REVIEW OF THE REGULATION OF FOOD DERIVED USING NEW BREEDING TECHNIQUES

A SUBMISSION TO THE FSANZ REVIEW

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6 April 2018

Food Standards Australia New Zealand

Canberra, 2300, Australia

April, 2018

Dear Sirs,

We welcome the opportunity to make comments on the call for submissions on the safety of New Plant Breeding Techniques. We note the information provided on the FSANZ web site regarding the call for submissions on this important topjc. We also take note that this consultation will not result in a change to the Australia New Zealand Food Standards Code (the Code), and that If at the end of the review, FSANZ determines that the Code needs to be changed, a proposal would need to be developed. Proposals involve a separate process involving further public consultation.

We understand that in the Code, the definition of food produced using gene technology refers to the technique where new pieces of DNA are inserted into a genome to create a genetically modified organism. Since this definition was developed new techniques have emerged, some of which produce results that are almost identical to conventional breeding methods such as cross-breeding and mutation breeding.

There are a range of techniques for modifying genomes. FSANZ have grouped these techniques based on the outcomes produced in the final product as follows:

- **Outcome one: Genome contains new DNA**

  Techniques such as transgenesis, cisgenesis and intragenesis involve taking a piece of DNA from one organism and inserting it into the genome of another organism. The result is a genome that contains new DNA.

- **Outcome two: Genome unchanged by gene technology**

  Techniques that are used to produce null-segregants involve an initial organism that has new DNA inserted into the genome (outcome 1 above). The new DNA helps with the breeding process (e.g. makes it faster) but serves no purpose once the objective of the

breeding has been achieved. Towards the end of the breeding process only organisms that have not inherited the new DNA are selected for food production purposes.

- **Outcome three: Genome changed but no new DNA (genome editing)**

  These techniques (e.g. CRISPR & ZFN) involve deleting a specific piece of DNA or editing of the DNA without adding new DNA.

  Our submission will address as much as possible the three outcomes as outlined in the information on the review from the FSANZ website as follows:

  Summary

  - The safety of foods produced by all the plant breeding technologies (this includes conventional techniques, GM food safety and New Plant Breeding Technologies (NPBTs)) should be approached on a case-by-case basis along a risk continuum, focussing on the safety and novelty of the plant product and not the technology used. Regulation and safety assessment should be managed by exception rather than according to entrenched, scientifically discredited, outdated regulatory protocols arbitrarily focussed on specific techniques of genome modification.
  - A new paradigm is necessary where the regulatory requirements for the safety of GM foods should be removed completely, or at the very least drastically reduced on a case-by-case basis, founded on the 25-30 years of experience that proves beyond any doubt that GM foods are as safe as other equivalent foods produced using conventional breeding techniques. We view 'case-by-case' assessment with a lighter touch on repetitive developments (the "me too's") is less politically risky. It's an interim step but at least in the right direction.
  - We understand that there may be some preference not to adopt a 'case-by-case' approach as the primary outcome, as this detracts from regulatory certainty during the development phase of a new product, and would prefer clarity from the outset regarding whether foods derived from organisms produced using plant breeding innovations are 'in' or 'out' of regulatory scope.
  - The regulatory requirements for the safety of food produced using New Plant Breeding Techniques (NPBTs) that fall under Outcome one: Genome contains new DNA and Outcome two: Genome unchanged by gene technology, according to the definition of Food Produced Using Gene Technology (as per Standard 1.5.2 of the Food Standards Code (the Code), should either require no safety testing, or only require reduced, case-by-case safety testing similar to GM foods as suggested above under a new paradigm. In particular, crop varieties that now have a long history of genome alteration with no evidence of increased food safety risk, such as corn, canola, cotton, soy, sugarbeet, potatoes, etc, should not have discriminatory regulatory requirements in excess of that for foods produced using conventional techniques for genome alteration. Similarly specific introduced traits such as herbicide resistance, insect resistance for example, have an equally long history of

safe use and have never been found to introduce unique food safety risks (ie. not pre-existing risks in the crop variety being modified)

- Those foods produced using NPBTs that do not fall under the definition of GM foods as per Standard 1.5.2 of the Code, i.e. Outcome three: Genome changed but no new DNA (genome editing), should be considered on a case-by-case using a common sense, first principles approach to assess their potential for any safety concerns similar to any other food produced using conventional plant breeding techniques. The vast majority of foods produced using NPBTs would not require any regulation as they fall into the same category as conventional breeding techniques.

The submission will develop a logic based on past and current experience using examples.

THE SAFETY OF GM FOODS

The technology to produce genetically engineered (GE) plants is celebrating its 30th anniversary and one of the major achievements has been the development of GE crops. The safety of GE crops is crucial for their adoption and has been the object of intense research work often ignored in the public debate. The overwhelming consensus of credible scientific debate and opinion has concluded that GM foods are safe. A very large number of studies and reviews, too numerous to mention all of them in the present submission, could be quoted to support this statement. For example, one recent review of the scientific literature on GE crop safety during the last 10 years has built a classified and manageable list of scientific papers, and analysed the distribution and composition of the published literature. Original research papers, reviews, relevant opinions and reports addressing all the major issues that emerged in the debate on GE crops have been collated, trying to catch the scientific consensus that has matured since GE plants became widely cultivated worldwide (Nicolia, et al. 2014). The scientific research conducted so far has not detected any significant hazards directly connected with the use of GE crops.

Another recent review by Bartholomeaus (Bartholomaeus 2018) has outlined meticulously powerful arguments for change in his conclusions:

> "Current regulatory burdens imposed discriminately on biotechnology developed crops generate greater risk than that they were intended to mitigate, and breach basic Human rights principles of equity and justice. Postulated risks that were originally argued as supporting the current regulatory imposts have been comprehensively discredited by both experience and increased understanding of the underlying nature and consequences of normal plant genome plasticity and variability. The cost shifting of the consequences of the regulatory affectations of the wealthy developed nations, with the income to compensate for the costs of those affectations, to the poorest of nations and communities, is arguably one of the most significant ethical lapses of our time. Increasing prosperity in some of the most

> populous nations and an increased capacity to compete for the limited supply of high value food commodities, however, is likely to shift the consequences of regulatory affectations back to the societies that originally generated them, with significant potential societal impacts. The challenges of climate change, substantially increasing world population, the shift in the world economic centre of gravity to Asia, and the overwhelming body of evidence for the safety of the broad range of plant development technologies indicate that a fundamental change to the regulatory regimes for "conventional" and biotechnology in food production is now urgently required."

Perhaps the best recent example for the safety of GM foods is the 2016 National Academies of Science (The National Academies 2016) findings of no health or safety risks linked to biotech crops. The point is that, today, we know that the methods are not dangerous. People have been looking for problems associated with simply using molecular techniques for 30 or 40 years now and haven't found them.

Currently, about 100 studies longer than 90 days have been conducted on GMO products in animals for risk assessment purposes. Only the infamous, scientifically discredited, Séralini and Carman studies have postulated serious safety issues. The bulk of the studies on GMOs — more than 2,000 — are 90 days or shorter, in line with accepted international guidelines. And many animal studies may not even be valuable, or even scientifically justifiable (Bartholomaeus, Parrott, et al. 2013). Some brief facts on GM foods are listed below:

- GMO's since 1996: Over 1000 scientific studies conducted
- 20+ years of use 3 trillion meals and snacks consumed
- 9 billion animals feed GM feed every year in US – no effects on weight or reproductive performance
- Zero food safety or health issues

And yet the extremely onerous and costly data requirements for the safety of GM foods by governments and food regulators around the world, including FSANZ representing Australia and New Zealand, have not changed even given the vast amount of evidence that GM foods are safe.

NEW PARADIGM

A new paradigm is necessary, as many regulatory assessment requirements are now unnecessary for crops such as corn, canola, cotton, and rice based on 20-30 years of crop testing and consumption by the community with NO adverse effects. A modified version of the traditional safety assessment approach for GM foods should be developed and implemented as soon as possible.

The focus of any future testing requirements for GM foods should be on the potential effect of levels of known natural biotoxins in crops (e.g. solanines in potatoes). Using a modified version of the Testable hypotheses regarding the likelihood of adverse effects should be developed on a case-by-case basis, and regulatory requirements based on likely risk and cost/benefit, especially where the trait is a "me too" (Insect resistance, herbicide-tolerance etc), not because the technology sounds scary!

And from Bartholomeaus (2018) "The new regulatory paradigm needs to embrace the principles of proportionality, consider the risks of regulation equally with the (lack of) risks being regulated and provide a balanced non-discriminatory regulatory environment within which various technologies can be applied to the increasingly urgent objective of food security."

In addition, a recent article published by the Council for Agriculture, Science and Technology (Council for Agriculture, Science and Technology 2018) concluded:

"In theory, scientifically sound regulations serve the public good by assuring a reasonable degree of product safety while not unduly stifling innovation. In a scientifically rigorous, risk-based safety assessment, the degree of regulatory scrutiny is commensurate with the degree of identified risk posed by the product in question. In reality, however, our current regulations are not based on product risk, but on spurious, undocumented risks posed by the process of genetic engineering. These regulations impose scrutiny well beyond that imposed on non-GE products posing similar risks. As well, the unnecessarily onerous and expensive regulations discourage and stifle innovation, especially in small businesses and universities."

And "The current process-based US biotechnology regulatory system is a scientifically unjustified barrier to agricultural innovation". There is a very strong argument for similar arguments being applied to the Australian and New Zealand situation.

NPBTS/GENE EDITING AND REGULATORY CHALLENGES

New Plant Breeding Technologies fall under the general theme of gene editing. Gene editing makes precise, intentional and beneficial changes in the genetic material of plants and animals used in food production, which can improve their health and sustainability. This often mirrors changes that could occur in nature or through traditional breeding. Gene editing helps farmers keep pace with the growing demand for more and better food, while using less water, land, nutrients and other resources.

Gene editing is a technology that offers tremendous benefit to society through food production improvements. The precision, potential to solve a broad array of challenges, and the relative affordability of the technology has resulted in growing interest in gene editing. As more agricultural organizations and food companies explore gene editing, the question as to their safety has been raised. For instance, consider tomato, whose DNA code consists

of around one billion GATC letters. In the natural background of the tomato DNA we can now precisely make an unprecedented one letter change without adding any (foreign) DNA. Compared with traditional breeding methods, this manifold increase in precision which genome-editing tools (including CRISPR) allow for, is similar to using a modern day telescope instead of the naked eye to observe and explore the heavens.

The improvements evoked by genome editing help to give plants desirable characteristics that enhance sustainable food production and better food quality and health in both the developed and developing world. The European Commission's scientific advice mechanism has emphasised that through genome editing methods, "the precision and control over changes made is greater than with the use of conventional breeding or established techniques of genetic modification. As a consequence, these new techniques result in fewer unintended effects".

A good example of how NPBTs could result in a reduction of a major human health concern, and increase food production worldwide, is in reducing levels of mycotoxins. Two of the most prevalent mycotoxins in agriculture are fumonisins and aflatoxins. Fumonisins are found almost exclusively in corn, while aflatoxins can be found on corn as well as cotton, peanuts, pistachios, almonds and walnuts. Other than the wider use of Bt crops–which are blocked in African countries because of widespread campaigning by anti-GMO 'environmental' groups–current methods to curb mycotoxins haven't been particularly effective. These include (besides border stops), breeding for fungal resistance, practices that impair fungal growth, biocontrol with antifungal strains, and trapping agents. Scientists have also been testing a type of short strand of RNA (known as "interference RNA" or "RNAi") for its ability to silence the genes responsible for making mycotoxin with some promising results. These genetic techniques are at least showing some effect in the field and the plants themselves, where other more traditional methods have failed. With 4.5 billion people exposed and hundreds of millions of dollars in crop damage every year, there's a lot at stake.

THE SAFETY OF NPBTS

- Depending on the regulatory policy operating in a country e.g. EU, US, Australia/NZ, some NPBTs utilise rDNA techniques e.g. cisgenics, transgenics, specific zinc finger nucleases, and already fall into the same category as GM food. This is the case for Australia/New Zealand where some foods produced using NPBTs fall under Standard 1.5.2 of the Code.
- For those foods produced using NPBTs that fall under the current definition of a GM food in Australia/New Zealand (Outcome one: Genome contains new DNA), their safety should be approached similarly on a case-by-case basis in the same way as for GM food safety, using the same modified version of a traditional GM food risk assessment as suggested above (ie. Drastic reduction to current requirements). The

safety of NPBTs using techniques that do not change the genome (Outcome two: Genome unchanged by gene technology) should be regulated in exactly the same way as those under Outcome one. This should result in minimal testing requirements on a case-by-case basis based on likely risk/benefit.

- For those foods produced using NPBTs that do not fall under the definition of a GM food in the Code e.g. CRISPRs, specific ZFNs, RNAi etc etc., (Outcome three genome changed but no new DNA (genome editing)) there should be no regulatory requirements because these NPBTs do not introduce foreign genes into the plant genome and can be considered as no different to conventional breeding techniques, some of which, e.g. mutagenic techniques, have been used now in conventional breeding for over 50 years.
- In general, food produced using NPBTs should be considered on a case-by-case using a common sense, first principles approach to assess their potential for any safety concerns similar to the approach for any other food produced using conventional plant breeding techniques.

INTERNATIONAL APPROACHES TO THE SAFETY OF FOOD PRODUCED USING NPBTS

To be fair, many international food safety regulators have been considering their approaches to the safety of food produced using NPBTs for some time now, but there is a need for further progress and commitment to achieve greater efficiencies to save on precious resources that will benefit government, industry and consumers.

For example, whether NPBTs such as RNAi and CRISPR pass regulatory muster is still a question being raised globally. RNAi is not a transgenic technique so it does not usually fall under the byzantine regulatory structure that has stunted so much innovation in genetic engineering. So far, the US FDA has approved the Arctic Apple, which reduces browning, and a potato that has reduced acrylamide content all thanks to RNAi, a technique that does not involve using genetic material from one species and transferring it to another species.

The **unclear regulatory status of genome edited crops** in most countries and the lack of distinction between non-transgenic genome edited and transgenic modified crops remain important hurdles for the deployment of genome editing in crop improvement. As the functions of more crop genes are revealed and regulatory frameworks are adapted to new technologies, genome editing can provide a powerful new tool to shape the future of agriculture and support global food security.

Furthermore, in recent work in 2015 using CRISPR on mushrooms where the process did not introduce any foreign DNA into the mushrooms, developers wanted to know if the product would be considered a “regulated article” by the Animal and Plant Health Inspection Service, a division of the U.S. Department of Agriculture tasked with regulating GMOs. APHIS replied that it does not consider CRISPR/Cas9-edited white button mushrooms as described to be

regulated. The mushrooms were not the first genetically modified crop deemed exempt from current USDA regulation, but they were the first made using CRISPR.

The heightened attention that CRISPR has brought to the gene editing field is forcing policymakers in the U.S. and abroad to update some of their thinking around what it means to genetically modify food. The rate of crop improvement must increase to meet the demands of a growing population. Although conventional breeding has delivered today's high-yielding crops, genome editing technologies e.g. CRISPR/Cas9, Cpf1; Gene Silencing, Gene Drives etc now offer a faster and **more precise** approach to generate novel crop varieties. If genomics can provide high-quality crop genome assemblies and functional annotation as starting material, genome editing has the potential to accelerate crop improvement and broaden the range of traits generated in novel varieties.

In relation to the Australian situation, recently the Office of the Gene Technology undertook a review of the potential regulatory requirements for gene edited crops and has recommended that they do not require any regulation under the OGTR Act since such crops are no different to conventionally developed crops where no new DNA has been introduced (www.OGTR.au). This is a pragmatic and refreshing approach and should be followed for consistency by FSANZ in relation to food produced using gene editing and extended to all foods produced using NPBTs.

OPPOSITION TO USE OF BIOTECHNOLOGY IN FOOD PRODUCTION

Some powerful voices, including activist "environmental" NGOs, want to ban this new methodology, and these NGOs spread their often-unsubstantiated opinions about the supposed risks of "unintended effects or unproven safety" resulting from genome editing. They argue that a plant resulting from a new breeding method should be legally considered the same as a genetically modified plant even when no (foreign) DNA has been inserted into the plant's genome. This interpretation would mean that such a plant will be stigmatised as GMO, although it is identical to its conventionally bred sibling. This would practically imply that such crop plants cannot be grown in large regions of the world such as the EU, and can only be imported into the EU after a notoriously long and expensive authorisation process. This will significantly hinder innovation in regions such as Europe, and eventually also other parts of the world and inhibits the development of better crops that are very much needed to feed our growing world population in the future. Greenpeace and other environmental and consumer groups have picked up the practice of condemning biotech foods primarily to raise money and without regard to science. Biotechnology in agriculture has suffered from campaigns of untruth. People are paid for, and attracted to, extremely engaging and horrifying stories. It's cheap and it's easy.

Greenpeace, for example, in responding to a racketeering suit brought against them by a sustainable forestry firm in Canada has admitted in court that their public statements "do

not hew to strict literalism or scientific precision", but rather should be seen as "hyperbole", "heated rhetoric", and "nonverifiable statements of subjective opinion" that should not be taken "literally" (Garneau 2017). Such disregard for basic honesty by major contributors to public debate exploit the general inability of the majority of the public, politicians, and policy makers to grasp the technical complexity of most scientific issues and skew the political discourse and resultant regulation. The regulatory environment of the EU, for example, has recently been argued to be "between Nonsense and Protectionism" (Tagliabue 2017) (Masip, et al. 2013), despite the extensive EC funded GMO research programs consistently affirming the safety of GM crops (Directorate-General for Research and Innovation 2010).

Furthermore, Friends of the Earth have launched a massive international campaign of opposition to any realistic regulatory approach to the safety of NPBTs. The only solution is to fight misinformation and lies with robust risk based, substantiated scientific approaches. There is no other shorthand for that.

THE COSTS OF FOOD PRODUCED USING BIOTECHNOLOGY

In the introduction to his paper, Bartholomeaus states "Regulation is not a morally neutral or costless process. All regulation imposes constraints, obligations, or liabilities on individuals and/or corporations and is therefore a restriction of their freedom. In an ideal regulatory environment, such imposts are strictly proportional to the risks or potential adverse outcomes associated with the activity being restricted, and the costs of implementation and compliance are proportionate to, and commensurate with, those associated with the risks being mitigated or obviated. The principles of proportionality and equality before the law have existed in the criminal code of various societies for thousands of years and are widely recognised as a foundation of National and International Law and subsidiary regulation (Ferran 2015, Cottier 2012, OECD 1995, OECD 2012).

Equally, regulatory risk should ideally not exceed the regulated risk. That is, the potential costs and broader immediate and longer term societal risks generated by the regulation should not be greater than the risk the regulation is intended to prevent. Unfortunately, we do not live in an ideal world and in practice regulation is conducted in a contentious and contested arena. In this environment evidence based and dispassionate consideration of the costs and benefits of regulation are prone to be obfuscated or misdirected by political, cultural, and ideological expediency based on selective, or mis-interpretation/ representation of the broader evidence base."

To bring a new crop protection product to market, the cost of discovery, development and authorization of a new plant biotechnology trait is US$136 million, and the time from the initiation of a discovery project to commercial launch is 13.1 years on average for all relevant crops. Regulatory science, registration and regulatory affairs account for the

longest phase in product development, estimated at 36.7% of total time involved. (Source: https://croplife.org/plant-biotechnology/regulatory-2/cost-of-bringing-a-biotech-crop-to-market/). The global costs to bring all of the currently approved crops produced using biotechnology (>100 as a conservative estimate over the last 30 years), is impossible to estimate accurately, but must be in the 100s of billions of dollars when regulatory and general social costs (government and societal) are included.

From Bartholomeaus (2018) "The principle of proportionality, embodying concepts of fairness, equity, and consistency, is fundamental to human rights, national and international law, and subordinate regulation. This principle, in theory, provides some limits on the potential unintended consequences that may result from disproportionate regulatory burdens distorting individual and corporate behaviour, the consequences of which may exceed the real or imagined harms the original regulations were intended to prevent. Current regulatory burdens applied in a number of jurisdictions on recombinant DNA technology and the new biotechnologies, however, as opposed to other less precise mechanisms of gene alteration in common use, are applied discriminately, are disproportionate to the known (lack of) plausible food safety risks, are ignorant of the broader knowledge of natural plant genome plasticity, and are consequently ethically highly questionable at best. Although major corporations developing GM crops are arguably beneficiaries of the reduced competition resulting from disproportionate regulatory burdens and their associated costs, this comes at the substantial detriment both to the respective jurisdictions and to developing economies seeking to improve the welfare of disadvantaged."

In relation to the regulatory process operating in Australia/New Zealand, FSANZ spends about A$1M in a total budget of approximately A$18M on risk assessment of GM and NPBTs. This costs includes employing and training expert staff – Executive Level 2 Principal Scientists, Executive Level 1 Senior Scientists, peer review by Section Heads, General Managers, CEO, and FSANZ Board – tempered by cost recovery but this adds costs to industry and eventually consumers. The process also involves review by all of the Australian States and Territory Departments of Health and/or Departments of Agriculture, and the New Zealand Government.

CONCLUSIONS

The point is that we now have vast experience on the safety of GM crops and foods (20-30 year report card) that can be drawn upon to inform us on how to approach any potential future risks of use of all of the plant breeding technologies. Science, and particularly regulatory science, has been slow or ill-equipped to respond to decades of abuse on GM food safety, and this trend is likely to flow on to the safety of foods produced using NPBTs. It has allowed isolated instances of intellectual corruption in lesser academic circles, or from totally unscientific sources, be held up by critics, skeptics and zealots of different persuasions, as proof that data on GM food safety has been manipulated, and that NPBTs

should be held under the same scrutiny. We should call out zealotry of any form where we see it. We should defer to the collective wisdom of the overwhelming consensus of scientific opinion and the vast number of peer-reviewed scientific papers that have produced the evidence that GM foods are safe, and that the same situation applies to foods produced using NPBTs.

The submitters again thank FSANZ for the opportunity to comment on this very important issue. We trust that FSANZ will take a pragmatic, science-based approach to this issue, and take this opportunity to change an unnecessarily onerous and politically expedient regulatory process that is now only predicated by outdated legal food standards and public perception. We look forward to the outcome of the review.

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Yours sincerely,

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Glossary of terms

DNA	DNA, or deoxyribonucleic acid, is the hereditary genetic material for most living organisms. DNA is present in cells in the form of a double-stranded helix that is composed of long strands of nucleotides. The unique sequence of nucleotides within the DNA molecule stores the genetic information.
Gene	The unit of heredity transmitted from generation to generation during sexual or asexual reproduction. More generally, the term is used in relation to the transmission and inheritance of particular identifiable traits. The simplest gene consists of a segment of nucleic acid that encodes an individual protein or RNA.
Genetically Modified Organism (GMO)	Often used to describe organisms that have been modified using gene technology. In plants, GMOs commercially available include corn (field and sweet), soybeans, sugar beets, cotton, alfalfa, papaya, squash, canola and potatoes. Farmers choose to use GM seeds to reduce crop damage from weeds, diseases and insects, as well as from extreme weather conditions, such as drought.
Genome	The entirety of an organism's hereditary information, containing all of the biological information needed to build and maintain a living example of that organism. An exact copy of the entire genome of the organism is in almost every cell.
Nucleotide	Form the basic structural unit of nucleic acids (DNA and RNA). They are composed of a phosphate group, a nitrogenous base, and a sugar (deoxyribose or ribose). For all types of living organisms, there are four types of bases in DNA: adenine (A), guanine (G), cytosine (C) and thymine (T). Thymine is replaced by Uracil (U) in RNA.
RNA	RNA or ribonucleic acid is chemically similar to DNA in that it is composed of long strands of nucleotides. Unlike DNA however it is typically present in a single stranded form. RNA plays an essential role in decoding DNA and directing the synthesis of proteins. RNA is also involved in regulating the expression of genes.
Transgenic Organism	Organisms that have had genes from other species inserted into their genome. Transgenic means that one or more DNA sequences from another species have been introduced by artificial means. Transgenic plants can be made by introducing foreign DNA into a variety of different tissues.