FOOD STANDARDS Australia New Zealand
Te Mana Kounga Kai – Ahitereiria me Aotearoa

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Supporting document 2

Consideration of costs and benefits

P1055 – Definitions for gene technology and new breeding techniques

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Executive summary

This Supporting Document (SD) contains the consideration of costs and benefits for P1055.

The SD:

- describes the problem with the current definitions for ‘food produced using gene technology’ and ‘gene technology’
- outlines why government action is required to address the problem
- summarises the proposed approach and how it meets the proposal objectives
- identifies the costs and benefits that may arise from the proposed approach and whether there is a net benefit
- gives opportunities for stakeholders to provide feedback to be considered in the final approach
- notes the consultation that has taken place prior to the 2nd Call for Submissions (CFS)
- explains the processes for implementation and evaluation of changes to the Code.

Impacts from the proposed changes include improved risk-proportionality leading to greater regulatory certainty. For industry this provides clear pathways to market and for government allows for efficient enforcement of the Code. Impacts may include costs of familiarisation with the new approach to industry and government.

FSANZ's view is that the benefits that would arise from the measures proposed by FSANZ are expected to outweigh the costs that would arise from those proposed measures. However, information received from this 2nd CFS may result in FSANZ arriving at a different conclusion.

Table of Contents

1. Introduction

FSANZ proposes to introduce a new definition for 'genetically modified food' to replace the existing definitions for 'food produced using gene technology' and 'gene technology' under Proposal P1055 – Definitions for gene technology and new breeding techniques (NBTs). The existing definitions are no longer fit for purpose because they are unclear, and do not reflect the diversity of techniques now in use, or that may emerge in the future.

The specific details of this change is discussed in section 2.3 and 3 of the 2nd Call for Submissions (CFS). This Supporting Document (SD) has been developed to accompany the 2nd CFS and focuses on issues related to the costs and benefits of the proposal. In assessing this proposal and in making its decision to prepare the proposed draft variation to the Code, FSANZ is required by Section 59 of the FSANZ Act to have regard to, among other things, whether the costs that would arise from a proposed measure outweigh their benefits.

The assessment was based on the best available information at the time the decision was made to prepare the proposed approach. That information included information provided in submissions received in response to the 1st CFS.

The analysis below is presented qualitatively as the preferred approach is not proposing specific changes to the food supply, but rather proposes an updated regulatory framework for genetically modified (GM) food with regard to NBTs. It is challenging to predict and quantify the impacts to the community, businesses, and government due to the uncertainty of how it may incentivise innovation by the food industry, what type of foods may be available to consumers because of the approach, and how long it may take for the community to experience these benefits.

FSANZ is now seeking submissions in relation to the proposed draft variation, including its consideration of the costs and benefits. Submissions received will inform FSANZ's decision whether to approve, amend or reject the proposed draft variation.

FSANZ will review its assessment of costs and benefits in light of the feedback received in response to this 2nd CFS and then prepare a Decision Regulation Impact Statement (DRIS). The DRIS will inform a final decision on whether to approve, amend or reject the draft variations proposed in this CFS. Before that final decision is made, the DRIS will be submitted to the Office of Impact Analysis (OIA) to confirm the quality and adequacy of the DRIS's analysis, and to review the DRIS for compliance under the Regulatory Impact Analysis Guide for Ministers' Meetings and National Standards Setting Bodies (OIA, 2023).

The OIA exempted FSANZ from the need to prepare a formal Consultation RIS in relation to the regulatory change proposed (reference number OBPR22-03666). The OIA was satisfied with the consultation undertaken for this proposal.

2. What is the problem?

In June 2017, FSANZ commenced a review of the Code to consider how it should apply to food derived using NBTs (NBT foods). The review concluded the definitions for 'food produced using gene technology' and 'gene technology' are no longer fit for purpose given the emergence of NBTs. The definitions were found to lack clarity, were outdated, and not reflective of the diversity of techniques now in use. The review also found there may be a case, based on risk, for some NBT foods to be excluded from the requirement of pre-market safety assessment.

Current definitions were adopted in 1998 with the intent of capturing the types of GM foods that existed at the time Standard 1.5.2 – Food produced using gene technology was developed. New techniques of GM have emerged since, referred to as NBTs.

A distinction is made between NBTs and older GM techniques because NBTs can be used to make a wider variety of genetic changes. NBTs can make the same genetic changes as older GM techniques and can also be used to make the same genetic changes as conventional breeding or changes that occur naturally.

FSANZ undertook a safety assessment to see if there was a risk justification for subjecting all NBT food to pre-market safety assessment under revised definitions, having regard to all available evidence to date, including new evidence since 2019 when the final report for the NBT review was published. The conclusion of the assessment supported the exclusion of NBT foods and refined ingredients considered to be equivalent in risk to conventional food from the requirement for pre-market safety assessment as a GM food.

Reducing regulatory burden for food and ingredients that have been found to carry low safety risk, such as NBT foods, may incentivise innovation in the food industry (Kollmann et al. 2020). Providing a clear and predictable pathway to market is important because new technologies, such as NBTs, although not widely available, could be useful tools that may contribute to more sustainable food production, climate change resilience and mitigation, cheaper food and innovative food products which benefit the food and agriculture sectors, where eventually consumers will benefit from these products of innovation (Brookes & Barfoot 2020; Qaim 2020; Kovak et al. 2022).

Outdated gene technology definitions also result in uncertainty and could lead to inconsistencies in the way such food is regulated. It is important for FSANZ to keep pace with the level of innovation occurring in the industry to ensure potential risks are managed appropriately and that public health and safety continues to be protected as new technologies are developed.

3. Why is Government action needed?

It is not possible to achieve the objectives outlined below using non-regulatory options. It is necessary to amend the current regulatory approach but not remove it entirely. Doing so will improve risk proportionality across the whole range of new and emerging genetic technologies and provide the capability to identify whether new products require pre-market safety assessment or not.

In undertaking its assessment, FSANZ had regard to statutory objectives and other obligations set out in the FSANZ Act, such as the desirability of an efficient and internationally competitive food industry. Refer to section 9.2 and 9.3 of the 2nd CFS for these considerations.

In addition, the following regulatory objectives were considered in the assessment of this Proposal:

- improve clarity about what foods are captured for pre-market approval as GM foods
- better accommodate new and emerging technologies
- regulate NBT foods in a manner that is commensurate with the risks they pose.

These regulatory objectives are briefly discussed below.

3.1. Improving clarity about what foods are captured for pre-market approval as GM foods

Revising the definitions in the Code for GM food is required in order to provide regulatory certainty about what foods are GM foods for Code purposes. A clear, unambiguous definition is important because it reduces uncertainty for the food industry about whether pre-market approval is required and therefore assists them to comply with food regulations. This also facilitates effective and consistent implementation, interpretation and enforcement which can reassure the community that food law is being appropriately implemented and enforced.

3.2. Better accommodate new and emerging technologies and regulate NBT foods in a manner that is commensurate with the risk posed

As discussed in section 2, the definitions in the Code for GM food do not reflect the steady emergence of new gene technologies being used to produce food, along with technologies currently in use that have been developed since the definitions in the Code were put in place.

Certain NBT foods are considered to be equivalent in terms of their safety to conventional food, with FSANZ concluding such equivalence can justify excluding certain food categories from pre-market safety assessment.

To avoid further periods of uncertainty as new technologies continue to emerge, FSANZ proposes to adopt definitions in the Code that are more risk proportionate where only those foods for which a pre-market safety assessment is justified would be captured. Adopting an approach that is forward-looking and agile with respect to technology development will facilitate industry innovation.

4. What options are to be considered?

FSANZ undertook a preliminary analysis of various options as part of the NBT review and consulted on three options in the 1st CFS.

At the 2nd CFS, FSANZ is seeking submissions on the draft variation to the Code which FSANZ prepared after considering the responses to the 1st CFS. The draft variation implements FSANZ's revised approach as described in the 2nd CFS.

Two options to address the identified problem are put forward in order to obtain feedback on the above:

1. Maintaining the status quo
2. Amend the definitions in the Code.

These are discussed in more detail below.

4.1. Option 1 – Maintaining the Status quo

In any consideration of changes to regulation, the status quo must be a part of FSANZ's assessment. The status quo is the option against which other options are considered.

Under this option, the current definitions for 'food produced using gene technology' and 'gene technology' would remain unchanged. Food would continue to be captured for pre-market safety assessment on the basis of the use of gene technology, as currently defined.

Option 1 does not achieve the proposal objectives as the definitions remain ambiguous and outdated. As a result, the problems identified in section 2 would continue.

4.2. Option 2 – Amend the definitions in the Code

Following submitter feedback from the 1st CFS and further assessment, the approach to amending the definitions in the Code has been revised. Further information on this can be found in section 2.3 and 3 of the 2nd CFS.

FSANZ is now proposing a revised approach that includes the following:

- a single outcomes-based definition for 'genetically modified food' based on the presence of novel DNA

- explicit exemptions from the new GM food definition for certain foods and substances added to food.

4.2.1. Simplifying definitions

At 2nd CFS the proposed approach has been simplified to focus on the outcome of the GM process, specifically whether novel DNA is present.

The intent of the approach is to continue to capture the types of foods that are listed in Schedule 26 of the Code, with some exceptions (see section 4.2.2 below). This is consistent with the original policy intent of Standard 1.5.2.

This provides a clear and objective measure to determine if a food is a GM food for Code purposes; novel DNA is either present in the organism or it is not.

Using the term 'novel DNA' will also be compatible with the GM labelling requirements in Standard 1.5.2, which are partly based on the presence of novel DNA in food for sale.

For further detail on:
- Outcomes-based definition – refer to section 2.3.2 of the 2nd CFS
- Presence of novel DNA – refer to section 2.3.3 of the 2nd CFS.

In addition to the proposed new definitions, a number of consequential changes to the Code are required to give effect to the new definitions or to clarify Code provisions that interact with the new definitions. Refer to section 3.4 of the 2nd CFS for further detail on consequential changes to the Code.

4.2.2. Approach for new breeding techniques

An outcomes-based approach is advantageous as it allows for greater flexibility to address technology developments and is less likely to become outdated because it is not based on a specific technique or technology.

FSANZ is also proposing to provide explicit exemptions from the new definition for certain foods based on their risk equivalence to conventional food, and where substances are already appropriately regulated under the Code.

For further detail on the intended regulatory outcomes under the proposed approach see Table 3 in the 2nd CFS.

For further detail on:
- Consideration of specific food categories – refer to section 2.3.4 of the 2nd CFS
- Explicit exemptions – refer to section 2.3.5 of the 2nd CFS.

5. What is the likely net benefit of the proposal?

The net benefit of the status quo option (option 1) by definition is zero as it involves no change. This would mean the issues identified in section 2 would continue. The status quo is the option against which all other options are considered. If no other options are likely to achieve a net benefit option 1 would be the preferred option.

Option 2 requires updating the definitions for 'food produced using gene technology' and 'gene technology' as proposed in section 4.2.

Table 1 briefly illustrates the potential impacts that may arise from the proposed measures for each stakeholder group. These are discussed in more detail in the following sections.

Table 1. Impact on different stakeholder groups arising from option 2

Stakeholder group	Notes on impact
Consumers	Potentially greater availability of innovative products that meet specific consumer needs. NBT foods that contain novel DNA will be considered a GM food for Code purposes and will be required to be labelled as 'genetically modified'. In the longer-term, as a result of competition food will most likely be cheaper than it would have been under the status quo given the ability of firms to achieve production efficiencies, adapt to issues like climate change and lower their regulatory costs. Please note this should be considered as a transfer between the food industry and consumers.
Food Industry	Improved regulatory certainty from simple and up-to-date definitions in the Code. Reduced regulatory burden for certain GM and NBT foods and ingredients getting to market. Increased incentives for businesses to innovate, leading to increased production efficiencies, creating foods with new attributes attractive to consumers and providing increased capacity to adapt to wider challenges such as climate change, resulting in increased profits. Benefits from harmonisation of regulatory requirements with international competitors.
Government	Potentially more efficient implementation of the Code through definitions that are easily understood and that can be consistently implemented and enforced. Clearer definitions will potentially facilitate better compliance with the GM food standard which benefits the food regulatory system. More risk proportionate definitions allow food agencies to direct their resources to areas of greatest need in terms of managing food-related risks.

As described in section 1, it is difficult to place monetary value on many of the costs and benefits involved in moving away from status quo.

In the long term, a broad adoption of NBT foods may lead to wider food system impacts. These could include economic benefits from productivity gains for food producers, and other improvements to food production in terms of sustainability and resilience to emerging challenges such as climate change-related shocks. These impacts could also lead to greater food security, and impacts which may eventually flow-on to consumers. As noted in section 1, further discussion of these impacts have not been explored in depth at this stage due to the challenges in predicting how the changes proposed in P1055 might incentivise innovation of NBT foods and how long it may take for the community to experience these benefits.

The analysis below instead qualitatively discusses the direct costs and benefits of proposed changes under option 2, and notes where indirect and longer term costs or benefits may arise. FSANZ welcomes additional information to be submitted through this 2nd CFS that may enable FSANZ to undertake a more quantitative impact analysis in the DRIS.

5.1. Consumer impacts

GM food is subject to the mandatory requirement to label with the words 'genetically modified'. GM labelling is not required for safety reasons because only those GM foods assessed as safe are approved for sale, but rather enables informed consumer choice. The GM labelling approach remains unchanged.

FSANZ acknowledges submitter concerns that labelling should apply to all GM foods, including NBT foods. However, FSANZ notes this view may stem from a desire for 'process-based' labelling to apply. Labelling requirements are based on the food 'product' for sale rather than the 'process'. The proposed new definition for 'genetically modified food' captures NBT foods that contain novel DNA, of which will be considered a GM food for Code purposes and accordingly will be required, unless exempt, to be labelled as 'genetically modified'.

For further information on FSANZ approach to GM labelling refer to section 4 of the 2nd CFS.

FSANZ supplemented the information gained through the consultation process with three pieces of bespoke consumer research designed to assess general community attitudes towards NBT foods. FSANZ also incorporated a number of questions about GM foods and NBTs used in food production into FSANZ's annual Consumer Insights Tracker, a nationally representative survey of 2,000 Australian and New Zealand consumers. Full detail of this research is included in section 6 of the 2nd CFS.

The evidence indicates that Australian and New Zealand consumer attitudes towards GM foods and NBTs are nuanced and can vary depending on the intended purpose. Consumers tend to have higher levels of support for applications that have health and/or environmental benefits rather than cosmetic or economic benefits. It found that the majority of consumers do not consider GM foods or food ingredients as a top food safety issue, however, when directly asked, a substantial proportion of consumers raised concerns about the long-term effects of using gene technology in food production. Consumer acceptance of NBT foods may be in large part contingent upon scientists and producers ensuring they are understood by consumers to be operating in good faith and in ways that have an explicit and realised benefit for wider society.

In the long term, consumers may receive benefits from innovations and efficiencies in the food industry in the form of cheaper, higher quality, and new food products (Kollmann et al. 2020). These products could offer direct benefits to consumers in terms of health and nutrition, convenience, and taste. The consumer research also suggests that consumers

value the indirect benefits that NBTs may bring to wider society around issues such as environmental sustainability, human health, and animal welfare.

Consultation Question 4: Do you have any information (e.g. studies or data) that may be able to quantify the impacts to consumers that may arise from the proposed changes?

Consultation Question 5: Have all the major impacts to consumers from the proposed approach been identified in the consideration of costs and benefits? Please provide evidence (where possible) to support the inclusion and magnitude of other impacts.

5.2. Food industry impacts

Proposed updates to definitions in the Code provide clarity to GM and NBT food developers and businesses of the regulatory pathways to bring GM and NBT food to market.

Compared to status quo, businesses producing for example, an NBT food that is equivalent in risk to its conventional counterpart, who were previously uncertain whether their product was required for pre-market safety assessment will benefit in terms of the large costs and time associated with the data generation for a regulatory dossier. This could be particularly beneficial to small and medium NBT food developers, where these costs act as a barrier to market entry.

Developers of GM and NBT foods often rely heavily on funding from investors, attributed in part to high start-up costs and lengthy timeframes during technology development. Greater investment into GM and NBT food development as a result of improved legal certainty will enable higher levels of innovation to occur. Innovating, such as improving the quality of a good or creating a new good, is one of the key ways firms compete with their rivals.

Innovation can also lead to improvement in a firm's productivity. This could assist in producing goods at a lower cost, and could help businesses afford the high cost of developing export markets. Innovating to develop cost-effective and differentiated products may assist firms in obtaining market share in the short to medium term, but will be necessary in the longer term just to maintain their competitiveness.

In the long term, there may be more food and food ingredients derived from GM or NBTs that meet unmet consumer needs, including health and nutrition related issues. It may also encourage businesses to find creative solutions to wider issues such as environmental sustainability or food security.

As has been noted in section 7.2 of the 2nd CFS a number of countries are opting to reduce or have no government oversight of NBT food that have the same product characteristics as conventional food.

As a result of the proposed measures being consistent with international regulatory approaches, Australian and New Zealand food businesses may find more success, compared to status quo, when competing in international markets with regard to GM or NBT foods. This impact is also in part due to the clear regulatory pathways and encouraged innovation discussed above. In the short term, there may be increased competition from other countries where similar frameworks are already in place.

Businesses may face some costs involved in familiarisation with the proposed approach. It is assumed these businesses will have certain information available to them of, for example, the presence of novel DNA in their product, and that this will not be burdensome to determine where their product fits within the Code.

FSANZ is proposing to clarify current labelling provisions of GM food to ensure the policy intent is retained in light of the new GM food definition. As this provides regulatory clarity some businesses may benefit from these amendments. FSANZ does not expect this to be a significant negative impact as use of GM ingredients in domestic products appears to be minimal.

Consultation Question 6: Do you have any information (e.g. studies or data) that may be able to quantify the impacts to the food industry that may arise from the proposed changes?

Consultation Question 7: Have all the major impacts to the food industry from the proposed approach been identified in the consideration of costs and benefits? Please provide evidence such as studies or data to support the inclusion and magnitude of other impacts.

5.3. Government impacts

There may be a small cost to government and enforcement agencies across Australia and New Zealand regarding familiarisation with proposed measures.

The proposed approach will potentially lead to more efficient implementation of the Code through definitions that are simplified and easily understood, which may lead to more consistent implementation and enforcement.

Improved regulatory certainty will facilitate better compliance with the GM food standard, and assist with effective enforcement.

As the proposed approach incorporates risk proportionality food agencies will benefit by being able to direct regulatory resources to areas of greatest need in terms of managing food-related risks.

Consultation Question 8: Have all the major impacts to government from the proposed approach been identified in the consideration of costs and benefits? Please provide evidence such as studies or data to support the inclusion and magnitude of other impacts.

5.4. Conclusion of analysis

For the reasons outlined above, FSANZ's assessment is that the benefits that would arise from the measures proposed by FSANZ are expected to outweigh the costs that would arise from those proposed measures. However, information received from this 2nd CFS may result in FSANZ arriving at a different conclusion.

FSANZ is not aware of information available to quantify the costs and benefits of the proposed changes and therefore the net benefit has not been quantified.

6. Who was consulted and how was their feedback incorporated?

Prior to the 2nd CFS, FSANZ undertook consultation during the 1st CFS. 1736 submissions were received from Government, individuals, community groups and NGOs, the research sector, and industry.

To review this feedback and responses from FSANZ, including feedback specifically provided on the costs and benefits of P1055, refer to the main body and Appendix 1 of the

2nd CFS. A summary of the feedback received was also published on the FSANZ website in November 2022.[1]

The proposed approach (and the consideration of costs and benefits) has been revised and presented again for stakeholder feedback in this 2nd CFS. In addition, the 2nd CFS presents the text of the proposed changes to the definitions (and related changes to other parts of the Code) as well as the accompanying explanatory statement.

Submissions received will be considered when developing the final approach. As mentioned, FSANZ will also finalise the impact analysis in light of the feedback received in the form of a DRIS.

7. What is the best option from those considered and how will it be implemented?

7.1. Why option 2 is the best option

As discussed in section 4 and 5, proceeding with the proposed approach is considered the best option, compared to status quo.

The measures proposed in option 2 address the problems raised in section 2, achieve the overall proposal objectives, and are expected to result in a net benefit.

Stakeholder comments have been fed into the approach at 2nd CFS and the approach is continuing to be consulted on. Furthermore, comments from this 2nd CFS will be used to further refine the final approach.

7.2. How the proposed changes will be implemented

If revisions to the definitions are agreed to, implementation and enforcement of the variation to the Code would be the responsibility of the food regulation agencies in New Zealand and Australian states and territories.

For this variation FSANZ is proposing no specific transition period for the proposal and that the 12 month stock in trade provisions contained in Standard 1.1.1—9 will be applicable. Refer to section 11 in the 2nd CFS for further details.

8. How will the chosen option be evaluated?

The primary responsibility for actively monitoring and evaluating food standards lies with the jurisdictional governments that have adopted the Code.

Jurisdictions develop the policy principles for food standards, therefore it is appropriate that they have responsibility for reviewing the outcomes of the standards against their policy principles.

Agencies with responsibility for food policy could act alone to evaluate or monitor the standards, or agencies could act jointly through the Food Regulation Standing Committee (FRSC). FRSC provides advice to food ministers on food regulation issues, which can then result in FSANZ taking action.

[1] P1055 1st CFS Stakeholder feedback summary report – https://www.foodstandards.gov.au/food-standards-code/proposals/p1055-definitions-for-gene-technology-and-new-breeding-techniques

References

Brookes G & Barfoot P (2020) GM crop technology use 1996-2018: farm income and production impacts. *GM Crops & Food, 11*(4). https://doi.org/10.1080/21645698.2020.1779574

Commonwealth of Australia, Department of the Prime Minister and Cabinet (2023) *Regulatory Impact Analysis Guide for Ministers' Meetings and National Standard Setting Bodies.*

Food Standards Australia New Zealand (2019) *Final report: Review of food derived using new breeding techniques*

Kollmann T, Palangkaraya A, Webster E (2020) *Innovation in Manufactured Food and Infant Formula Sectors.* The Centre for Transformative Innovation, Swinburne University of Technology.

Kovak E, Blaustein-Rejto D, Qaim M (2022) Genetically modified crops support climate change mitigation. *Trends in Plant Science, 27*(7). https://doi.org/10.1016/j.tplants.2022.01.004

Qaim M (2020). Role of New Plant Breeding Technologies for Food Security and Sustainable Agricultural Development. *Applied Economics Perspectives & Policy, 42*(2). https://doi.org/10.1002/aepp.13044