CONSUMERS SA

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PROPOSAL P1055 – DEFINITIONS FOR GENE TECHNOLOGY AND NEW BREEDING TECHNIQUES

Consumers SA (CSA) represents South Australian consumers' interest, encouraging the dissemination of information on issues affecting consumers, providing a forum for discussion and presenting a South Australian consumer perspective to all levels of government. CSA, established in 1977, is a permanent element of the consumer protection movement in South Australia and receives national recognition through membership of the Consumers' Federation of Australia.
CSA is a non-profit making and non-political organisation. CSA thanks Food Standards Australia New Zealand for the opportunity to put forward its views on P1055.

There is one overriding premise that should be recognised within Food Standards Australia New Zealand with regards to food produced using gene technology and new breeding techniques, and that is wherever a gene has been manipulated in whatever manner or process, it is still gene technology and should be regulated. This is the case even when no foreign DNA is present in the manipulated product. (4) In addition, a gene is any material BASIS FOR INHERITANCE OR EXPRESSION of traits. As such, consumers have the right to know what has been done to their food, through appropriate labelling. They must also be reassured that there is proper regulatory control for public protection and not deregulation purely for industrial advantage.

With regards to the new breeding techniques, it is apparent that the review of the definitions are designed to require less oversight, particularly with regard to gene editing. The argument for this is put forward that the 'biochemical process of editing are like the processes that cause natural mutation'. (1)
This is simply not true.

The European Court of Justice and the New Zealand high court have both ruled that genome editing techniques should remain under the regulations specific to genetically modified organisms. (1)
Australia should follow suit, particularly as FSANZ's proposal also covers New Zealand. Currently, parts of FSANZ's proposal appear to ignore the court ruling in New Zealand.

'Some uses and outcomes of the use of gene technology can be made to appear natural, but this is a diversion from how and why gene technology should be regulated. Instead we should recognise that gene technologies allow more people to produce and amplify modified organisms more quickly and in more environments. Any potential harmful outcomes of that use of gene technology increase as it is used more. What makes gene technology useful is also what makes it risky.' (1)

'Safety increases with the use of some technologies, such as car brakes. The more cars with brakes, the safer our roads. *No tool of gene technology, including gene silencing and genome editing, becomes safer the more it is used.'(1)* (my emphasis)

There is other scientific evidence that gene editing has unintended side effects.
CRISPR gene editing is often presented as a straight forward, precise and safe procedure. But recent research findings (https://pubmed.ncbi.nlm.nih.gov/33846636/) on CRISPR gene editing for gene therapy applications show it can lead to massive damage to chromosomes. It is known as Chromothripsis.(2)

The authors of the new study, published in Nature Genetics, conclude that 'chromothripsis is a previously unappreciated on-target consequence 'of the double-strand breaks in the DNA that CRISPR gene editing is designed to bring about. The fact that the damage occurs 'on-target' – at the intended edit site – means that any attempts to target CRISPR gene editing more precisely will not solve this problem, as pointed out in the Nature Biotechnology article by one of the researchers on the study, David Pellman of the Dana-Farber Cancer Institute and Harvard Medical School. He said, 'You cannot make this go away by making the cutting more specific.' (2)

While the initial break in the DNA can be targeted to a specific site in the genome, the subsequent 'repair' cannot be controlled by the genetic engineer.(4)

The major worry with chromothripsis in therapeutic settings is that it can lead to cancer or an inherited disease in children of the affected parent. It would only take a single cell to be affected by chromothripsis to result in a cancer. This has implications for animal gene editing, as edited animals could be prone to cancer. But it also spells bad news for plant gene editing, where chromosomal damage would lead to changes in the function of genes that could in turn result in unexpected toxicity or allergenicity, as well as unpredictable effects on wildlife' (2)

If some products are made using techniques that could cause chromothripsis, or even lesser unintended changes, are exempted from a safety review, then any unintended effects that could cause harm will go undetected. Recalling as well that exempted products can be modified by an unlimited number of applications of the same technique, the potential for harm increases in those serially treated organisms.

Similar to the FSANZ argument that 'if a NBT food is similar or identical in product characteristics, and that conventional foods have a history of safe use, then we can conclude that NBT food is as safe as a conventional food, these NBT foods would not need a safety assessment before being sold', the UK government has sided with a small majority of academic institutions (58%) and public sector bodies (55%) that advocate for deregulation. However we note that a significant 42% of academic institutions and 45% of public sector bodies, as well as the larger majority of the public (87%) and business (64%) , believe regulation and mandatory risk assessment is worthwhile. From an end user point of view, we would say it is essential.

There is no consensus that the risk of harm of using any techniques of gene technology will not increase with deregulation as proposed by FSANZ, in fact we think it inevitable.

It should be noted that the Swiss National Council (lower house of the Swiss Federal Assembly, , the parliament of Switzerland has extended the moratorium of GM plants by another four years until the end of 2025.. Gene-edited GM plants were explicitly included in the moratorium. (17)

With further regard to labelling. If gene manipulated new breeding technique foods are not labelled, as we understand FSANZ is in favour of, how would a consumer know an allergic reaction or some other problem was due to gene edited food? How would a recall be managed?

It is often pointed out that there are benefits of gene manipulation in various medicine fields and this is so. However those products are thoroughly and comprehensively tested in animals and then on humans in randomised controlled trials before release, and monitored for adverse effects after release. Moreover, the recipient is an individual who expects to gain a benefit from the treatment, has had the risks and benefits explained to them and then has personally made the decision whether to avail themselves of the technology/treatment or not. This is not the case with mass produced food, particularly if the food s

not labelled. If FSANZ does not regard a food to be GM, the food will avoid labelling as being derived using GM techniques, resulting in consumers being completely unable to make a personal, informed choice about whether they want to eat it or not.

For an excellent analysis of the new GM techniques and the consequences of them being deregulated, FSANZ should refer to the paper from IHER Inc., the Institute of Health and Environmental research Inc.. (5)
Dr. Carman describes in some detail the technique SDN-1 (site-directed nuclease-1), the hazards of which are also supported by the Public Health Association of Australia (PHAA) and points to the numerous scientific papers that have been published in peer-reviewed scientific journals showing that the SDN-1 techniques are not as precise as previously thought and can have numerous 'off target' effects on the engineered organism, such as affecting other genes in the organism. If introduced into the Australian food supply without any safety assessment, including for allergic, toxic, reproductive or cancer-causing effects and unlabelled, consumers will have no choice and be eating them whether they want to or not.

The second technique is referred to as dsRNA (double stranded ribonucleic acid) method. This process can silence or activate genes. The section on this technique gives grave cause for concern. One application is as an insecticide. An insect eats a plant that either contains or has been sprayed with the insecticide and silences a gene which kills the insect. Or the insect can be sprayed with dsRNA, and it is known that agricultural sprays can travel far distances and can persist in soil or water and for other organisms to take it up.

As the author states, 'There is some evidence that dsRNAs produced by GM plants may survive digestion in people. The US Environmental Protection Agency's (EPA's) Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), Scientific Advisory Panel recommends ongoing research and monitoring because it is uncertain that all dsRNA molecules created by genetic engineering would be safe to consume. (6)
If such dsRNA molecules survive digestion in people, there is a risk that they could also change how those people's genes are expressed (6)

There is also evidence that gene silencing may be inherited by the offspring of some organisms that eat the dsRNA (7,8,9) Indeed patents held by Monsanto (now Bayer) not only state that this occurs, but also claim the offspring as their patented property (8,9). While changes to the actual base pairs that are the building blocks of genes will still require regulation (10.11) it is important to note that you can change how genes are regulated without changing the base pairs (7,8,9) And you can further do that in a way that allows the changes to be inherited (7,8,9). One such method is called RNA-directed DNA methylation. And that method will be deregulated.' (10,11)

The author goes on to explain the problems with deregulating null segments, the implications for consumers, farming implications and trade implications should these techniques be deregulated.

In addition there is inadequate screening for unintended mutations. 'Most studies that look for unintended mutations in gene-edited plants grossly underestimate the number of mutations resulting from gene editing and associated processes such as tissue culture (growth of plant tissue or cells in a growth medium). This is true for studies that conclude that gene editing causes many such mutations and those that conclude that it causes few or none. The reason is that the authors of these studies use inadequate detection methods – short range PCR and short-read DNA sequencing – to look for mutations. They only look at short stretches of the DNA around the targeted editing site and computer programme-predicted off-target sites.' (4)

As Kosicki and colleagues found in a study on human cells, short-range PCR and short-read DNA sequencing can miss genetic errors, such as large deletions and insertions and complex rearrangements (14, 15). The researchers concluded that a combination of long-range PCR and long-read DNA sequencing is need to spot the full range of unintended mutational effects. (14)

FDA scientists have made the same recommendation, with regard to gene-edited animals (16)

As might be concluded from all the above, gene editing is neither precise nor controllable, and could have unintended effects that threaten public health, the environment and trade.
The evidence also shows that genetic changes through gene editing are not the same as would happen in nature or through mutation breeding. In addition the outcome from genetic changes through gene editing – and the risk they pose are poorly understood. As such NBTs should remain under GMO

Regulation. It follows that any food produced by whatever gene manipulation, should be labelled as being so.

Consumers SA does not support using comparison to conventional food for NBTs, to enable lack of regulation.
There is much more to be taken into consideration than just chemical and biological characteristics in establishing safety.
Conventional foods have a long history of use and adaptation. Food produced through gene manipulation does not. A further flaw in the system, (Webinar 12/11/21) is the exclusion criteria, and whether it is appropriate is for the developers to determine. FSANZ will offer guidance but the decision still rests with the developer. And as noted, FSANZ has no role to date in enforcement.

Labelling or more precisely lack of labelling for foods produced through NBTs is also based on 'conventional' foods which again is not supported.

The European Network of Scientists for Social and Environmental Responsibility (ENSSER) in their response to a similar call in the EU's Inception Impact Assessment for such deregulation states:
'We urge to keep all new GM techniques covered under the current directive and its obligations, in particular as they are new; necessary research, evidence and empirical data will only emerge over time and cannot be assumed. There is already a body of evidence and research that reveals the falsity of current simplistic assertions, assumptions and extrapolations regarding, precision, 'equivalent to nature', safety and clarity or risks.

We are disturbed that neither science nor the precautionary principle prevail in the current initiative/IIA, and that instead half sciences are used, assumptions asserted as facts and the crucial issue of scale being ignored.'
A new study published in the scientific journal Plants presents the specific risks of new genetic engineering techniques (17) The study shows that inducing supposedly small alterations in the genome of crop plants can nevertheless generate complex changes. The results of the study highlight the need for plants developed using new genetic engineering techniques to undergo case-specific risk assessment, taking both the properties of the end product and risk posed by the applied procedures into account.

Again (17) 'Scientists find yet more genetic errors from CRISPR gene editing. Scientists at the university of Uppsala have found that CRISPR'Cas gene editing in zebra fish caused large structural changes at on-target and off-target sites (both at the intended edit site and elsewhere in the genome). Off-target sites can be very similar to the target site, which mean that the 'gene scissors' can also cut at these sites and cause unintended mutations. The publication shows that major unintended DNA changes are possible.'

Conclusion:
There is ample evidence in the literature to see that there are numerous studies from around the world that have found these NBTs are not specific and can cause unintended effects. It is therefore essential that all such applications should be considered on a case-by-case basis. Consumers SA calls on FSANZ to take a more precautionary approach to deregulation.

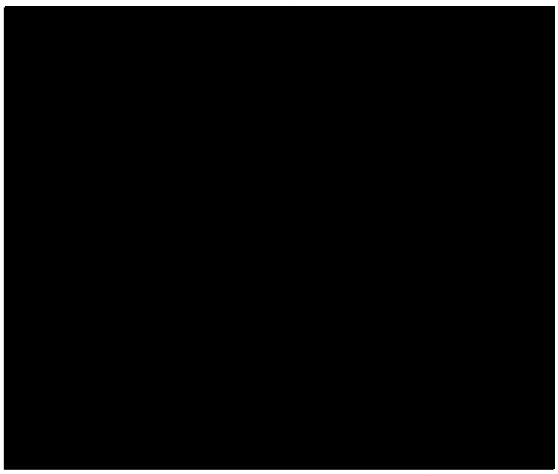
Consumers SA has no objection to a definition for gene technology that is more suited to legislation that will allow for other genetic techniques to be captured as they become available – providing it does not deter from any application being assessed on a case-by-case basis and all risks are taken into consideration. We do not endorse manufacturers deciding what is and what is not a gene technology technique.

Consumers SA does not support food produced by any gene technique being exempted from

labelling requirements. Consumers should have accurate information with which to make an informed decision about their purchase. To do otherwise could seriously reduce consumer confidence in our food regulatory system and the safety of our food supply.

We look forward to your further consideration.

Yours sincerely,



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