1. Why are you not suggesting labelling all NBTs?

The answer to this question can be found in Section 4 of the 2nd Call for Submissions (CFS). All the documents can be found on the P1055 webpage. For your convenience, FSANZ has extracted the relevant information:

> *FSANZ acknowledges submitter comments that labelling should apply to all GM foods, including NBT foods and notes this view may stem from a desire for 'process-based' labelling to apply. Process-based labelling requires a food to be labelled when GM food has been used anywhere in the production process, irrespective of the presence of novel DNA or novel protein, or whether the nature of the food has changed compared to counterpart food not produced using gene technology. However, when Standard 1.5.2 was developed in 2000, food ministers adopted a labelling policy for informed consumer choice based on the final food 'product' for sale i.e. labelling for the presence of GM material (novel DNA/novel protein or altered characteristics in the final food). The current 'product-based' labelling approach is a balance between the need for consumers to be provided with meaningful information to make informed choices with the need for such requirements to be practical and enforceable and reflects the policy intent set by ministers. Further, a process-based approach does not reflect how current labelling requirements operate, including that certain labelling exemptions may apply. For example, labelling is not required for foods where the accidental presence of a GM component is less than 10 g/kg (1%) per ingredient of the final food.*
>
> *FSANZ considers this balance would be maintained by aligning the outcome-based revised approach for pre-market safety assessment and approval with the existing 'product-based' approach for labelling.*

2. What detection methods will FSANZ use to verify exempt products?

Australian state or territory food regulatory agencies and the Ministry for Primary Industries (MPI) in New Zealand are responsible for the implementation, interpretation and enforcement of the Australia New Zealand Food Standards Code (the Code). It is within their remit to verify if products are compliant with the Code, including the application of detection methods.

Detection methods employed by these agencies will depend on the product or specific food category they wish to identify. Section 2.3.5 of the 2nd CFS contains detailed information on foods and substances proposed to be exempted under the proposed new definition for GM food (p.20-23).

In the case of detecting food derived from genome editing, you can find relevant information in Appendix 1: FSANZ response to issues raise in submissions to the 1st CFS, in Item 10 of *Table B. Excluding low risk foods from a revised definition*. For your convenience, FSANZ has extracted the relevant information:

> *In the 1st CFS, FSANZ noted that some NBT foods will not contain any novel DNA and will be indistinguishable from conventional foods. The absence of novel DNA makes it challenging to trace and distinguish NBT foods from conventional food products.*

These challenges were highlighted in a working document published by the European Commission (EC), as well as more recent papers (Guertler et al. 2023; Weidner et al. 2022). While detection methodologies exist to reliably detect small edits in a genome, they cannot determine how the edit was introduced, i.e. whether it was from genome editing, conventional mutagenesis or natural mutation.

References

Guertler P, Pallarz S, Belter A, Eckerman K, Grohmann L (2023) Detection of commercialized plant products derived from new genomic techniques (NGT) - Practical examples and current perspectives. Food Control. 109869. 10.1016/j.foodcont.2023.109869

Weidner C, Edelmann S, Moor D. et al. (2022) Assessment of the Real-Time PCR Method Claiming to be Specific for Detection and Quantification of the First Commercialised Genome-Edited Plant. Food Anal. Methods 15, 2107–2125. https://doi.org/10.1007/s12161-022-02237-y

3. What labelling information are you going to require for the products that are exempted?

Foods for sale in New Zealand and Australia are subject to generic labelling requirements in the Code, including requirements for food identification (name of the food and ingredient names), lot identification, supplier information, date marking, directions for use and storage, nutrition information and percentage labelling. If the food for sale is an approved novel food, the Code may specify certain labelling requirements as a condition of use.

These requirements apply irrespective of whether a food for sale is a genetically modified food or not.

4. How will FSANZ be able to ensure consumer protection and adequate information if exempt foods are not labelled?

Labelling is not based on safety reasons because only those GM foods assessed by FSANZ as safe through a pre-market assessment are approved for sale. The regulatory labelling approach reflects the status quo for GM foods.

In terms of consumer protection, you can find FSANZ's comprehensive safety assessment on the P1055 webpage. As a summary, the following text is found in the 2nd CFS document:

Executive summary

Our assessment has concluded that when a food derived using NBTs is equivalent in its characteristics to food derived through conventional breeding, it also presents the same low risk. Because of this low risk, a pre-market safety assessment by FSANZ is not needed, and such food should therefore not be GM food for Code purposes.

2.1.2 Excluding NBT foods from revised definitions

FSANZ notes that most foods in our food supply are not subject to pre-market scrutiny, as the general provisions under the Code and food law are sufficient to protect public

health and safety. Pre-market approval is typically reserved for those foods which, on evidence-based consideration, require an additional layer of public health and safety protection via a FSANZ safety assessment. For example, pre-market approval is required for novel foods.

Foods derived through conventional breeding do not typically trigger pre-market approval requirements under the Code (e.g. as novel foods). When a new food is developed through conventional breeding, it can be marketed without any involvement from FSANZ providing the new food is safe and suitable and complies with relevant provisions of the Code, including those relating to novel food.

By establishing that specific types of NBT foods should not be GM food for Code purposes, FSANZ is declaring that some applications of NBTs are equivalent to conventional breeding in terms of their outcome and should therefore not be subject to different treatment or requirements under the Code.

5. How will FSANZ enforce labelling of all food created through New Biotechnologies (NBTs) for consumer information?

As noted in our response to Question 2, state and territory food regulatory agencies in Australia and the Ministry for Primary Industries in New Zealand are responsible for enforcement of the Code. Stakeholders may contact the appropriate agency in their jurisdiction directly about enforcement matters. FSANZ provides contact information for food regulatory agencies on its website at: https://www.foodstandards.gov.au/contact/food-regulatory-agencies.

Further, requirements in the Code work in conjunction with requirements in consumer protection legislation in Australia and New Zealand which prohibit misleading or deceptive conduct, and false or misleading representations about goods and services. In Australia, the Australian Competition and Consumer Commission (ACCC) enforces the *Competition and Consumer Act 2010* (Cth); and States and Territories enforce their own consumer protection legislation. In New Zealand, the New Zealand Commerce Commission (NZCC) enforces the *Fair Trading Act 1986* (NZ) which prohibits false and misleading conduct by businesses.

6. Please can you point me to the FSANZ Act where FSANZ was required to assess the need to incentivise innovation rather than public health?

The primary objective of the FSANZ Act is the protection of public health and safety (Subsection 18(1)(a)). This was the primary consideration in FSANZ's assessment. Information regarding this can be found in Section 9.2.1 of the 2nd CFS and included here for your convenience:

The proposed approach protects public health and safety by continuing to require that GM foods are subject to pre-market safety assessment and approval under the Code.

The exclusion of low risk foods from pre-market assessment and approval as GM foods is supported by FSANZ's safety assessment and its conclusions. Excluded foods that are equivalent in risk to conventional foods are still required to be safe and suitable and comply with the relevant provisions of the Code. A food that is excluded from regulation as a GM food but has a change in characteristics, which is considered sufficient to warrant a safety assessment by FSANZ, may be subject to regulation as a novel food.

In undertaking its assessment, FSANZ considered other objectives of the FSANZ Act including the desirability of an efficient and internationally competitive food industry (Subsection 18(2)(c). Information about this can be found in Section 9.3 of the 2nd CFS. For your convenience, FSANZ has extracted the relevant information:

> *The proposed risk proportionate approach to the regulation of GM foods, which includes clear definitions and is aligned internationally, will contribute to a more efficient food industry by reducing regulatory uncertainty, facilitating innovation and supporting international trade in products.*
>
> *Consistent with Australia's and New Zealand's obligations under the WTO, FSANZ will make a notification under the TBT and SPS agreements.*

7. What were the reasons the GE definitions were not "fit-for-purpose"?

An earlier review (2017-2019) concluded the definitions for 'food produced using gene technology' and 'gene technology' 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.

Full details can be found on the following webpage: Food derived using new breeding techniques – review. For your convenience, we highlight the following paragraphs from our final report:

> *The main reason for commencing the review was because of the uncertain regulatory status of NBT foods under Standard 1.5.2 – Food produced using gene technology of the Code. Food that comes within the scope of Standard 1.5.2 is required to undergo pre-market assessment and approval before it may be sold. To be subject to such requirements a food must meet the definitions for 'food produced using gene technology' and 'gene technology':*
>
> *Food produced using gene technology means a food which has been derived or developed from an organism which has been modified by gene technology.*
>
> *Gene technology means recombinant DNA techniques that alter the heritable genetic material of living cells or organisms.*
>
> *FSANZ has considered the wording of these definitions and has identified two aspects that are a source of uncertainty in relation to NBTs. The first is the ambiguous nature of the wording "derived or developed from" in the definition of 'food produced using gene technology', and the second is the absence of a definition for the term "recombinant DNA techniques" in the definition for 'gene technology'.*
>
> *The ambiguity surrounding the meaning of "derived or developed from" is relevant to foods derived from genome editing, grafting and null segregant organisms (see Appendix 2). For example, it is unclear how "derived or developed' from should be interpreted in the case of a null segregant that has not itself inherited a genetic modification introduced using gene technology but is nonetheless descended from an organism that has been modified using gene technology.*

The above wording could be interpreted as either including or excluding food derived from null segregant organisms but a broader interpretation, which would be consistent with the views of some submitters, is that food derived from null segregants is currently captured by the definition for 'food produced using gene technology'.

The absence of a legal definition for "recombinant DNA techniques" makes it unclear whether certain NBTs are considered to be 'gene technology'. A common scientific understanding of the term however is that it refers to the recombining or joining of DNA from two different sources. In practice, "recombinant DNA techniques" in the definition for 'gene technology' has resulted in foods derived primarily from transgenic organisms being captured for pre-market assessment and approval. The applicability of the term "recombinant DNA techniques" to some of the genetic modifications introduced using genome editing is unclear, particularly as there is no recombinant DNA that remains in the final food producing organism.

8. In round 1 of P1055 a majority of submitters called for stronger definitions, labelling and no exemptions on gene edited foods. Why were these suggestions not considered in the options for submitters in P1055 2nd round?

Feedback from all submitters is valued and contributes to the rigor of FSANZ's assessment and regulatory approach.

In terms of excluding NBT foods from revised definitions (e.g. gene edited foods), FSANZ provided a response in Section 2.1.2 of the 2nd CFS. This response is included below for your convenience:

While most submitters agree with FSANZ that the definitions are unclear and outdated and should be revised, divergent views exist regarding the level of risk posed by NBT foods, and whether all NBT foods should be subject to pre-market safety assessment and approval as GM food. FSANZ notes these are long held views and are consistent with those expressed in earlier consultations on NBTs. Such views are also reflected in consumer research undertaken by FSANZ, although the results of that research indicate community attitudes are more nuanced and can vary depending on the intended purpose of the genetic modification (section 6).

In terms of the safety of NBTs and derived foods, FSANZ acknowledges the concerns expressed by many submitters to the 1st CFS and their strong opposition to the exclusion of any NBT foods from a revised definition. FSANZ has carefully considered the issues and concerns raised by these submitters, however no new information was provided by submitters, nor has FSANZ become aware of any new scientific evidence since the 1st CFS, that would cause FSANZ to alter its previous safety assessment or conclusions. FSANZ therefore maintains that sufficient scientific justification exists to exclude NBT foods and refined ingredients from pre-market assessment and approval as GM foods when they are equivalent in characteristics and of similar low risk as conventional foods.

FSANZ notes that most foods in our food supply are not subject to pre-market scrutiny, as the general provisions under the Code and food law are sufficient to protect public health and safety. Pre-market approval is typically reserved for those foods which, on evidence-based consideration, require an additional layer of public health and safety

protection via a FSANZ safety assessment. For example, pre-market approval is required for novel foods.

Foods derived through conventional breeding do not typically trigger pre-market approval requirements under the Code (e.g. as novel foods). When a new food is developed through conventional breeding, it can be marketed without any involvement from FSANZ providing the new food is safe and suitable and complies with relevant provisions of the Code, including those relating to novel food.

By establishing that specific types of NBT foods should not be GM food for Code purposes, FSANZ is declaring that some applications of NBTs are equivalent to conventional breeding in terms of their outcome and should therefore not be subject to different treatment or requirements under the Code.

In terms of the definitional approach, FSANZ provided a response in Section 2.2.2 of the 2nd CFS. This response is included below for your convenience:

Feedback from submitters indicates different views exist among stakeholders regarding the definitional approach proposed by FSANZ at the 1st CFS. While some submitters were generally comfortable with an expanded 'gene technology' definition being used in combination with product-based exclusion criteria, FSANZ notes the concerns raised by other submitters particularly around clarity, complexity, potential for inconsistent regulatory outcomes, and that the proposed approach would be onerous in terms of compliance.

FSANZ has carefully considered the issues raised and on reflection accepts that the proposed approach was unnecessarily complex and did not hit the mark in terms of meeting the specific intent and objectives of the proposal. Following further consideration, FSANZ also agrees the approach, as proposed at the 1st CFS, may produce unintended outcomes in terms of what foods would be considered GM food for Code purposes, and that some of these outcomes could potentially be inconsistent with FSANZ's own safety assessment, that is, capture foods with equivalent characteristics to conventional foods, which would be counter to the regulatory intent.

FSANZ has also had regard to the suggestion from some submitters that the approach be revised so definitions are based on the presence of foreign DNA in the genome, including how that could be drafted. FSANZ's assessment in response to these suggestions is that there would be merit in exploring a revised approach based on foreign DNA. FSANZ notes other countries have also used this approach (see SD1), and that it may help to simplify the new definitions and make them clearer and less onerous in terms of compliance, with benefits also for implementation and enforcement. Importantly, it is also FSANZ's assessment that such an approach will deliver more consistent outcomes in terms of excluding certain low risk foods from GM food regulation based on their risk equivalence to conventional foods.

In terms of labelling, FSANZ provided a response in Section 4.1.2 of the 2nd CFS. This response is included below for your convenience:

FSANZ has noted previously that approved GM food is subject to the mandatory requirement to label with the words 'genetically modified' (subsection 1.6.2 of the 1st CFS). Labelling requirements are based on the food 'product' for sale rather than the

'process'. Unless exempt, food must be labelled as 'genetically modified' if it contains novel DNA or novel protein, or it has a characteristic that is altered (e.g. a different fatty acid profile).

This labelling approach is retained under the proposed new definitions for 'genetically modified food' and 'novel DNA' (see section 2.3 in this report). Foods that meet the new definition of 'genetically modified food' (see section 3.2 in this report) and are approved for use will be subject to mandatory GM labelling requirements in the Code. The revised and new definitions in section 3 are intended to provide greater regulatory certainty about what foods are GM foods for Code purposes.

FSANZ acknowledges submitter comments that labelling should apply to all GM foods, including NBT foods and notes this view may stem from a desire for 'process-based' labelling to apply. Process-based labelling requires a food to be labelled when GM food has been used anywhere in the production process, irrespective of the presence of novel DNA or novel protein, or whether the nature of the food has changed compared to counterpart food not produced using gene technology. However, when Standard 1.5.2 was developed in 2000, food ministers adopted a labelling policy for informed consumer choice based on the final food 'product' for sale i.e. labelling for the presence of GM material (novel DNA/novel protein or altered characteristics in the final food). The current 'product-based' labelling approach is a balance between the need for consumers to be provided with meaningful information to make informed choices with the need for such requirements to be practical and enforceable and reflects the policy intent set by ministers. Further, a process-based approach does not reflect how current labelling requirements operate, including that certain labelling exemptions may apply. For example, labelling is not required for foods where the accidental presence of a GM component is less than 10 g/kg (1%) per ingredient of the final food.

FSANZ considers this balance would be maintained by aligning the outcome-based revised approach for pre-market safety assessment and approval with the existing 'product-based' approach for labelling. For example, FSANZ notes food derived using genome editing that does not involve the insertion of novel DNA is equivalent to food derived from conventional breeding. FSANZ has outlined the rationale for the outcomes-based approach in section 2.3 in this report.

In regard to submitter comments that most Australians do not want to consume GM foods (see Table E in Appendix 1), the evidence indicates that Australian and New Zealand consumer attitudes towards GM foods are nuanced and can vary depending on the intended purpose; that attitudes towards NBTs are generally more positive compared to GM foods; and that the majority of consumers do not consider GM foods or food ingredients as a top food safety concern. Furthermore, FSANZ's recent Consumer Insights Tracker (2024) indicates at least a third of Australian and New Zealand respondents say they would purchase and consume GM banana if it became available for sale (see section 6 in this report). As noted above, approved GM foods will continue to be labelled to enable informed consumer choice.

9. What are the benefits of harmonisation with international competitors?

FSANZ must have regard to the promotion of consistency between domestic and international food standards, and the desirability of an efficient and internationally competitive food industry

under Subsection 18(2) of the FSANZ Act. This can be found in Section 9.3 of the 2nd CFS, and has been included below:

> The promotion of consistency between domestic and international food standards:
>
> *There are no relevant international food standards relating to GM food or NBT food. The assessment considered developments in the regulation of NBT foods in other countries (Section 7.2 and Supporting Document 1). FSANZ's approach, as revised in this 2nd CFS, aligns internationally with regulatory approaches that have been adopted, or are proposed to be adopted, by other countries around the world.*
>
> The desirability of an efficient and internationally competitive food industry:
>
> *The proposed risk proportionate approach to the regulation of GM foods, which includes clear definitions and is aligned internationally, will contribute to a more efficient food industry by reducing regulatory uncertainty, facilitating innovation and supporting international trade in products.*
>
> *Consistent with Australia's and New Zealand's obligations under the WTO, FSANZ will make a notification under the TBT and SPS agreements.*

FSANZ had regard to harmonisation in weighing up the potential benefits and costs of the proposed measures as required under Section 59 (2(a)) of the FSANZ Act. This can be found in Section 5.2 of Supporting Document 2 – Consideration of costs and benefits (SD2), and included below:

> *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* [arising from the proposed measures].

10. Why is harmonisation relevant to the protection of Australia and New Zealand's unique public health conditions?

As highlighted in the response to Q6, the primary objective of the FSANZ Act, which is specific to Australia and New Zealand, is the protection of public health and safety.

Harmonisation with international regulatory approaches is a by-product of countries around the world reaching similar conclusions to FSANZ in their safety assessment of NBT foods. Further details can be found in Section 7.2 of the 2nd CFS and a subsection is included here for your convenience:

> *FSANZ has continued to monitor the situation internationally and notes that since the 1st CFS, a number of countries have either formalised their approach to NBTs or have provided updates on their direction. Worldwide, countries are opting to reduce or have no government oversight of NBT food with the same product characteristics as conventional food. This is wholly consistent with the direction being taken by FSANZ.*