CropLife Australia

December 2021

Definitions for gene technology and new breeding techniques

Submission to FSANZ

1 INTRODUCTION

CropLife Australia (CropLife) is the national peak industry organisation representing the agricultural chemical and biotechnology (plant science) sector in Australia. CropLife represents the innovators, developers, manufacturers and formulators of crop protection and agricultural biotechnology products. CropLife's membership is made up of companies that are patent holding and generic, Australian and international and small and large, and accordingly, advocates for policy positions that deliver whole of industry benefit.

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 is a member of CropLife Asia and part of the CropLife International Federation of 91 CropLife national associations globally.

CropLife welcomes the first call for submissions on Proposal *P1055 – Definitions for gene technology and new breeding techniques* (P1055) outlined in the Consultation Paper and supporting materials.[1] CropLife supports FSANZ's preferred approach of Option 3 to amend the definitions of "gene technology" and "food produced using gene technology" in the Australia New Zealand Food Standards Code (the Code)[2] and the overarching objective evident in the Consultation Paper of adopting a more risk-proportionate regulatory approach.[3] These changes are crucial reforms to future-proof FSANZ's regulatory approach and provide clarity and certainty on the regulatory status and assessment requirements for food produced using new breeding techniques (NBTs foods) – these needs were clearly demonstrated in the findings of the *Review of food derived using new breeding techniques* (the Review).[4]

1 Food Standards Australia New Zealand, 'Proposal P1055 – Definitions for Gene Technology and New Breeding Techniques' <https://www.foodstandards.gov.au/code/proposals/Pages/p1055-definitions-for-gene-technology-and-new-breeding-techniques.aspx>.
2 Food Standards Australia New Zealand, 'Food Standards Code' <https://www.foodstandards.gov.au/code/Pages/default.aspx>.
3 Food Standards Australia New Zealand, 'Proposal P1055 – Definitions for Gene Technology and New Breeding Techniques'.
4 Food Standards Australia New Zealand, 'Final Report - Review of Food Derived Using New Breeding Techniques' <https://www.foodstandards.gov.au/media/Pages/Final-Report---Review-of-food-derived-using-new-breeding-techniques.aspx>.

We emphasise that maintaining the status quo of outdated and unclear definitions (Options 1 and 2) that are not fit for purpose is not an option. For technology developers, the lack of a clear pathway to market or disproportionate regulation of all NBT foods in the same manner as genetically modified (GM) foods deters investment and innovation in Australian agriculture.

The Consultation Paper recognises that regulation should not be unnecessarily restrictive and instead be commensurate with identified risks. This view is strongly supported by CropLife, noting that care is needed to balance adequate and proportionate regulation with an appropriate and justifiable regulatory burden for technology developers, while also ensuring the safety of Australia and New Zealand's food supply.

Our understanding of the proposal by FSANZ is that the preferred "hybrid" approach involving revision of the two definitions, "gene technology" and "food produced using gene technology", aims to:

(i) Capture all foods that are not "conventional" via a broadened process-based definition of "gene technology" that extends to all biotechnology-based methods for genetic modification, including the diversity of those that are "new and emerging";
and

(ii) In a second step, identify on a case-by-case basis if a resulting food product requires premarket safety assessment in the same manner as a GM food, or if is excluded from this, on the basis of meeting a list of specific criteria.

It is also proposed by FSANZ that implementation of the above would be supported by non-regulatory measures, including the establishment of an "advisory committee" on NBT foods and specific guidance materials that are yet to be developed.

We strongly support and emphasise the findings of the Review that NBT foods should be regulated in a manner that is proportionate to the risk they pose and welcome the recognition that some NBT foods have the same characteristics as conventional foods, and as such, should be regulated in the same manner as conventionally produced food. In addition to being risk-proportionate, regulation should also be consistent such that if two products are similar, they should be regulated in the same manner. This is consistent with current scientific knowledge and understanding, as elaborated in FSANZ's detailed safety assessment of NBTs.[5] Furthermore, this approach is in line with progressive approaches being implemented in other international jurisdictions.[6]

[5] Food Standards Australia New Zealand, *Supporting Document 1 Safety Assessment: Full Technical Report*, 2021 <https://www.foodstandards.gov.au/code/proposals/Documents/P1055 SD1 Safety Assessment.pdf>.

[6] Page 19 to 20 - Food Standards Australia New Zealand, 'Proposal P1055 – Definitions for Gene Technology and New Breeding Techniques'.

In principle, CropLife Australia supports a regulatory approach that places greater emphasis on the actual risk posed by the product. We have concerns, however, with the proposal for an all-encompassing definition of "gene technology" that extends the regulatory ambit of FSANZ and do not believe this to be risk-proportionate, scientifically justified or consistent with the policy to regulate GM foods. The Consultation Paper and Supporting Document 1 recognise that many NBTs do not result in "foreign DNA" remaining in the final organisms used for food and that this contrasts with older transgenic methods. We highlight that "older" GM technologies are often considered within the scope of "new" fields such as synthetic biology (e.g., metabolic engineering) and that certain genome editing approaches (e.g., those known as "SDN-3" for targeted insertion of transgenes) have outcomes that are comparable to transgenics. The regulatory scope of FSANZ in regard to NBTs should not extend beyond such GM foods.

Below we have provided specific comments on elements of FSANZ's preferred approach, Option 3, including proposals for relevant definitions.

2 A CLEAR & CONSISTENT REGULATORY SYSTEM

All food or food ingredients derived from GM crop plants are rigorously assessed by FSANZ to ensure that they present no unacceptable risk to consumers. In 2011 it was estimated that this required developers to spend on average thirteen years and US$136 million researching and developing each new crop biotechnology product.[7] Costs and timeframes have almost certainly increased since then.

Increased innovation, productivity, investment and trade are not tenable without nationally consistent agricultural regulations that are efficient and scientifically robust. We appreciate that FSANZ also has regard to the desirability of an efficient and internationally competitive food industry and the need for clear and consistent regulatory requirements to achieve this.

While it is important for governments to provide for appropriate and rigorous regulation of biotechnologies, any regulation must be mindful of the effects that poorly considered and excessive regulation will have through increasing production costs and discouraging investment and innovation, while not delivering any improvement in safety, health or environmental outcomes.

Importantly, we draw your attention to the need for explicit acknowledgement that, under the preferred approach of Option 3, GM foods will continue to require premarket safety assessment and approval by FSANZ and these may include certain foods derived from what FSANZ terms "new breeding techniques" that have comparable characteristics. It is not made clear in the Consultation Paper that certain NBT foods may still require regulation in the same manner as GM foods.

[7] Phillips McDougall, *The Cost and Time Involved in the Discovery, Development and Authorisation of a New Plant Biotechnology Derived Trait*, 2011 <https://croplife.org/wp-content/uploads/2014/04/Getting-a-Biotech-Crop-to-Market-Phillips-McDougall-Study.pdf>.

3 DEFINITIONS

In the Consultation Paper, FSANZ proposes to expand the definition of "gene technology" to capture all methods for GM, including those that are "new and emerging", to help minimise the potential for gaps in regulatory coverage now and into the future. This, in effect, captures everything that is not a "conventional breeding" method as "gene technology" and thus, the corresponding definition of "conventional breeding" in the Code must also be considered in parallel.

A clear dichotomy between "gene technologies" and "conventional breeding" methods, and the products thereof, no longer exists and maintaining this is an overly precautious approach that does not provide future proofing. This distinction is not consistent with the continuum of technologies and tools that exist today, which FSANZ also recognises,[8] nor is it consistent with FSANZ's own assessment that:[9]

- Despite significant genetic changes to food organisms using conventional methods, they continue to have a long history of safe use;
- The genetic changes that can be introduced using NBTs are consistent with those that could occur naturally, result from conventional breeding methods, or result from older GM (transgenic) techniques;
- The most important consideration is whether the food has been changed in a way that may raise safety concerns – the methods used, the size of the genetic change, or whether it was intended or unintended – is irrelevant to food safety;
- That exclusions should apply to NBT foods that have the same product characteristics as conventional food.

In our view, despite the perceived complexity of the current (and future) technology toolbox, the outcomes continue to fall within three general categories (also recognised by FSANZ):[10]

(i) those that could arise via naturally occurring mechanisms
(ii) those that can be achieved using conventional means
(iii) those that can only be achieved via transgenesis.

8 Page 14, section 4.1.1 - Food Standards Australia New Zealand, 'Proposal P1055 – Definitions for Gene Technology and New Breeding Techniques'.
9 Page 13 and 22 - Food Standards Australia New Zealand, 'Proposal P1055 – Definitions for Gene Technology and New Breeding Techniques'.
10 page 13 - Food Standards Australia New Zealand, 'Proposal P1055 – Definitions for Gene Technology and New Breeding Techniques'; Food Standards Australia New Zealand, *Supporting Document 1 Safety Assessment: Full Technical Report*.

The distinction between GM food and conventional food was originally made with the inception of the Code because the former "*generally results in outcomes that could not be achieved through conventional methods*".[11] There remains no policy or scientific justification for the scope of regulatory oversight to extend beyond those changes that cannot arise naturally or via conventional means i.e., beyond transgenesis and the resulting GM foods.

CropLife proposes two new interrelated definitions below, each followed by explanatory text. We do not propose a change to the definition of "food produced using gene technology".

Gene technology

Definition proposed by CropLife:

"Gene technology" means techniques that modify a genome by introducing foreign DNA that remains in the final organism used for food.

We agree with FSANZ that the definition of "gene technology" should be as simple and clear as possible and not technically complex. This is what we have proposed above. Our proposed definition also pairs with our proposed definition for "foreign DNA".

FSANZ has posed the definition of "genetic engineering" adopted by the USDA, or an adaptation of this, as a possible suitable definition: "*techniques that use recombinant, synthesised or amplified nucleic acid to modify or create a genome*", i.e., a definition that broadly incorporates biotechnologies beyond "recombinant DNA". Our proposal for gene technology (and foreign DNA) simplifies this for the purposes of the Code and will in effect exclude certain NBT approaches upfront that do not result in the introduction of "foreign DNA" into the final food product. Compared to the USDA example suggested by FSANZ (and other potential options used in other jurisdictions), our definition does not include several technical terms that would also need to be defined e.g., recombinant, synthesised, amplified, modified, create.

[11] Page 10 - Food Standards Australia New Zealand, 'Proposal P1055 – Definitions for Gene Technology and New Breeding Techniques'.

Our proposed definition of "gene technology" retains a key element of the current definition – introduced DNA – but this is refined from the ambiguous term "recombinant DNA" to "foreign DNA", for which we have proposed a definition that reflects the process ("transgenesis") that results in GM food (see discussion in Consultation Paper).[12] This reference to "foreign DNA" incorporates one of the proposed NBT food exclusion criteria (see section 5 below), it focuses regulatory scope on GM foods, and it reduces the burden on developers who would otherwise need to work though all exclusion criteria for NBT foods for which there is no scientific justification.

Foreign DNA

Definition proposed by CropLife:

"Foreign DNA" means the stable integration into the genome of one or more genes that originate from outside the organism's cross-compatible gene pool and are inaccessible through conventional methods.

We agree with the explanation in the Consultation Paper that "foreign DNA" originates from a different species and its insertion into the genome of an organism constitutes transgenesis. The term "foreign DNA" is technically more precise than "recombinant DNA", which, despite rarely being defined, is commonly used in early GMO legislation and generally refers to joining any two or more pieces of DNA together.[13]

We acknowledge that in capturing everything with a broad definition of "gene technology", FSANZ may be attempting to address concerns expressed by some stakeholders in the Review that some NBT foods could enter the food supply without safety assessment.[14] This is incorrect if the foods not captured are only those that are equivalent to or can be achieved by conventional methods, because the history of safe use supports the food safety of such products. Such products should be treated similarly to conventional products from a regulatory point of view and be exempt from GM regulatory scope. Taking an overly precautious approach via the definition of "gene technology" does not in fact address regulatory "gaps". Rather, it extends the process-based regulatory reach of FSANZ beyond GM food. We stress that our proposed definitions of "gene technology" and "foreign DNA" do not change the regulatory status of GM foods that are currently, and have historically been, within regulatory scope, as originally intended and they will not exclude those NBT foods that have comparable (transgenic) characteristics.

[12] Page 24 - Food Standards Australia New Zealand, 'Proposal P1055 – Definitions for Gene Technology and New Breeding Techniques'.
[13] Page 9 - Food Standards Australia New Zealand, 'Proposal P1055 – Definitions for Gene Technology and New Breeding Techniques'.
[14] Page 17 - Food Standards Australia New Zealand, 'Proposal P1055 – Definitions for Gene Technology and New Breeding Techniques'.

We also highlight that as currently proposed by FSANZ, the developer must assess if the exclusion criteria apply on a case-by-case basis to an NBT food, with the options of assistance from guidance materials (to be developed by FSANZ) or an Advisory Committee. Thus, the onus of applying the exclusion criteria rests with developers. Further, it is concerning that the Consultation Paper suggests that if a developer incorrectly applies the criteria, they could be subject to (yet to be defined) compliance measures.

Where an NBT product is captured due to a broad process-based definition, but it cannot be distinguished from a conventional product, having to address a list of exclusion criteria is clearly not a proportionate or justifiable burden on developers. This could also prove prohibitive for smaller developers of NBT foods.

We note that FSANZ takes into consideration practical issues relating to implementation and enforcement, including the well-documented challenges with the detection and unique identification of certain NBT products. Our proposed definitions of "gene technology" and "foreign DNA" will not capture such NBT foods within regulatory scope.

Conventional breeding

The current definition of "conventional breeding" in Schedule 26 of the Code states that "*conventional breeding means all methods used to produce plants, excluding techniques that use gene technology*". The resulting foods are considered to be "conventional foods" and the methods understood to be included are cross-breeding and selection, classical mutagenesis methods and various cell and tissue culture techniques.[15]

Schedule 26 also provides two other interconnected definitions: "line" and "transformation event". The definition of "line" includes reference to "conventional breeding" as well as "transformation event", with the definition of the latter referring to "gene technology".

With our proposed amendment to "gene technology", we do not consider a definition of "conventional breeding" to be necessary in the Code. Our proposal is clear and it does not rely on the outdated process-based conventional versus biotech dichotomy. Rather, it is consistent with FSANZ's safety assessment, which concludes that there are GM foods - which are the foods within its regulatory scope - and there are conventional or conventional-equivalent foods that are not within its regulatory scope.

[15] Page 9 - Food Standards Australia New Zealand, 'Proposal P1055 – Definitions for Gene Technology and New Breeding Techniques'.

Regarding the two other interconnected definitions, if necessary for clarity, alternative terms (to conventional breeding) could be substituted in the definition for “line”. We note that with our proposed amendment to “gene technology”, the existing definition of “transformation event” remains relevant, however it would not be correct if a broader definition (such as the USDA example) were to be adopted.

4 NON-REGULATORY MEASURES

With the clear proposals we have made for the definitions of "gene technology" and "foreign DNA", there should be no, or very limited need for additional measures to support the implementation of Option 3. We do not support the establishment of an Advisory Committee, our expansion on this is outlined below. In addition to this, the development of any guidance material should be limited to assist with assessments regarding "foreign DNA". We do, however, provide comments on the proposals made by FSANZ – these are aimed at highlighting the need for clarification on many aspects of these proposals should it ultimately be decided that they are introduced.

Advisory Committee

FSANZ proposes that an Advisory Committee (AC), modelled on the AC for Novel Foods, be established to facilitate implementation of the revised definitions. CropLife's understanding is that consultation with the AC would be a voluntary option for developers where, e.g., they were uncertain about the applicability of the NBT food exclusion criteria to a product. We also understand that any advice given would be of a non-legally binding nature, however, we are not clear why the proposed AC would be a preferable avenue to a general consultation with FSANZ which would apparently serve the same purpose of providing developers with non-binding advice. Our preference is for the regulatory body to provide documented, clear and consistent advice regarding the regulatory status of an NBT food.

Very little is elaborated in the Consultation Paper on the proposed AC, and CropLife emphasises that if one is established, use of it by developers must be voluntary, and many questions must be clarified, e.g.:

- The composition of the AC and criteria for membership.
- How will the AC make an assessment – will they follow the same guidance material that is proposed to assist developers?
- How will the work of the advisory committee be funded?
  It is important for developers to know if this will be based on cost-recovery. As consultation with the AC is voluntary, we expect that there would be no fee charged.
- What will be the timelines for the provision of advice?
- What will be the legal status of the advice?
- What recourse will be available to developers if they do not agree with the advice given by the AC and what would the consequences be for not following it?
- What sources of data and information, and how much, will be required for a consultation with the AC?

- How will data and information provided by a developer to the AC be managed - noting the sensitivities regarding commercial confidential information and freedom of information.
- What aspects of the consultation process can be confidential and what will be public – noting that the current AC for Novel Foods posts their advice on the FSANZ website. Developers may have a competitive need to keep the totality of a consultation confidential.

Guidance materials

FSANZ also proposes that guidance materials will be developed to assist developers with application of the exclusion criteria. We reiterate our view that these criteria should not be necessary with our proposed definitions of "gene technology" and "foreign DNA", but guidance materials may be of assistance to developers in assessing if the absence of "foreign DNA" requirement is met.

CropLife emphasises that any such materials must be clear and thorough enough for developers to be able to assess their products themselves without necessitating interpretative advice from FSANZ or the proposed AC. We stress that any consultation with FSANZ or an AC should be consistent with the same guidance. We suggest that the guidance materials should present example scenarios to provide developers with further clarity. For example, what actions would need to be taken if a developer determined that a food did not require premarket assessment prior to commercialisation, and subsequently circumstances change in regard to FSANZ requirements.

The Consultation Paper notes that the guidance material will also outline "*what evidence should be retained in order to demonstrate compliance*".[16] It must be specified who the developer would need to demonstrate compliance to. This suggests that even where food complies with the definitions and all of the exclusion criteria (if required), it is still in effect considered regulated.

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 risk-proportionate and product-based assessment process.

[16] Page 23 - Food Standards Australia New Zealand, 'Proposal P1055 – Definitions for Gene Technology and New Breeding Techniques'.

Importantly, we encourage FSANZ to develop and have any guidance material available at the same time as the revised definitions are implemented. We also urge consultation on any guidance materials before they are used for implementing the new definitions (and any exclusion criteria) to ensure that these (and any additional) important questions are addressed.

Summary

With these definitions, CropLife has reviewed approaches taken in other jurisdictions and has aimed to make proposals that are clear and proportionate. We have also reviewed our contributions made previously for the 2016 Technical Review of the Gene Technology Regulations,[17] the three phases of the 2017 Review of the National Gene Technology Scheme (NGTS),[18] the subsequent implementation proposals for the NGTS,[19] and the 2018 FSANZ Review of Food Derived Using New Breeding Techniques.[20] In these submissions, our proposals and their rationale remain consistent, and they have stood the test of time and continued accumulation of scientific knowledge and regulatory experience.

In the Consultation Paper, FSANZ points out commonalities between NBT regulatory developments in other jurisdictions regarding product-based exclusions, with these having a basis in the genetic modification being similar to that which can occur naturally (via spontaneous mutation processes or genetic recombination) or with the use of conventional breeding methods, the absence of foreign DNA in the resulting organism, or a combination of both of these.[21] Our proposals are consistent with these approaches.

17 CropLife Australia, 'Submission to Discussion Paper on Options for Regulating New Technologies', 2016 <https://www.croplife.org.au/wp-content/uploads/2017/06/CropLife-Sub_OGTR-Discussion-Paper-161216.pdf>.

18 CropLife Australia, 'Submission to Phase 2 of the Review of the National Gene Technology Regulatory Scheme', 2017 <https://www.croplife.org.au/resources/submissions/croplife-submission-to-phase-2-of-the-review-of-the-national-gene-technology-regulatory-scheme-2/>; CropLife Australia, 'Submission to Phase 3 of the Third Review of the National Gene Technology Scheme', 2018 <https://www.croplife.org.au/resources/submissions/croplife-submission-to-phase-3-of-the-third-review-of-the-national-gene-technology-scheme/>; CropLife Australia, 'Submission to the 2017 Review of the National Gene Technology Regulatory Scheme', 2017 <https://www1.health.gov.au/internet/main/publishing.nsf/Content/C28DC671DFEB6FDBCA2581CF00775388/$File/CropLife Australia.pdf>.

19 CropLife Australia, 'Implementing Recommendations of the Third Review of the National Gene Technology Scheme: Phase 1', 2019 <https://www.croplife.org.au/wp-content/uploads/2019/11/CropLife-submission-Third-Review-GM-Phase-1.docx.pdf>; CropLife Australia, 'Consultation Regulation Impact Statement – Modernising and Futureproofing the National Gene Technology Scheme', 2021 <https://www1.health.gov.au/internet/main/publishing.nsf/Content/B4E10B99E4051128CA25872D002A6D82/$File/CropLife Australia Submission.pdf%0A>.

20 CropLife Australia, 'Submission to Consultation Paper on Food Derived Using New Breeding Techniques', 2018 <https://www.croplife.org.au/resources/submissions/croplife-submission-to-consultation-paper-on-food-derived-using-new-breeding-techniques/>.

21 Page 20 - Food Standards Australia New Zealand, 'Proposal P1055 – Definitions for Gene Technology and New Breeding Techniques'.

Importantly, the CropLife proposals remain consistent with the objective of a more risk-proportionate regulatory approach to regulatory oversight of NBT foods, maintaining regulatory oversight for GM foods and capturing NBT foods that are similar to GM foods. We reiterate that the products of gene technologies that do not contain foreign DNA are indistinguishable from conventional products and therefore these should not require evaluation against all of the proposed NBT food criteria before being excluded from regulatory scope. This view is consistent with:

- FSANZ's own analysis that some outcomes of NBTs are "*similar if not identical to outcomes using conventional breeding methods*".[22]
- FSANZ's explanation in the Consultation Paper, which we agree with, that the process of 'transgenesis' results in GM food and that this process results in the introduction of "foreign DNA". We highlight that certain NBTs result in similar outcomes to older transgenesis techniques and these would not be excluded from regulatory scope by the definitions we have proposed.
- The rationale for the other proposed exclusions – "null segregants" and "refined ingredients" (see Section 5 below).
- The conclusions of the FSANZ technical workshops.[23]
- The rationale underlying the exclusion criteria of certain genome editing applications (generally known as "SDN-1") from the regulatory scope of the Office of the Gene Technology Regulator (OGTR) in Australia. While the OGTR is concerned with the regulation of different risks to FSANZ, the basis for this exclusion is relevant to the rationale presented by FSANZ, since SDN-1 organisms may ultimately be used for food – these applications result in mutations that are no different to naturally occurring (spontaneous) mutations and they do not result in GMOs.[24]

22 Page 13 - Food Standards Australia New Zealand, 'Proposal P1055 – Definitions for Gene Technology and New Breeding Techniques'; Food Standards Australia New Zealand, Supporting Document 1 Safety Assessment: Full Technical Report; Food Standards Australia New Zealand, 'Supporting Document 2 Safety Asesent: Plan English Summary', 2021 <https://www.foodstandards.gov.au/code/proposals/Documents/P1055 SD2 Safety Assessment Plain English Summary.pdf>.

23 Page 10 - Food Standards Australia New Zealand, 'Proposal P1055 – Definitions for Gene Technology and New Breeding Techniques'.

24 National Gene Technology Scheme, Modernising and Future-Proofing the National Gene Technology Scheme: Proposed Regulatory Framework to Support Implementation of the Third Review of the Scheme, 2020 <https://www.health.gov.au/sites/default/files/documents/2021/08/national-gene-technology-scheme-consultation-regulation-impact-statement-consultation-regulation-impact-statement.pdf>.

5 EXCLUSION CRITERIA

The Code currently defines "food produced using gene technology" as "*a food which has been derived or developed from an organism which has been modified by gene technology*".

FSANZ has proposed to incorporate specific exclusions into this definition for certain products that they have determined to be equivalent in risk to conventional food, including certain "NBT foods". As we have already stated at length, we completely agree with FSANZ's summation that NBT foods that have the same characteristics and risk as conventional foods should not be GM food for Code purposes. This means that they should not require premarket safety assessment and approval as a GM food or be labelled as such.

With the clear proposals we have made for the definitions of "gene technology" and "foreign DNA", there is no need to revise the definition of "food produced using gene technology", or for the proposed set of exclusion criteria for NBT foods. We do however provide comments on the NBT food exclusion criteria proposed by FSANZ that are aimed at clarifying these should it ultimately be decided that they be implemented.

For NBT foods, FSANZ has proposed five exclusion criteria, with the food required to satisfy all five of them before it can be excluded.[25] We stress that the exclusion criteria must be clear and unambiguous to avoid uncertainty, and they must not impose unnecessary burden and cost for developers. In making assessments against the criteria, it should not be necessary for a developer to generate datasets of a scale comparable to that required for a GM food, or to consult with the proposed Advisory Committee. Importantly, in addressing the exclusion criteria, any data generation must be hypothesis-driven and based on scientific rationale. We also seek clarity for those criteria requiring investigation, e.g. "key nutrients", in regard to the databases or other sources of "documentation" that would be appropriate.

We have made proposals for amendments for each of the NBT food criteria below.

(i) "no foreign DNA introduced using gene technology is present in the tissue or cells from which the food is derived"

With our proposal to integrate the requirement for "no foreign DNA" into the definition of "gene technology", this criterion is no longer required. Further, we do not consider this criterion appropriate in the context of product (food)-based characteristics – the presence or absence of foreign DNA in tissue or cells is associated with the technology (process) used.

[25] Page 26 - Food Standards Australia New Zealand, 'Proposal P1055 – Definitions for Gene Technology and New Breeding Techniques'.

(ii) "the trait introduced using gene technology does not modify the levels of key nutrients, endogenous toxicants or anti-nutrients so they are outside the documented range for an equivalent conventional food"

CropLife recommendation:
"the trait introduced using gene technology does not modify the levels of **known** key nutrients, endogenous toxicants, or anti-nutrients so that they are outside the documented range for an equivalent conventional **or previously approved** food **produced using gene technology**."

Regarding "key nutrients", this exclusion criterion must not presume a requirement for developers to generate data for an exhaustive list of "key nutrients", even if a specific list is provided. The potential requirement to assess such data should be hypothesis-driven and based on scientific rationale, i.e., if there is no reasonable hypothesis that the developed trait affects the final food content, such as protein, fat or carbohydrate content, it would not be scientifically justified to need to produce such data. Further, if a "key nutrient" is outside the "documented range" of variability, there needs to be a reasonable hypothesis that it could result in a higher level of food safety risk e.g., deficiency or overconsumption.

Furthermore, FSANZ's use of the term "documented" with respect to key nutrients, endogenous toxicants or anti-nutrients, does not recognise what might be possible through nature or conventional breeding methods. In specifying "documented", this exclusion criterion creates disparity with conventionally bred food. For example, if a food produced using conventional breeding methods has nutrient levels that are higher than ranges previously documented, it will not be regulated, but for NBT foods with higher than known nutrient levels, this will be a trigger for regulation as a GM food.

(iii) "the trait introduced using gene technology does not result in the synthesis of a substance that is not present in existing conventional food"

CropLife recommendation:
"the trait introduced using gene technology does not result in the synthesis of a substance that is not **known to be** present in existing conventional **or previously approved** food **produced using gene technology**."

Similar to our comments on exclusion criterion (ii) above, the potential requirement to assess the production of a substance that is not present in existing conventional food should be hypothesis-driven and based on scientific rationale, i.e., the intended trait is expected to result in the synthesis of such a substance.

Clarity is needed with the application of this criterion for scenarios such as the substance being present in other foods, but not in the food that has been modified. We also highlight the potential for the future identification of substances produced as a result of natural processes or conventional breeding methods. It may be that at present, a substance could be synthesised as a result of a trait introduced via an NBT, and in the future, the same substance is discovered to also be produced via natural processes or through the use of conventional breeding methods in that food or in a different (conventional) food.

(iv) "the food does not contain endogenous proteins modified using gene technology that are now significantly similar to known toxins or allergens"

CropLife recommendation:
"the food does not contain endogenous proteins modified using gene technology **in a way that introduces or increases homology with** ~~**that are now significantly similar to**~~ known toxins or allergens.

This recommendation aims to clarify that endogenous proteins with previously established homology to known toxins or allergens that are not impacted by the modification would not trigger this criterion.

(v) "the endogenous allergen content of the food has not been modified as a result of gene technology"

CropLife recommendation:
"the **known** endogenous allergen content of the food has not ~~**been modified**~~ **increased beyond the documented range** as a result of gene technology."

Null Segregants

In addition to the five NBT food exclusion criteria proposed by FSANZ, we also note FSANZ's proposal to specifically exclude "food from null segregants".[26] Exclusion of this category of foods is scientifically sound and CropLife supports this. We note that this specific exclusion is addressed by the definition of "gene technology" proposed by CropLife and we do not propose a separate definition of "null segregant".

[26] Page 16 - Food Standards Australia New Zealand, 'Proposal P1055 – Definitions for Gene Technology and New Breeding Techniques'.

6 OTHER MATTERS

Labelling

It must be made clear that if a food does not require pre-market approval, it does not require GM labelling. Under the current proposal it appears that products exempt from pre-market assessment will need to be labelled as GM food under the Food Standards Code under some circumstances. This discrepancy must be clarified.

CropLife also highlights that the allergen database is live and continually updated.[27] If an allergen were to become known following the market release of a new product, it could be considered more appropriate to change a product's labelling e.g., the addition of allergen advice, rather than conducting a product recall.

Application handbook

In line with the development of guidance materials, the Application Handbook should also be updated, specifically section 3.5.1 – Foods produced using gene technology.[28] For example, there is opportunity to develop a more explicit risk tiering protocol.

International alignment

We appreciate that FSANZ is keeping abreast with the diverse international developments in regulatory approaches to NBTs and are cognisant to the benefits of international harmonisation for an efficient and internationally competitive food industry.

Option B of the Decision RIS

The responsibility of regulating genetic technologies and their products is shared between the Office of the Gene Technology Regulatory (OGTR) and FSANZ. CropLife commends FSANZ on its ambition towards the development of a science-based and risk-proportionate assessment process. We draw similarities between FSANZ's proposed process and that which is required of the Department of Health in progressing the outcomes associated with the regulatory framework to update and enhance the operation of the National Gene Technology Scheme (Scheme) where following stakeholder feedback, the Gene Technology Minister's meeting endorsed industry's preferred option, Option B – a risk-tiering model.

27 University of Nebraska-Lincoln, 'AllergenOnline' <http://www.allergenonline.com>; NCBI, 'Protein' <https://www.ncbi.nlm.nih.gov/protein>.

28 Food Standards Australia New Zealand, 'Application Handbook', 2019 <https://www.foodstandards.gov.au/code/changes/Documents/FSANZ Application Handbook 1 July 2019.pdf>.

CropLife's feedback, which was primarily addressing GM definitions, notifiable dealings and authorisation pathways, were addressed. Also captured are CropLife's statements regarding enhancements to Option B, including those associated with:

- Recognition of safe use and previous risk assessments
- Streamlining of applications between regulators
- Provision of a specific regulatory pathway for clinical trials involving GMOs.

To therefore ensure the delivery of a Scheme that is more flexible, streamlined and risk-proportionate, and a regulatory process that is future-proof, it is crucial that the Commonwealth Department of Health drafts legislation that delivers a fully enhanced and comprehensive Option B, i.e. one that will genuinely modernise the system and deliver on the sector's intentions. Achieving a fully enhanced and comprehensive Option B will also support the continued advancement and prosperity of the agricultural and medical research sectors.

Should the comprehensive industry feedback acknowledged in the Decision RIS not be fully captured in subsequent draft legislation, then the new Scheme will not be genuinely future proofed and as such, all efforts to date would be undermined. The Department of Health has responsibility to deliver a genuinely modern system that delivers on the sector's intentions for the benefit of both agricultural and medical biotechnology innovations.

We are encouraged to see the considered, appropriate and science-based approach that FSANZ has adopted in Proposal P1055 and anticipate the Department of Health following suit in its delivery of draft legislation that captures the full intention of Option B.

7 CONCLUSION

CropLife commends the Food Regulation Standing Committee for their aspiration to identify opportunities to modernise and future-proof regulatory practices throughout the food regulation system, while delivering on the Australian Government's commitment to reduce unnecessary regulation.

CropLife is pleased that views expressed throughout the Consultation Paper recognise that regulation of NBT foods should not be unnecessarily restrictive but instead be more risk-proportionate, commensurate with identified risks and informed by credible science and evidence.

Whilst CropLife is supportive of a regulatory approach that places greater emphasis on the risk posed by the product than the technology used and the resulting genetic changes, further refinement and clarity is needed regarding the proposals and suggestions put forward in P1055. In this submission we have made proposals aimed at providing a vastly less complex approach with a focussed regulatory scope, i.e., on GM foods and GM-equivalent NBT foods.

Our proposals remain consistent with our views previously submitted in several consultations held by FSANZ (the Review), the OGTR (review of the Gene Technology Regulations) and the Department of Health (review of the National Gene Technology Scheme), and they remain aligned with the views of the international seed industry.

Australian farmers need biotechnology innovations to remain globally competitive to best support the production of safe, nutritious and affordable food, feed and high-quality fibre, while being even more environmentally sustainable. Australia needs a regulatory process that is fit-for-purpose, future-proof, scientifically credible and offers certainty to regulated sectors and the Australian community more broadly.