Public Health Association
AUSTRALIA

Public Health Association of Australia submission to Food Standards Australia New Zealand on Food Derived Using New Breeding Techniques

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Contents

Preamble

The Public Health Association of Australia

The Public Health Association of Australia Incorporated (PHAA) is recognised as the principal non-government organisation for public health in Australia and works to promote the health and well-being of all Australians. The Association seeks better population health outcomes based on prevention, the social determinants of health and equity principles. PHAA is a national organisation comprising around 1900 individual members and representing over 40 professional groups.

The PHAA has Branches in every State and Territory and a wide range of Special Interest Groups. The Branches work with the National Office in providing policy advice, in organising seminars and public events and in mentoring public health professionals. This work is based on the agreed policies of the PHAA. Our Special Interest Groups provide specific expertise, peer review and professionalism in assisting the National Organisation to respond to issues and challenges as well as a close involvement in the development of policies. In addition to these groups, the Australian and New Zealand Journal of Public Health (ANZJPH) draws on individuals from within PHAA who provide editorial advice, and review and edit the Journal.

In recent years, PHAA has further developed its role in advocacy to achieve the best possible health outcomes for the community, both through working with all levels of Government and agencies, and promoting key policies and advocacy goals through the media, public events and other means.

Vision for a healthy population

The PHAA has a vision for a healthy region, a healthy nation, healthy people: living in an equitable society underpinned by a well-functioning ecosystem and healthy environment, improving and promoting health for all.

Mission for the Public Health Association of Australia

As the leading national peak body for public health representation and advocacy, to drive better health outcomes through increased knowledge, better access and equity, evidence informed policy and effective population-based practice in public health.

Priorities

Key roles of the organisation include capacity building, advocacy and the development of policy. Core to our work is an evidence base drawn from a wide range of members working in public health practice, research, administration and related fields who volunteer their time to inform policy, support advocacy and assist in capacity building within the sector. The aims of the PHAA include a commitment to:

- Advancing a caring, generous and equitable Australian society with particular respect for Aboriginal and Torres Strait Islanders as the first peoples of the nation;
- Promote and strengthen public health research, knowledge, training and practice;
- Promote a healthy and ecologically sustaining human society across Australia, including tackling global warming, environmental change and a sustainable population;
- Promote universally accessible people centred and health promoting primary health care and hospital services that are complemented by health and community workforce training and development;
- Promote universal health literacy as part of comprehensive health care;
- Support health promoting settings, including the home, as the norm;
- Assist other countries in our region to protect the health of their populations, and to advocate for trade policies that enable them to do so;
- Promote the PHAA as a vibrant living model of its vision and aims.

Introduction

PHAA welcomes the opportunity to provide input to Food Standards Australia New Zealand (FSANZ) and in particular, to provide input into the FSANZ document titled: "Consultation paper: Food derived using new breeding techniques, February 2018" [1] hereafter called "the FSANZ Consultation Paper". New breeding techniques are hereafter abbreviated as NBT, as per the FSANZ Consultation Paper.

As outlined in the Public Health Association of Australia's objectives:

> *Health is a human right, a vital resource for everyday life, and a key factor in sustainability. Health equity and inequity do not exist in isolation from the conditions of society that underpin people's health. The health status of all people is impacted by the social, political, and environmental and economic determinants of health. Specific focus on these determinants is necessary to reduce the unfair and unjust effects of conditions of living that cause poor health and disease.*

The PHAA notes that:

- Health inequity differs from health inequality. A health inequality arises when two or more groups are compared on some aspect of health and found to differ. Whether this inequality (disparity) is inequitable, however, requires a judgement (based on a concept of social justice) that the inequality is unfair and/or unjust and/or avoidable. Inequity is a political concept while inequality refers to measurable differences between (or among, or within) groups.[2]
- Health inequity occurs as a result of unfair, unjust social treatment – by governments, organisations and people,[3] resulting in macro politico-economic structures and policies that create living and working conditions that are harmful to health, distribute essential health and other public services unequally and unfairly, preventing some communities and people from participating fully in the cultural, social or community life of society.

PHAA Response to the Consultation paper: *Food derived using new breeding techniques, February 2018*

PHAA's policy on Genetically Modified Foods

This submission is based on PHAA's policy on Genetically Modified Foods, which can be seen at https://www.phaa.net.au/documents/item/1700.

The PHAA develops policies via a lengthy and thorough process that involves review of a draft policy by the Vice President (Policy) of the PHAA, the placing of the draft policy on the Policy Forum in the Member Centre of the PHAA website, consideration of issues by the PHAA Policy team, liaison with the relevant Special Interest Group/proposer, and finally, approval by PHAA membership at the Annual General Meeting (AGM). The official policy is then published on the PHAA website. A Policy Statement is deemed to be current for three years after which it must be revised or archived[4]. PHAA's policies require evidence to support them, based on references from the peer-reviewed literature.

The PHAA has had a policy on GM foods since 1999. The policy has been revised and re-endorsed five times.

The policy has been informed by the training and experience of the members of the PHAA, which includes experts in food, nutrition, disease control, epidemiology, toxicology, medicine, and medical research. The PHAA has a Food and Nutrition Special Interest Group.

There are several items in the policy that are relevant to the topic of this submission.

First, the PHAA regards organisms developed using the new technologies described in the FSANZ Consultation Paper as GMOs. Specifically, PHAA's policy on Genetically Modified Foods includes the following paragraph in its description of GMOs. "New techniques include crops designed to produce a new RNA molecule rather than a new protein,[5] and new gene editing techniques (e.g. CRISPR) that can also be used as a "gene drive" to spread altered DNA rapidly through a population and for developing synthetic biology.[6]"

Furthermore, the PHAA considers that GMOs should be regulated and that a GMO cannot be considered to be safe until there is independent, peer-reviewed evidence that it is safe. Assumptions of safety should never be used. It should be noted that various members of the PHAA have been, and continue to be, involved in investigations into claims of safety of e.g. tobacco, alcohol, pharmaceutical drugs, food-related substances, environmental toxins etc. and are aware that industry-related claims of safety are often overturned once independent laboratory, clinical and epidemiological research has been undertaken. As a result, members have learnt to be wary of claims of safety and to require evidence to support such claims.

As a result of problems in the past when substances (e.g. pharmaceutical drugs) and procedures (e.g. surgical procedures) were claimed to be safe and efficacious, but were later found to cause harm, a process has been developed that now is regarded as the gold standard of how to assess safety. It is a step-by-step process where each step is concluded and assessed before the next step is undertaken. If a substance or procedure fails a step, the process stops. First, animal studies are conducted to determine benefits and harms. Then the four phases of human clinical trials are conducted, where Phase I looks at harm in a small number of volunteers, Phase II looks at benefits in a small number of volunteers, Phase III studies benefits and harms in a much larger number of people using a double-blind randomised controlled trial, and then the substance is monitored in the community (Phase IV). More conservative epidemiologists still do not regard a substance or procedure to be safe and efficacious until several Phase III clinical evaluations have been conducted by different research groups and the results pooled using a Cochrane review meta-analysis. [7]

Even then, there are numerous examples of evidence of harm being found only during Phase IV of the process, i.e. after the substance or procedure had passed clinical trials, had obtained regulatory approval and was being monitored in the community. Vioxx (also known as rofecoxib), an anti-inflammatory drug, is one example. By the time independent researchers had concluded that it caused harm and the drug was withdrawn from sale against the wishes of the manufacturer, it was estimated to have caused 139,000 heart attacks and killed 26,000 people.[8]

Public health professionals have repeatedly seen this kind of outcome. Consequently, to a public health professional, because no organism made using these new techniques appears to have gone through Phases I, II and III of human clinical trials, these organisms cannot be considered to be safe for human health. For the same reason, neither can previous versions of GM foods. Moreover, the quality of animal studies used to support claims of safety of GM crops has been highly criticised as being poorly conducted, largely undertaken by vested interests, and lacking in endpoints that are relevant to human health.[9] There is therefore a dearth of evidence that organisms made using these new techniques are safe.

Once a substance is released into the food supply or the environment, epidemiological studies such as cohort or case-controlled studies are required to determine if they cause harm in the population. These studies compare the health outcomes of people exposed to a substance, to those who are not exposed.

There are thousands of examples of where these studies have been used, including numerous examples investigating the effects of infectious diseases, tobacco, alcohol, asbestos and heavy metals such as lead (e.g. the Port Pirie study, leaded petrol) and mercury (e.g. Minamata disease) on health.

In order to do this type of study, it is important to be able to identify those who are exposed and those who are not exposed. If FSANZ assumes that these new techniques are safe and hence do not need to be regulated, then these GMOs will likely appear in the food supply in a way that may make it almost impossible to determine who is exposed and who is not, thereby making it almost impossible to properly undertake epidemiological studies on their effects in the population. For example, the effects of eating these new GMOs couldn't be properly elucidated if it could not be determined who had been eating them because foods from these organisms were not labelled. If FSANZ decides that they are not GMOs, then they will not be labelled. Given that these new techniques are very recent and their long-term effects are unknown, this would be a profoundly unwise step. That is, it would be a profoundly unwise step to, at this stage, through a lack of regulatory oversight, cause to happen a process that would prevent later epidemiological studies into the health effects of these new organisms.

A view has often been expressed that we would know if a GM food caused harm to people because we would notice it, and because no-one has ever noticed anyone experiencing adverse effects from eating GM food, then the assumption is that GM food must be safe to eat. The Vioxx example shows that this belief is unfounded. Each year, millions of people go to hospital and millions die from a variety of ailments and unless an epidemiological study is undertaken to determine if an exposure has contributed to a given illness or death, any link may not be found. With Vioxx, the red flag should have been raised with an extra 139,000 heart attacks and 26,000 deaths, but was not.

Not only does the PHAA have members who undertake these types of epidemiological studies, but it also has members who "pick-up the pieces", such as clinicians, once evidence of harm has been found. Consequently, the PHAA is well aware of the huge human and social costs that can accrue when things go wrong because an incorrect assumption was made that something was safe, or incomplete, or insufficient information was given by vested interests to regulators and the public.

As a result, PHAA's policy on GM food states:

- Food regulation should aim to protect public health and provide information to consumers.
- The precautionary principle should be applied to GMOs.
- Most safety assessments on GM crops are done by people associated with the GM industry and there are relatively few independent assessments[10], particularly when a new GM crop is submitted to Food Standards Australia New Zealand (FSANZ). FSANZ does not require animal feeding studies to assess safety.[11] Industry animal studies usually involve short-term toxicology studies of a few days and do not measure allergic, reproductive or cancer outcomes. Any longer studies tend to use farm animals (e.g. chickens) that are not physiologically comparable to humans and measure outcomes that are not measures of human health (e.g. meat and milk production)[12]. Reviews of the latter studies tend to find little adverse effects, while some reviews of raw industry data[13] and independent toxicology studies have found adverse effects.[14]
- Regulators should use thorough, independent experimental evidence in assessments rather than assumptions. GM foods should not be considered safe until they have undergone long-term animal safety assessments utilising endpoints relevant to human health and conducted by independent researchers.
- A comprehensive monitoring and surveillance system should be instigated to track the effects of GM foods.

- The labelling system should be improved to include all ingredients (including refined) originating from GM organisms (including micro-organisms), and from animals fed GM feed.
- Labelling laws should be policed.
- Australian governments should impose a freeze on importing GM foods, growing GM crops commercially and patenting genetic resources for food until thorough independent research into their effects is undertaken.
- The PHAA will advocate for publicly funded, independent research into the effects of GM crops, and for GMOs being made freely available to any researcher researching agronomic, environmental or health aspects of GM crops.
- The PHAA will advocate for a strong public health presence in the staff, advisory committees and Boards of the APVMA, OGTR and FSANZ to improve safety assessment procedures.

Burden

Whenever burden is discussed, only the regulatory burden to those who are developing and commercialising organisms using these new techniques is discussed. There is no mention of another, more important burden. If organisms developed using these new techniques are not regulated, then they will be released into the food supply without any safety assessments. However, if in reality some of these organisms are not safe, then these organisms may cause a huge health and financial burden for Australia. And while the regulatory burden is largely carried by a few entities that wish to profit from these organisms, a health burden can be a much higher cost that is carried by potentially thousands of individuals, including primary health care providers, hospitals, State and Federal governments, taxpayers and those who get ill and their families. Consequently, of these two burdens, it is clearly preferable to err on the side of a regulatory burden rather than a health burden.

The discipline of Public Health Economics informs us that the latter burden can be huge. Consequently, it is suggested that FSANZ conduct a Health Impact Assessment (HIA) of any deregulation of these new techniques to determine the latter cost. According to the CDC, a HIA "brings together scientific data, public health expertise, and stakeholder input to identify the potential health effects of a proposed policy, plan, program, or project. An HIA offers practical recommendations for ways to minimize risks and capitalize on opportunities to improve health."[15]

Consultation Questions 3.1.1

Do you agree, as a general principle, that food derived from organisms containing new pieces of DNA should be captured for pre-market safety assessment and approval?

Yes.

Should there be any exceptions to this general principle?

No.

In this section of the FSANZ Consultation Paper, FSANZ discussed whether GM rootstock grafting should be regulated. In that discussion, FSANZ has assumed that GM DNA would not move from the GM rootstock into the non-GM fruiting part of the plant, and in particular, would not be present in the fruit or seeds of the plant. There is no evidence that this would occur for all possible GM rootstock plants, and the assumption should be tested on every new GM rootstock before approval. There appears to be a further belief expressed in the FSANZ Consultation Paper that concern only lies with DNA being present in the non-GM part of the plant. There is no mention of the possibility of RNA, proteins or other substances moving

from the GM rootstock into the edible part of the plant. Yet FSANZ's own report on new plant breeding techniques (2012)[16] stated that food obtained from a GM rootstock plant "may contain novel RNA and/or protein as a result of the genetic modification to the rootstock. Depending on the genetic modification, the food may also have altered composition or other characteristics." The report also stated that: "It was the view of the panel that foods produced using these techniques [including GM rootstock grafting] should be regarded as GM food and undergo premarket safety assessment."

Consequently, GM rootstock plants should be undergo pre-market safety assessment and approval, and as part of that assessment, the composition of the edible part of the plant should also be assessed to determine if it has changed as a result of the GM rootstock.

Consultation Questions 3.1.2

Should food from null segregant organisms be excluded from pre-assessment and approval?

No.

If yes, should that exclusion be conditional on specific criteria and what should those criteria be?

Not applicable.

If no, what are your specific safety concerns for food derived from null segregants?

The diagram provided by FSANZ (Figure 2 on page 9 in the Consultation paper) on how null segregants are developed shows a theoretical ideal of how a null segregant should look after development and selection, being one where the progeny have not inherited any new DNA. This theoretical ideal assumes that the process of inserting DNA into the genome was specific and precise and there were no unintended insertions or changes, either at the site of insertion or elsewhere in the genome. There is sufficient evidence that this assumption is incorrect. For example, seven years after the release of GM Roundup Ready soy, Monsanto found two DNA segments present in it that they were previously unaware of, a situation that FSANZ acknowledged[17]. Consequently, all null segregants should undergo pre-assessment and approval to ensure that no new DNA remains in the organism rather than assuming that none exist.

Consultation questions 3.1.3

Are foods from genome edited organisms likely to be the same in terms of risk to foods derived using chemical or radiation mutagenesis? If no, how are they different?

If yes, would this apply to all derived food products or are there likely to be some foods that carry a greater risk and therefore warrant pre-market safety assessment and approval?

Foods from genome edited organisms are **not** likely to be the same.

The recent Technical Review of the Gene Technology Regulations 2001 Discussion paper[18] provides numerous sound arguments for regulating organisms derived from NBTs, including:

- It will "give legal clarity as to which technologies are subject to regulation, and so provide certainty for researchers and industry".

- "These techniques were developed very recently and, because there is not enough scientific understanding of how they work or possible unintentional effects, full regulatory oversight is needed to protect human health and safety and the environment."
- "These techniques might unintentionally interfere with the functioning of an organism's genome, for example through unforeseen interactions between altered genes and native genes, or through the altered genes having unexpected effects on biochemical pathways. Because such effects might pose risks, the techniques should be regulated as gene technology."
- "The precision of oligo-directed mutagenesis and site-directed nucleases is not established. The processes involved can give rise to unintended changes to the genome. Because such effects might pose risks, the techniques should be regulated as gene technology."
- "Small sequence changes might give rise to significant risks"
- "Successive rounds of modification …. could result in substantial changes which would not be subject to regulatory oversight"

In addition, a recent review of CRISPR methods[19] states that for plant cells, "The Cas9 and gRNA expression cassettes are often put in one plasmid, which is then delivered into plant cells using conventional transformation methods.", and then, after discussing how one can microinject or transfect in vitro–synthesized Cas9 mRNA (or protein) and gRNA(s) into animal embryos and plant protoplasts, the authors state that "however, because the regeneration capacity of protoplasts is very low for most plant species, the direct injection method only suits few plants." Consequently, the use of CRISPR/Cas9 to alter plants will in most cases result in a plant that has actually undergone a conventional genetic engineering process (which requires regulation) in order to introduce the CRISPR/Cas9 editing system into plant cells, in addition to any further editing of the genome that may occur by the CRISPR/Cas9 editing process.

Furthermore, inserting DNA into the genome in order for CRISPR-related molecules to be generated will result in those molecules being produced throughout the life of that plant and in future generations of that plant. As the CRISPR system is a means of using molecular "scissors" to cut DNA with the aim of then deleting or inserting genes, this means that the plant will be continually exposed to the molecular "scissors", which is likely to increase the probability of off-target effects over time.

In medicine, it is understood that even tiny changes in the DNA of a person can have such serious effects that the person dies. In two of many examples, the most common genetic mutation causing cystic fibrosis (a disease of the lungs resulting in premature death) is a deletion of three nucleotides in the genome, while Tay-Sachs disease (a disease that destroys nerve cells in the brain and spinal cord, usually resulting in death in early childhood) can result from a single base deletion or insertion in the genome . Note that the presence of foreign DNA was not required in order to make the change dangerous. The DNA change itself was dangerous. While the examples given are for homo sapiens, the potential to cause serious problems in other species holds.

In plants, such small edits can result in toxic products being unexpectedly produced and therefore all organisms made using small edits should be fully regulated and fully safety assessed before they enter the environment.

It should also be noted that small edits made repeatedly can result in producing an organism that is substantially different to the starting organism.

Risk

The FSANZ Consultation Paper states (page 5), that "There has been ongoing scientific and public debate about the nature of the risks associated with foods produced using NBTs" before stating "The issue being considered for this review is whether (and the extent to which) the food products of NBTs require pre-

assessment for safety, before they can be sold as, or used as ingredients in, food." Surely, it would be wise to settle the debate about the risks first, determine what (if any) risks exist and then determine whether safety assessments are needed. That is, for each NBT applied to a given organism: determine the nature of any risks, the strength of each risk and the impact of each risk, before contemplating the type of safety assessment needed for that organism, on a case-by-case basis. It is therefore of concern that, by suggesting deregulation of NBTs, FSANZ has decided that these new techniques have no risk, without doing a risk assessment first, a process that could be considered to be a lack of due diligence.

Public health professionals have considerable expertise in measuring and reducing risk. Amongst other things, epidemiology is about how to quantitatively measure risk. It is a cornerstone of public health. Drawing upon this knowledge, several things are made clear about these new techniques.

The first is that there seems to be uncertainty and debate about how these new techniques actually work, even amongst genetic engineers. Risks cannot be adequately determined without a full and proper understanding of the techniques. The second is that these new techniques are in their infancy and are constantly changing as techniques evolve, so that an understanding of the techniques used today may not provide an understanding of the techniques used tomorrow. Third, safety assessments of organisms made using these new techniques take time and therefore lag behind the development of the techniques themselves. For example, a review of histopathology studies of the gastro-intestinal tracts of rats where the rats were fed GM crops containing one or more of three commonly-used GM genes, found that there were no published histopathology studies for 81% of the 47 approved crop varieties. Furthermore, of the studies that were done, half were published at least nine years after approval[20]. As a result of this lag, there is little experimental evidence to be found in the peer-reviewed literature where the risks of these new techniques have actually been measured in animals or humans.

Consequently, any decision that is made now that they are safe must be based on opinion and assumption rather than evidence. This includes any advice to FSANZ from any expert panels or advisory groups it has convened, particularly if those groups have included people who wish to profit in some way from the deregulation of these new techniques. It should also be noted that such people tend to be those who know how to genetically alter crops but tend to have no training or experience in human health and who therefore cannot legitimately comment on whether such products may harm health.

Consequently, any decision now that they are safe would be scientifically unsound and deregulating something that is not known to be safe would be unwise. To conclude that products of the new genetic techniques do not require regulation is to effectively decide, *ipso facto*, that every product of the new techniques is safe, before an adequate safety assessment is done on **any** product of the new techniques to determine if **any** product is safe. This could be considered to be a contravention of the Object of the FSANZ Act.

The Austrian Government is one of the few governments worldwide to consider the biosafety risks of these new techniques. They concluded that there is insufficient knowledge about the risks posed by these new techniques and that they should be regulated in the same way as earlier methods, and on a case-by-case basis[21].

ENSSER Statement

The statement was written by scientists associated with the European Network of Scientists for Social and Environmental Responsibility (ENSSER) in response to a push from the GM industry to have these new GM techniques deregulated in Europe. The statement can be found on-line at: https://ensser.org/wp-content/uploads/2017/09/ENSSER-NGMT-Statement-v27-9-2017.pdf and the list of scientists who first signed it can be found on-line at: https://ensser.org/wp-content/uploads/2017/09/SIGNATORIES-TO-NGMT-STATEMENT.pdf .

The ENSSER statement contains important information about why these new techniques should be regulated. For example, advocates for deregulating the use of these new techniques in areas such as agriculture ignore the fact that it is well understood that when these new techniques are used in medicine, they can result in unexpected and unprecedented genetic modifications. Because of this, these new techniques are heavily regulated for medical applications. To regulate these new techniques in medicine but to deregulate them in areas such as agriculture would be policy double-speak. That is, apparently the techniques are so precise, predictable and safe that they do not need regulation, while at the same time being so imprecise, unpredictable and unsafe that they do require regulation.

The Statement also makes it clear that these new techniques are regulated for medical use for a good reason – these new techniques result in many unexpected changes at the place where genetic engineers are trying to alter DNA, as well as at other sites in the DNA where they are not trying to alter DNA.

The ENSSER statement is also in agreement with this submission, being, the new techniques can result in toxic products being unexpectedly produced, and therefore, all organisms made using these new techniques need to be fully regulated and fully safety assessed before they enter the environment or the food supply.

The over 60 scientists who have signed the statement therefore call on these new techniques to be regulated at the strictest level of GMO regulation.

DIY genome editing

The accessibility of some of the new techniques to the general public through "do it yourself" projects leads to particular risks that need addressing. Two examples of many are provided here. In the first example, there are credible reports[22] that kits that allow the general public to do this are already on sale. Specifically, "at an event for synthetic biology start-up firms in San Francisco" in February 2016, "Amino Labs showed off the Amino One", a briefcase-sized "table-top lab for the consumer market", where "beginners will be able to modify bacterial cells to create medicinal chemicals, scents and even foodstuffs such as yogurt, beer and bread." In addition, "Amino Labs wants people to improvise, hacking together different scents and materials". The article makes it clear that these kits will by now have been shipped to people who backed its crowdfunding campaign and that "the price is expected to fall to a few hundred dollars once the company begins mass-producing the devices in 2017."

In a second example, Indiegogo hosted a crowd-funding project[23] that promised "Everything you need to make precision genome edits in bacteria at home including Cas9, gRNA and Donor DNA template for an example experiment" for as little as $130. And for $3,000, "We will set you up with everything you need to start your own extensive home lab doing molecular biology and genetic engineering. We will guide you through setting it up and we will also provide you with a CRISPR kit and other kits to get you started!" and that "everyone will be able to use these kits (they contain everything you need, no extra equipment is required), even if you have had zero experience with Biotechnology (there will be extensive written protocols and videos available)".

Given that other companies are likely to follow suit and that the capacity of the biotechnology achievable by such kits is only likely to increase, it is likely that the results of DIY kits could end up in the food supply in the future. That is, it is quite likely that even a small food producer with little genetic expertise could use such a kit to "play around" with microbes to produce e.g. beer or cheese with altered taste characteristics and then sell the food produced to the public. If there is no regulation of the products of these new techniques, then such products, made by amateurs, could be eaten by the public without any safety assessments or regulatory oversight.

Consultation questions 3.2

Are you aware of other techniques not currently addressed by this paper which have the potential to be used in the future for the development of food products?

Yes, for example dsRNA/RNA interference techniques.

The risks of these techniques to human health and the environment have been thoroughly reviewed by Heinemann et al (2013).[24] These authors reviewed 100 publications and concluded that there was sufficient evidence that these techniques posed risks to human health and the environment. Evidence was presented that gene silencing may be inherited by the offspring of some organisms that eat the dsRNA, and that dsRNA produced by these new GM crops could survive digestion in people and change how those people's genes are expressed. A review of how three government safety regulators (for either food or the environment) regulated the technology found that the safety of dsRNA molecules was usually not considered at all, and if it was considered in any way, these regulators, including FSANZ, simply assumed that any dsRNA molecules were safe, rather than requiring proof that they were safe. The authors found many scientific studies showing that these assumptions were incorrect.

The authors developed and provided a safety testing procedure for all GM plants that may produce new dsRNA molecules, as well as for products where the active ingredient is dsRNA. This is summarised in the following figure, and this submission supports that suggested process.

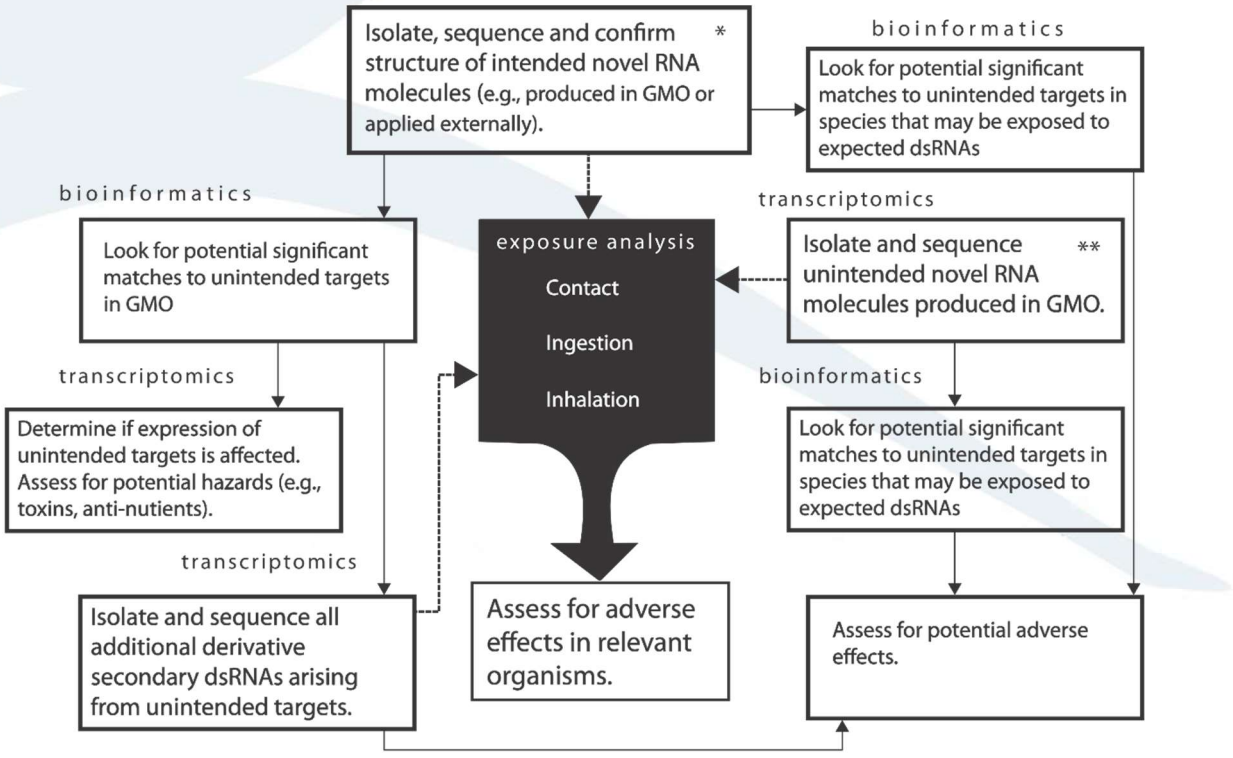

Figure 3. Sequential approach to assessing the potential for adverse effects arising from dsRNA-initiated modifications to organisms. Bioinformatics is used to capture known hypothetical targets of both intended and unintended dsRNAs so that potential adverse effects can be assessed. Transcriptomics is used to verify and characterise all relevant changes at the transcriptome level. Exposure analysis is used to design the appropriate kinds of organism-level tests for adverse effects. (*) Starting point for intentional introduction of dsRNAs; (**) starting point for unintended changes to the transcriptome. Bioinformatics assessments are inferences or judgments made based on predictions. Assessments made following exposure are based on data from experiments.

Should food derived from other techniques, such as DNA methylation, be subject to pre-market safety assessment and approval?

Yes.

Methylation is a process of altering genetic expression and hence should be regarded as a form of genetic modification. Furthermore, methylation techniques may result in methylation of other, non-target sections of DNA, thereby changing the expression of other genes in unintended ways. In addition, as the FSANZ Discussion Paper states, methylation can result in changes to DNA expression that can be inherited by subsequent generations. Consequently, food derived using methylation techniques should be subject to regulation and undergo a pre-market safety assessment.

Consultation questions 3.3

Do you think a process-based definition is appropriate as a trigger for pre-market approval in the case of NBTs? If no, what other approaches could be used?

Australia currently has a process trigger whereby an organism that is determined to be a GMO is subject to regulation. Proponents of quickly commercialising new GM techniques have been arguing for a product trigger for regulation, which would change the regulatory system to instead focus on the intended outcome of the change to the genome only and would ignore any risks inherent in the genetic modification process that was used, any risks in the spread of the GMO after commercial release into the environment, any economic risks to the Australian economy, and any risks to health and the environment. Because the developer of a GMO then will not have to undertake safety and other assessments before commercial release, the developer will benefit financially by reducing costs. However, the new techniques can result in unexpected off-target effects, including the production of toxic substances being unexpectedly produced. Consequently, the lack of safety studies prior to release would increase the probability of a toxic GMO being released for human consumption. In addition, the associated lack of labelling and monitoring would make it harder to undertake epidemiological and other studies to determine if the GMO has harmed health or the environment. It would shift the focus onto "proof of harm", whereby those harmed by the GMO would need to prove that the GMO had harmed them, rather than preventing harm in the first place.

A product trigger could also result in many of the currently-regulated GMOs becoming deregulated. For example, the GM industry could argue that because plants can develop resistance to a given herbicide (e.g. Roundup) without the need for genetic modification, then crops genetically modified to be resistant to the herbicide should be deregulated, because the product is the same: the plant is tolerant to a herbicide. As most of the GM crops world-wide are designed to be herbicide tolerant, this could result in most GM crops grown elsewhere in the world being allowed into the Australian food supply without any safety assessment, regulatory permission or oversight.

Consequently, Australia should retain a process trigger for regulating food derived from organisms developed using NBTs.

If yes, how could a process-based approach be applied to NBTs?

Foods derived from organisms developed using new breeding techniques should be regulated in the same manner as organisms developed using older techniques and all such organisms should be subject to a pre-market safety assessment.

Are there any aspects of the current definitions that should be retained or remain applicable?

See above. Furthermore, it appears that FSANZ no longer uses the same definition of gene technology as the OGTR. This seems to be an odd decision and should be reversed in order to provide regulatory clarity in Australia.

Consultation question 3.4

Are there other issues not mentioned in this paper, that FSANZ should also consider, either as part of this Review or any subsequent Proposal to amend the Code?

Yes.

Detection

There has been some discussion about whether it is possible for organisms developed using NBTs to be detected. Three things should be noted here.

The first is that detection techniques for these new organisms are currently available using omics techniques such as transcriptomics, proteomics and metabolomics. As these techniques improve over time, their ability to detect these new organisms will improve. The current and potential future uses of these techniques for detection is discussed at length in Chapter 7 of the National Academies of Science report of 2016[25]. That report concluded that these techniques could play an important role in the regulation of crops developed using these new techniques.

It should also not be assumed that omics methods will be the only methods of detection available in the future.

The second is that it is highly unlikely that a patented organism would be released by a company or organisation for sale without some means of protecting their intellectual property (IP) rights over that organism. After all, there is little point in spending large amounts of time and money on developing a new GMO if developers cannot recoup their investment money and make a profit from the sale of their product. It is therefore logical that the developer will have a means of genetically ”branding” a GMO to ensure that it is not used without a licence, i.e. so that it can be legally proven that a particular GM organism belongs to a particular company so that payment can be enforced for any use of that GMO.

The third is that difficulty with compliance has not prevented Commonwealth and State Governments and the judiciary from enacting compliance procedures elsewhere. In one of many examples, it is legal to take opioids as long as they are prescribed by a doctor. It is illegal to take them otherwise and illegal use can result in a jail sentence. Until recently, codeine was exempt and easily available. The usual detection test for taking opioids is to detect certain opioid breakdown products in the urine. However, this test will also test positive for codeine consumption. If someone being monitored for opioid use under a court order tests positive for opioids via the urine test, that person could say “I took a codeine tablet” to avoid prosecution. Those monitoring such orders often describe this happening. Yet these difficulties in enforcing compliance have not stopped courts imposing court orders upon people to abstain from illegal opioid use and for that abstinence to be monitored.

Finally, FSANZ could require that no food made from an organism developed using NBTs be allowed into the food supply unless a detection method was available for that organism.

Alignment with the Object of the Food Standards Australia New Zealand Act 1991.

The PHAA notes that the Object of the Food Standards Australia New Zealand Act 1991 (hereafter called "the FSANZ Act" is:

"… to ensure a high standard of public health protection throughout Australia and New Zealand by means of the establishment and operation of a joint body to be known as Food Standards Australia New Zealand to achieve the following goals:

(a) a high degree of consumer confidence in the quality and safety of food produced, processed, sold or exported from Australia and New Zealand;

(b) an effective, transparent and accountable regulatory framework within which the food industry can work efficiently;

(c) the provision of adequate information relating to food to enable consumers to make informed choices;

(d) the establishment of common rules for both countries and the promotion of consistency between domestic and international food regulatory measures without reducing the safeguards applying to public health and consumer protection."

If FSANZ determines that food from organisms developed using NBTs are not GMOs, then those organisms will enter our food supply without any regulatory requirements, safety assessments or testing. They will also enter the Australian food supply without labelling so that consumers will have no choice as to whether to eat them or not. This would deny adequate information to consumers to allow them to make informed choices, in contravention of paragraph (c) of the Object of the FSANZ Act, and therefore likely reduce consumer confidence in the quality and safety of food produced, processed, sold or exported from Australia, in contravention of paragraph (a) of the Object of the FSANZ Act. Furthermore, any relaxation of the regulatory framework of GMOs would increase the risk of a GMO causing ill-health in the human population, and the lack of regulatory oversight and labelling will make it very difficult to be able to conduct epidemiological assessments into their long-term impacts. As described more fully above and in PHAA's policy on GM food, the PHAA finds this unacceptable.

In addition, while some countries have determined that organisms made using these new techniques are GM, other countries have decided that they are not. Many countries have yet to make a determination, but as reviews commissioned by the Austrian and Norwegian governments have concluded that there is insufficient knowledge about the risks of these new techniques, and that products derived from them should undergo a comprehensive case-by-case risk assessment, [26] it is likely that the EU will regulate these new techniques. Therefore, it is likely that there will be a patchwork of different regulatory requirements globally, with some of Australia's trading partners having regulatory requirements and not others.

Therefore, while some argue that regulating these new organisms could lead to trade restrictions for Australia, it is also true that exempting these organisms from regulation could also lead to trade restrictions when Australia exports to countries that require these organisms to be regulated and labelled.

Of greater importance, however, the recent OGTR Review of the Gene Technology Regulations Discussion Paper[27] noted that "New Zealand has recently amended its legislation to clarify that techniques developed after 1998, including genome editing, are within the scope of regulation as GMOs". Consequently, the New Zealand Government has, by definition, determined that these new techniques are GM.

This occurred after New Zealand's Environmental Protection Authority (EPA) decided that two new breeding techniques did not produce GMOs and could go into New Zealand fields without any formal consultation or assessment. In a similar process suggested for Australia in the OGTR Discussion Paper, certain traditional plant breeding techniques had been excluded from New Zealand's laws and the EPA

decision effectively added to the exemption list. In a warning for any Australian process, the Sustainability Council of New Zealand appealed that decision in the New Zealand High Court and won[28]. The Court quashed the EPA's decision. The Court agreed with the Sustainability Council that only the Cabinet or Parliament can decide which techniques are exempt, and that the EPA had misinterpreted the law and failed to exercise proper caution.

As FSANZ sets food standards for New Zealand as well as Australia, if FSANZ determines that organisms made using NBTs are not GMOs, then FSANZ's decision would conflict with a legal determination made in New Zealand and the subsequent decision of the New Zealand Government to regulate these NBTs. Such a decision by FSANZ would therefore be against paragraph (d) of the Object of the FSANZ Act, being "the establishment of common rules for both countries and the promotion of consistency between domestic and international food regulatory measures". Such a decision may make FSANZ unworkable as a bi-country regulator.

As a result of the issues raised above, if FSANZ deregulates NBTs, FSANZ may also contravene paragraph (b) of the Object, being "an effective, transparent and accountable regulatory framework within which the food industry can work efficiently".

Scientists' access to materials to test

GMOs are currently not freely available to researchers to be able to conduct independent safety assessments or environmental impact assessments. For example, if researchers try to buy seeds for GM crops from a seed merchant to conduct a health and safety assessment, they are required to sign a legal agreement stating that they will not undertake research on the seeds or give them to anyone else to do research on. This severely impedes research into the safety of GMOs by restricting safety assessments to only those researchers who have been approved by the GM company, leading to a potential bias towards reporting findings that are favourable to the industry and avoiding the reporting of adverse findings. Note that there are numerous scientific papers describing how research conducted by pharmaceutical companies and their affiliated researchers tends to report positive outcomes while independent researchers tend to find adverse effects. Often, adverse effects of a new pharmaceutical drug only become apparent once this independent research is done. It is therefore recommended that legislation be enacted to make it a condition that the GMO to be made freely available to any researcher researching agronomic, environmental or health aspects of GMOs before allowing a GMO into the food supply. This should apply for GMOs developed under existing or new techniques.

Safety data

There are numerous examples where safety issues of various pharmaceutical drugs only came to light when the company's raw data were re-analysed by independent researchers. The case of Vioxx, described above, is one example. Despite numerous clear examples of adverse effects lying hidden in plain sight in company data, there is no requirement for any safety or environmental data, used to justify the company's position that a GMO is safe, being released for independent scientists to look at. While some argue that such data are given to government regulators for scrutiny, FSANZ has a policy of not analysing raw data given to it by GM companies. Instead, FSANZ relies upon what the GM company says about the data. This could be regarded as a lack of due diligence. As a result of numerous examples from other areas of research, it is recommended that it be mandated that all safety data generated by a GM company about a GMO be given to FSANZ, that FSANZ be required to analyse the data, and that the data be made freely available on-line to all interested independent researchers at the time that an application is made to FSANZ.

Oversight of FSANZ

Oversight of FSANZ is provided by its Board. The Board has been criticised in the past for being weighted towards those with strong past or present affiliations with the food industry, which could be considered to be a bias towards industry input and away from independent advice from public health experts. The PHAA notes that there has been a considerable effort and improvement in this balance over recent years. The PHAA also takes this opportunity to recommend that it be mandated that the Board of FSANZ contain representatives from several public health bodies in order to obtain free and unfettered advice from independent experts. For example, from a State Government Communicable Disease Control branch (for advice on food-borne disease), the Food and Nutrition Special Interest Group of the Public Health Association of Australia (FANSIG of the PHAA), the Dietitians Association (for advice on nutritional matters), a University-employed toxicologist, a member of the Australian Faculty of Public Health Medicine (AFPHM, for advice on public health medicine), and the Australian Epidemiological Association. A medical representative from e.g. the Australian Medical Association (AMA) and a consumer representative should also be included. It is further recommended that such independent advisors constitute the majority of the Board of FSANZ.

Better safety assessments of GMOs

Currently, FSANZ requires no animal or human studies in order to make a determination that a GMO is safe for release into the environment or to enter the Australian food supply. Moreover, as described above, the quality of any animal studies used to support claims of safety of GM crops has been highly criticised as being poorly conducted, largely undertaken by vested interests, and lacking in endpoints that are relevant to human health. There is therefore a lack of evidence that GMOs are safe, particularly compared to the standards required of pharmaceutical drugs. It is therefore recommended that regulation of GMOs to enter the food supply be aligned with the much better standards of the European Union, which now requires 90 day sub-chronic rat toxicology studies to be undertaken for GMOs that are to enter their food supply. We further recommend longer, chronic studies to better reflect the Australian population's exposure to GMOs. It is further recommended that those rat studies actually meet OECD guidelines and that animal testing be required to assess all four major areas of concern, being allergies, reproductive outcomes, toxicology and cancer. If the GMO passes these tests, it should be further tested in basic human trials before release. This is particularly the case for GMOs that will enter the Australian food supply, because 24 million Australians would then likely be exposed to the GMO and to any adverse effects from that GMO.

Labelling

GMOs made using existing and future techniques should be labelled for three reasons. First, labelling allows GMOs to be traced and monitored in the environment and in the food supply, thereby allowing epidemiological studies to be undertaken. This allows early detection of any adverse effects of a GMO which in turn allows for the speedy withdrawal of that GMO from the environment and/or food supply, which will minimise harm to the population and costs to the State and Commonwealth governments of Australia. Second, it permits regulatory oversight of GMOs. Third, labelling allows for consumer choice. Allowing choice is important to maintain trust in the Australian food supply. Furthermore, labelling should be improved to match the standards of the European Union, where oil from GM crops is also labelled. In fact, as PHAA's policy states, all ingredients (including refined), originating from GMOs (including micro-organisms) should be labelled, as should products such as milk, meat and eggs from animals fed GM fed.

A surveillance system

It is recommended that a surveillance system be established in Australia to monitor the effects of GMOs in the food supply. In this way, early detection of any adverse effects of a GMO can be made, which in turn

allows for the speedy withdrawal of that GMO from the food supply, in order to minimise harm to the population and the financial burden to Australian State and Commonwealth governments.

Conclusion

The PHAA welcomes the opportunity to provide input to FSANZ's consultation paper on food derived using new breeding techniques. The PHAA is the principal non-government organisation for public health in Australia with approx. 1900 members representing over 40 professional groups. The PHAA has had an evidence-based policy on GM foods since 1999, revised every three years. The PHAA has drawn heavily upon that policy to write this submission. In addition, the PHAA has many experts who measure risk and determine safety and that expertise has also been drawn upon to write this submission. The PHAA is therefore delighted to provide public health input into the FSANZ process.

The PHAA is particularly keen that the following points are highlighted:

- Food regulation should aim to protect public health and provide information to consumers.
- It is more important to protect public health than promote commercialisation.
- The precautionary principle should be applied to GMOs.
- FSANZ should use thorough, independent experimental evidence in assessments rather than assumptions. These new organisms should not be considered safe until they have undergone long-term animal safety assessments utilizing endpoints relevant to human health and conducted by independent researchers.
- FSANZ's safety assessments should be improved to at least the standards of the EU and animal studies should meet OECD guidelines.
- All safety data generated by a GMO developer should be given to FSANZ, FSANZ should be required to analyse the data, and the data should be made freely available on-line to all interested independent researchers at the time that an application is make to FSANZ.
- These new techniques are in their infancy. Their risks are unknown because there is little to no evidence to be obtained about the risks for these new organisms from any of: animal studies, human studies or the peer-reviewed literature. Consequently there is essentially no evidence that they are safe and any opinion that they are safe is not based on scientific evidence, but simple opinion.
- Food derived from all NBTs should be regulated including GM rootstock grafting, null segregants, CRISPR, dsRNA technology and methylation.
- RNA interference techniques should be regulated as per the suggested process in Heinemann et al (2013).
- Epidemiological studies to determine if there is any harm from exposure to these new organisms will be almost impossible to conduct if these new organisms are not regulated, because it will be almost impossible to determine who was exposed and who was not exposed. It would be a profoundly unwise step to, at this stage, through a lack of regulatory oversight, cause to happen a process that would prevent later epidemiological studies into the health effects of these new organisms.
- A process-based definition is the appropriate trigger for pre-market approval for NBTs.
- All food derived from organisms developed using NBTs should be labelled, and labelled to EU standards.

- GMOs should be made freely available to any researcher researching agronomic, environmental or health aspects of GMOs before allowing a GMO into the food supply.
- The Board of FSANZ should contain a higher proportion of public health experts and a majority of the Board should consist of experts independent of the food industry.
- A freeze should be applied on the commercialisation of these new organisms until thorough independent research into their effects is undertaken.
- A comprehensive monitoring and surveillance system should be instigated to track the effects of GM foods.
- Regulating the technology does not mean that Australia will suffer from trade disruptions.
- Regulating the technology means that Australia will be in general agreement with the laws of New Zealand. FSANZ regulates food for both Australia and New Zealand and different definitions of what constitutes a GMO between those two countries would put it in a difficult position.
- Detection methods for these new technologies are available and improving.

Please do not hesitate to contact me should you require additional information or have any queries in relation to this submission.

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