckland GE-free Coalition	Sustainability Council of New Zealand		
(1703)	Consumers SA	Sustainable Agriculture & Communities Alliance (SACA)		
	Friends of the Earth and Gene Ethics (joint submission)	5 private individuals		
	Institute of Health and Environmental Research Inc.	1264 campaign submissions		
	Physicians and Scientists for Global Responsibility	427 modified ⁵ campaign submissions		
Research (6)	Australian Academy of Science with Australian Academy of Technology & Engineering (joint submission)			
	CSIRO			
	La Trobe Institutional Biosafety Committee			
	Murdoch University, WA State Agriculture Biotechnology Centre			
	Plant & Food Research			
	The Life Sciences Network			
Industry (20)	Agcarm	EuropaBio		
	Australian Beverage council	Fonterra Co-operative Group Limited		
	Australian Organic Limited	Grain Trade Australia		
	Australian Seed Federation	Horticulture New Zealand Incorporated		
	Barley Australia	InterGrain		
	BASF	International Flavors & Fragrances Inc.		
	Buy Pure New Zealand	New Zealand Beverage Council		
	Chr. Hansen	New Zealand Food and Grocery Council		
	Confidential	NOVALAIT AOTEAROA LIMITED		
	CropLife Australia	Organic Industries of Australia Ltd		

⁵ These are campaign submissions where additional language was included by the submitter