**BASF Australia Ltd submission on Proposal P1055: Definitions for gene technology and new breeding techniques**

**3 December 2021**

BASF Australia Ltd (BASF) is a large and diverse business with a broad portfolio of fungicides, herbicides, insecticides and biological crop protection products, as well as seeds, traits, seed treatment products and digital solutions. Our scientific expertise extends much further than agriculture. We also provide innovative solutions for human nutrition, professional pest control, ornamentals, turf and landscape management. BASF has a strong history in the development of gene technology products and also in the development of plant varieties developed using conventional breeding techniques.

BASF is a global expert in seeds and traits, supporting farmers along the whole value chain and ensuring the success of our customers around the globe. We have a broad portfolio and unique traits with food products that are exported and imported globally. Our comments on P1055 are particularly relevant to FSANZ given that Australia is an import market for BASF products.

In Australia, we are involved in commercial seed sales and trait licensing, and our experience with the cultivation of genetically modified crops dates back to the inception of work in this area in cotton and canola in the mid-1990s. In this submission, our comments are predominantly relevant to our agricultural business, however we also wish to comment on other aspects of FSANZ's proposal that are relevant to BASF including the assessment of refined ingredients e.g. processing aids. In drafting our submission, BASF has worked closely with industry bodies and as a result our response aligns with CropLife Australia and the Australian Seeds Federation.

As a company we welcome the opportunity to comment on Proposal P1055: Definitions for gene technology and new breeding techniques to support FSANZ's preferred approach (Option 3) as outlined in the Consultation Paper[1]. We particularly welcome the intention of adopting a more risk-based regulatory approach to food safety with the proposed amendments to the definitions for *"food produced using gene technology"* and *"gene technology"* in the Australia New Zealand Food Standards Code (the "Code"). Amendments to relevant definitions are particularly necessary to provide regulatory clarity for foods developed using "new breeding techniques" (termed "NBT foods"[2]). The current definitions in the Code lack clarity with regard to NBT foods, and are therefore not fit for purpose, and result in uncertainty about any regulatory assessment and approval requirements. The lack of clarity regarding a pathway to market for NBT foods, coupled with disproportionate regulatory oversight for certain NBT applications, presents disincentives for investment and innovation in Australia's biotechnology sector.

[1] Food Standards Australia New Zealand, 1st call for submissions – Proposal P1055, 07 October 2021 173-21, available at: https://www.foodstandards.gov.au/code/proposals/Pages/p1055-definitions-for-gene-technology-and-new-breeding-techniques.aspx.

[2] Abbreviations, acronyms and terminology used in this submission are consistent with that used by FSANZ in the Consultation Paper.

Maintaining the status quo is not an option and FSANZ should amend relevant definitions with the aim to implement a more proportionate and future-proof regulatory model.

BASF appreciates the recognition by FSANZ that NBT foods can have identical characteristics as foods produced via conventional breeding methods, and therefore they present equivalent risk, and such foods should not require pre-market assessment and approval in the same way that GM foods do. This is consistent with current scientific understanding and the rationale presented by FSANZ in the Consultation Paper as well as their supporting safety assessment of NBTs[3], as well as what is being implemented for NBTs in other international jurisdictions.

Our understanding is that FSANZ is proposing a 'hybrid' regulatory approach including: (i) a broadened process-based definition of "*gene technology*" that captures everything that is not conventional, and extending to all methods for genetic modifications including those that are new and emerging; and (ii) a revised definition of *"food produced using gene technology"* that incorporates product-based exclusions with criteria to be met, and identified and evaluated on a case-by-case basis. FSANZ presents this as a more risk-based and future-proof approach. They also propose that this approach is supported by non-regulatory measures including the establishment of an "advisory committee" that can be voluntarily used by technology developers where they need advice on applying exclusion criteria, as well as guidance materials that are yet to be developed.

We support a regulatory approach that emphasises the risk posed by the product and we also acknowledge that GM foods will remain subject to pre-market assessments and approvals by FSANZ. However, we do wish to raise concerns with the proposal for an all-encompassing, broad definition of "*gene technology*" that widens the regulatory scope of FSANZ. We do not believe this to be consistent with current scientific knowledge and understanding, nor is it commensurate to risk.

Both the Consultation Paper and Supporting Document 1 recognise that many NBTs do not result in "foreign DNA" remaining in the final food product, which contrasts with foods developed using older transgenic methods. We highlight that certain NBTs have outcomes that are comparable to transgenics (e.g. SDN-3), and contend that the regulatory scope of FSANZ in regard to NBTs should not extend beyond such GM foods.

Below you will find our specific comments on elements of FSANZ's proposal below, including amendments for relevant definitions.

## 1. Proposed Amendments to Definitions in the Code

In the Consultation Paper, FSANZ proposes to broaden the definition of "*gene technology*" in attempt to capture all biotech methods that may be used for genetic modification now and in the future. The rationale presented is to improve clarity about what foods are captured for pre-market approval, provide greater regulatory certainty now and into the future, and capture new and emerging genetic technologies for assessment.

[3] Supporting Document 1.

The Code currently defines *"conventional breeding"* as being distinct to *"gene technology"*, i.e. a method used is either conventional or gene technology. Given that many NBT foods have equivalent characteristics to conventional foods, the need for greater precision with the definition of "*gene technology*" becomes more important. We emphasise that maintaining such a division between "*gene technology*" and "conventional breeding" methods is no longer scientifically unjustified, and it is inconsistent with current scientific knowledge and the continuum of tools that exist today for genetic modifications[4]. Additionally, it is not aligned with FSANZ's own assessment that the genetic changes introduced using NBTs are consistent with those that can occur naturally, that can result from conventional breeding methods, or that can result from older GM (transgenic) techniques, and that exclusions should apply to NBT foods that have the same product characteristics – and therefore risk - as conventional food.[5]

BASF agrees with FSANZ's summation that the types of genetic changes resulting from the diversity of tools available for modifying food organisms continue to fall within three general categories: (i) those that could arise through naturally occurring processes (e.g. spontaneous mutation), (ii) those that could be achieved using conventional breeding methods, and (iii) those that could be achieved through transgenesis. While the distinction between GM food and conventional food may have been appropriate for regulatory purposes at time the Code was established because GM food "generally results in outcomes that could not be achieved through conventional breeding",[6] this is no longer scientifically sound.

### 1.1. Gene technology

The proposal to adopt a broad definition of "*gene technology*" widens FSANZ's regulatory scope under the objectives of "future-proofing" and addressing "gaps" in regulatory oversight, however, there is no policy or scientific justification for this. We believe the scope of FSANZ's regulatory oversight in regard to "*gene technology*" should remain focused on those changes that cannot arise naturally or via conventional means, i.e. transgenesis and the resulting GM foods.

Taking into consideration the points above, BASF proposes two new interrelated definitions below for "*gene technology*" and "*foreign DNA*", each followed by explanatory text.

[4] Consultation Paper, page 14.
[5] Consultation Paper, page 22.
[6] Consultation Paper, page 10.

FSANZ states in the Consultation Paper that the definition of "*gene technology*" should be simple, clear, and not technically complex[7] - we agree, and this is what we are proposing above.

**Box 1: Definition of *gene technology***

Current definition in the *Code*:

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

Definition proposed by BASF:

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

FSANZ has posed the adaptation of USDA's definition of "genetic engineering" as a possible suitable definition: "techniques that use recombinant, synthesised or amplified nucleic acid to modify or create a genome"[8]. Our proposal for gene technology (and foreign DNA) is a simpler version that does not include several technically complex terms that require defining if included (e.g. recombinant, synthesized, amplified, modified, create). Furthermore, our definition will also, in effect, exclude certain NBTs upfront that do not result in the introduction of "foreign DNA".

### 1.2. Foreign DNA

This proposed definition of *"gene technology"* retains key elements of the current definition in the Code – introduced DNA, but we have amended this from "recombinant DNA" to "foreign DNA" as this better reflects the process (transgenesis) that results in GM food[9]. We agree with the explanation in the Consultation Paper[10] that "*foreign DNA*" originates from a different species, and its insertion into the genome of an organism constitutes transgenesis, however, the term "*foreign DNA*" is technically more precise than using "recombinant DNA" with regards to the process of "transgenesis".

[7] Consultation Paper, page 24.
[8] Consultation Paper, page 24.
[9] Consultation Paper, pages 9, 14.
[10] Consultation Paper, page 9.

This reference to *"foreign DNA"* incorporates one of the NBT food exclusion criteria (see 2.1 below). We propose that the term *"foreign DNA"* is included in the definition rather than forming a criterion. A definition for the term "*foreign DNA*" is in Box 2 below.

**Box 2: Definition of *foreign DNA***

BASF proposal:

*"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 understand that expanding the definition of "*gene technology"* to capture everything that is not conventional breeding is an attempt to future-proof the regulatory model with evolving scientific tools. However, taking such an overly precautious approach through the definition of "*gene technology"* does not address the lack of regulatory clarity or gaps in regulatory oversight, rather it just extends FSANZ's regulatory scope beyond GM foods without justification, it also increases the regulatory burden for developers, and it is therefore counterproductive.

In the proposed approach, the onus is on the developer to determine whether an NBT product meets the exclusion criteria, with assistance from guidance material (to be developed by FSANZ) and via an independent advisory committee (voluntary process). If an NBT product is captured due to this broadened process-based definition but it is indistinguishable from a conventionally bred product, having to address a list of exclusion criteria is not proportionate to risk and is an unnecessary burden on technology developers (especially smaller developers), disincentivising innovation. Capturing "*foreign DNA"* in the definition, as we have proposed, is on the scientifically sound basis that products of "gene technologies" that do not contain "*foreign DNA"* (per our proposed definition) are indistinguishable from conventional products. These products should, therefore, not require evaluation against the NBT food criteria.

FSANZ also discusses the practical issues of implementation and enforcement in the Consultation Paper,[11] highlighting the well-documented challenges regarding detection and uniquely identifying certain NBT products should they be regulated. Our proposed definitions of *"gene technology"* and *"foreign DNA"* will not capture such NBT products within regulatory scope.

### 1.3. Conventional breeding

In regard to "*conventional breeding"* there is currently a definition in Schedule 26 of the Code: "conventional breeding means all methods used to produce plants, excluding techniques that use gene technology", with the

[11] Consultation Paper, page 16-17.

resulting foods considered to be "conventional foods". The methods that are understood to be included by this definition are cross-breeding and selection, classical mutagenesis methods, and various cell and tissue culture techniques[12].

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 conventional versus biotech dichotomy.

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*".

Regarding the two other interconnected definitions, 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 proposed by FSANZ, were to be adopted.

In formulating these definition proposals, BASF has reviewed approaches taken in other jurisdictions, and notes the review of examples of these by FSANZ[13]. We also reinforce our messaging delivered through the multiple reviews and consultations in recent years including the 2016 Technical Review of the Gene Technology Regulations, the 2017 Review of the National Gene Technology Scheme (NGTS), the implementation proposals for the NGTS, and the 2018 FSANZ Review of Food Derived Using New Breeding Techniques. Our views and proposals have remained consistent throughout these reviews, and have remained relevant and scientifically sound as further scientific knowledge and regulatory experience has accumulated. We also note that our views are aligned with that of the international seeds industry (International Seeds Federation) that the final plant product should not be included in the scope of GM regulation where: (i) there is no novel combination of genetic material (i.e. there is no stable insertion in the plant genome of one or more genes that are part of a designed genetic construct), or (ii) it solely contains the stable insertion of inherited genetic material from sexually compatible species, or (iii) the genetic variation is the result of spontaneous or induced mutagenesis.

Our views are also consistent with:

- FSANZ's own analysis that some outcomes of NBTs are "similar if not identical to outcomes using conventional breeding methods";[14] see also the safety assessment undertaken by FSANZ.[15]
- FSANZ's explanation in the Consultation Paper, which we agree with, that the process of "transgenesis" results in GM food, and that this process requires the introduction of "foreign DNA". We highlight that

[12] Consultation Paper, page 9.
[13] Consultation Paper, pages 19-20.
[14] Consultation Paper, page 12.
[15] Consultation Paper, page 13; Supporting Document 1 and Supporting Document 2; available at: https://www.foodstandards.gov.au/code/proposals/Pages/p1055-definitions-for-gene-technology-and-new-breeding-techniques.aspx.

certain NBTs result in similar outcomes to older transgenesis techniques, and these would not be excluded from regulatory scope by the definition we have proposed above.

- The rationale for the other proposed exclusions – "null segregants" (see 2.2. below), and "refined ingredients" (see 2.3 below).
- The conclusions of the FSANZ technical workshops.[16]
- The rationale underlying the exclusion 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.[17]

BASF emphasises that products of "gene technologies" that do not contain "foreign DNA" are similar if not identical to conventional products. These products therefore should not require evaluation against all of the NBT food criteria before being excluded from regulatory scope.

## 2. Excluded Food Produced using Gene Technology

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 which are aimed at clarifying these should it ultimately be decided that they are implemented.

The proposal in the Consultation Paper involves adding three categories that are excluded from this definition, each requiring specific criteria to be met. For each of these, we have specific comments and proposals for amendment.

### 2.1. NBT food that is the same as conventional food

FSANZ has proposed to incorporate specific exclusions for certain products that they have determined to be equivalent in risk to conventional food, including certain "NBT foods". BASF wholeheartedly agrees with FSANZ's summation that NBT foods comparable in their characteristics and consequently indistinguishable from conventional foods, should not be subject to regulation as a GM food. Accordingly, these NBT foods should not be subject to a pre-market assessment and approval, and should not require GM labelling.

BASF emphasises that if the term *"foreign DNA"*, as defined above, is included in the definition for "*gene technology"* this would eliminate the need for exclusion criteria, as any product containing "foreign DNA" would

[16] See Consultation Paper, page 10.
[17] Updating Gene Technology Regulation in Australia – Regulation Impact Statement for Consultation. Office of the Gene Technology Regulator 2017.

be considered GM and would be required to go through a pre-market assessment. Conversely, any NBT product that does not contain "foreign DNA" is considered equivalent to conventional food products and should not require a pre-market assessment.

FSANZ has proposed five exclusion criteria, with the NBT food needing to meet all five so it is not considered a "*food produced using gene technology"* and can be excluded from pre-market assessment.

If it is ultimately determined that exclusion criteria are the most appropriate measure to assess the equivalence of NBT food to conventional food, we emphasise that both the exclusion criteria and any associated guidance material[18] must be clear and unambiguous to avoid uncertainty, allowing applicants to easily determine if their product either does or does not meet specific exclusion criteria. We have made some comments below.

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

BASF have proposed integrating the requirement for "no foreign DNA" into the definition of "*gene technology"* as defined above. With this amendment, criterion (i) would no longer be required. Further, we do not consider this criterion appropriate in the context of product (food)-based regulations as the presence or absence of foreign DNA is associated with the technology (process) used.

**(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; and**

BASF proposes introducing the qualifying word "known" into this criterion, as well as incorporating levels that have been assessed as safe previously by FSANZ:

"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** ~~food~~."

Regarding "key nutrients", it is unclear what FSANZ considers to be a "key nutrient", and we stress that 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. Also, when a "key nutrient" is outside the "documented range" of variability, there needs to be a reasonable hypothesis that this could result in a greater food safety risk, e.g. deficiency or overconsumption.

[18] Consultation Paper, page 23

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; and**

BASF again proposes the qualifying word "known" and incorporating levels that have been assessed as safe previously by FSANZ:

"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** ~~food~~."

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 (conventional) 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 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; and**

BASF proposal:

"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.**

BASF proposes the qualifiers "known" and reference to the "documented range":

"the **known** endogenous allergen content of the food has not ~~**been modified**~~ **increased beyond the**

**documented range** as a result of gene technology."

### 2.2. Null segregants

FSANZ's safety assessment found that because null segregants have not inherited the genetic modification introduced using gene technology, they are the same as conventionally bred organisms.

BASF strongly agrees with FSANZ's conclusion that food from null segregants should not be considered GM food for Code purposes. Exclusion of this category is scientifically sound, and BASF supports that null segregants should not require pre-market safety assessment and approval as a GM food, or be labelled as such. We also note that this exclusion is addressed by the definition of "*gene technology*" proposed by BASF, and we do not propose a separate definition of "null segregant".

### 2.3. Refined ingredients

BASF also strongly agrees with FSANZ's safety assessment on refined ingredients noting that certain ingredients from GM food may also have equivalent characteristics to conventional food, but only when the food is refined or purified in such a way that novel DNA or novel protein resulting from the foreign DNA insertion is removed[19].

BASF strongly supports FSANZ's conclusion that food from refined ingredients should not be considered GM food for Code purposes. This means that they should not require pre-market safety assessment and approval as a GM food, or be labelled as such. We again note that this exclusion is addressed by the definition of *"gene technology"* proposed by BASF.

## 3. Non-Regulatory Measures

With the clear proposals for the definitions of "*gene technology*" and "*foreign DNA*", we do not believe there is any need for additional non-regulatory measures to support implementation. Guidance material should be available to developers only to assist in the determination of *"foreign DNA"*. Our comments on the Advisory Committee are predominantly aimed at clarification of the role and functioning of the proposed Advisory Committee, should one ultimately be established.

### 3.1. Advisory committee (AC)

BASF emphasises that the definitions of "*gene technology*" and "*foreign DNA*" we have proposed above would eliminate or at least diminish the need for an AC, as any product containing "foreign DNA" would be considered GM and would be required to go through a pre-market assessment. Conversely, any NBT product that does not contain "foreign DNA" is considered equivalent to conventional food products and should not require a pre-market assessment. This is a straightforward determination with the proposed definitions.

[19] Consultation Paper, page 16

Our current understanding of FSANZ's proposition for an AC is that this would be a voluntary process to help technology developers determine the applicability of the exclusion criteria to their product. In the Consultation Paper, very little is elaborated on the proposed idea for an AC. Should an AC be established, it must be voluntary and many questions must be clarified. These include:

- The composition of the AC.
- How the work of the AC will be funded - it is important for developers to know if this will be based on cost-recovery.
- What will be the timelines for the provision of advice?
- What will be the legal status of the advice, and what recourse will be available to developers if they do not agree with the advice given?
- What kind 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.

We are also not clear why the AC is proposed instead of 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.

### 3.2. Guidance material

With our proposed definitions of "*gene technology*" and "*foreign DNA*", guidance material in relation to excluded products should be limited to assessing the absence of "foreign DNA". Any guidance material must be clear and detailed enough for applicants to be able to assess their products themselves, without necessitating advice from FSANZ or the proposed AC. Further, clear guidance materials would eliminate the need for an AC.

BASF would like further clarity on what sort of information and data will need to be compiled as "evidence" to demonstrate "compliance"[20]. In particular, clarity is needed on who will be enforcing "compliance", who shall retain the evidence and for how long, and what obligations there are for the developer, if, for example, the regulatory status changes and the developer is required to provide data. We would also like to emphasise that any information and data retained by FSANZ or other body to demonstrate "compliance" must be managed with regard to commercial confidentiality requirements.

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

[20] Consultation Paper, page 23

for implementing the new definitions (and any exclusion criteria) to ensure that these (and any additional) important questions are addressed

## 4. Other Comments

### 4.1. 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 Code in some circumstances. It must be made explicitly clear to technology developers that NBT food products that are excluded from GM regulatory scope do not require GM labelling. This discrepancy must be clarified.

### 4.2. Allergen labelling

BASF also highlight that the allergen database[21] is live and continually updated. 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.

## 5. Conclusion

BASF commends the Food Regulation Standing Committee on their aspiration to identify opportunities to modernise and future-proof the FSANZ regulatory model, while delivering on the Australian Government's commitment to reduce unnecessary regulation.

We wholeheartedly agree with FSANZ's assessment that some NBT foods have identical characteristics as food produced via conventional breeding, and therefore should not require pre-market assessment and approval in the same way that GM foods do. BASF supports amending the relevant definitions in the Code to give effect to this, but we find FSANZ's proposal overly complex and burdensome for developers, lacking in clarity in the non-regulatory measures, and disproportionate in its regulation of certain NBT foods which could be also obtained via conventional or traditional means. We therefore make alternative proposals to clearly focus regulatory oversight on GM and GM-equivalent NBT foods.

The Australian biotechnology industry needs a regulatory process that is fit-for-purpose and future-proof, allowing Australia farmers to remain globally competitive. Our amendments to FSANZ's proposals aim to further refine P1055 with the aim to improve our regulatory process so that it is consistent with current scientific knowledge and proportionate to risk.

[21] University of Nebraska-Lincoln, 'AllergenOnline' http://www.allergenonline.com; see also NCBI, 'Protein' https://www.ncbi.nlm.nih.gov/protein