AUSTRALIAN FOOD & GROCERY COUNCIL

AFGC SUBMISSION

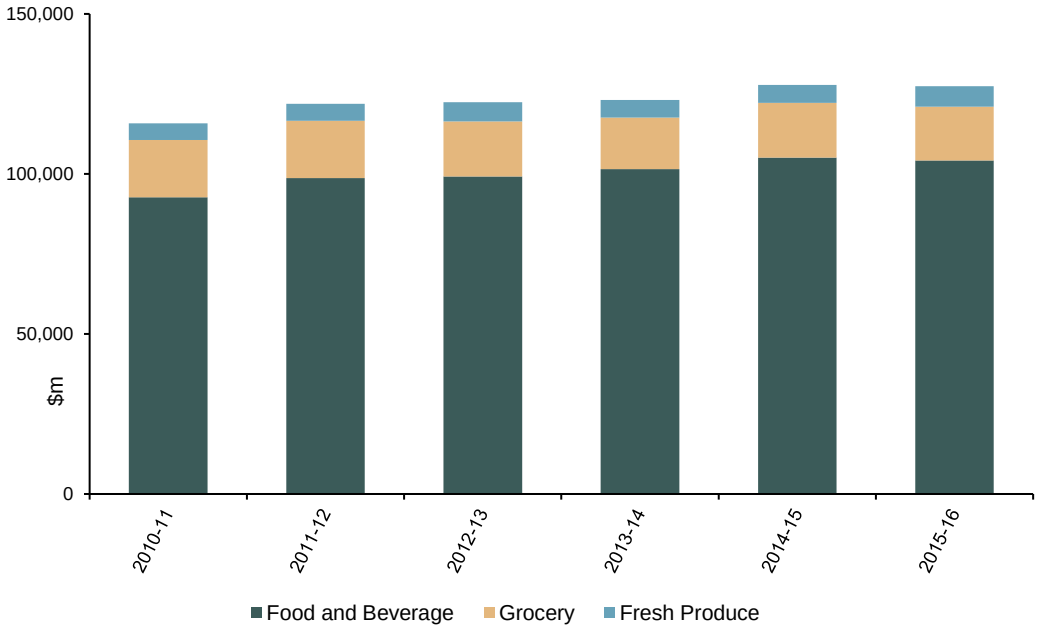
FSANZ CONSULTATION PAPER: FOOD DERIVED USING NEW BREEDING TECHNIQUES

Sustaining Australia

PREFACE

The Australian Food and Grocery Council (AFGC) is the leading national organisation representing Australia's food, drink and grocery manufacturing industry. The membership of AFGC comprises more than 180 companies, subsidiaries and associates which constitutes in the order of 80 per cent of the gross dollar value of the processed food, beverage and grocery products sectors.

*Figure 3.1: Composition of the defined industry's turnover ($2015-16) (*million*)*



With an annual turnover in the 2015-16 financial year of $127.4 billion, Australia's food and grocery manufacturing sector is Australia's largest manufacturing industry, representing 32.4 per cent of total manufacturing turnover in Australia. The diverse and sustainable industry is made up of over 30,748 businesses and accounts for over $67.9 billion of the nation's international trade. These businesses range from some of the largest globally significant multinational companies to small and medium enterprises. Industry made $2.9 billion in capital investment in 2015-16 on research and development.

The food and grocery sector makes a substantial contribution to the Australian economy and is vital to the nation's future prosperity. It employs more than 320,300 Australians, representing about 2.6 per cent of all employed people in Australia, paying around $17.3 billion a year in salaries and wages. The industry makes a large contribution to rural and regional Australia economies, with almost 40 per cent of the total persons employed being in rural and regional Australia. It is essential for the economic and social development of Australia, and particularly rural and regional Australia, that the magnitude, significance and contribution of this industry is recognised and factored into the Government's economic, industrial and trade policies.

Australians and our political leaders overwhelmingly want a local, value-adding food and grocery manufacturing sector.

[1] AFGC SUBMISSION

The AFGC provides this submission in response to the February 2018 FSANZ Consultation Paper "*Foods Derived Using New Breeding Techniques*" (the Consultation Paper).

The AFGC considers the Consultation Paper to be a clear and concise description of what can be a somewhat technical and specialist subject, and congratulates FSANZ for its work to develop an accessible summary of the issues involved.

The AFGC notes that this consultation does not intend to question the current regulation of foods derived from genetically modified organisms, including their labelling. The AFGC submission is accordingly focussed on those questions specifically raised in the Consultation Paper but it is, in the AFGC's view, inappropriate to constrain such debate too early in the consultation process. The potential regulation of new breeding techniques must be proportionate to the risks involved, and if current regulation is not also proportionate across different means of achieving the same outcome, that regulation becomes an arbiter of science and process rather than of outcomes, in effect trying to look into a crystal ball to determine which food production techniques are to be (unregulated) 'winners' and which are (regulated) 'losers'. Such regulation has the potential to create as many public health and safety risks (including through opportunity costs) as it seeks to address – the labelling regime applying to food sterilisation through ionising radiation being a prime example at a time when foodborne illness is also high on the agenda of the Ministerial Forum on Food Regulation.

The fundamental questions not addressed in the Consultation Paper can be found in the first two of 'The Seven RIS Questions" set out on page 5 of *The Australian Government Guide to Regulation* (AGGR, 2014): What is the problem you are trying to solve, and why is government action needed? At one level, these questions have simple answers in that FSANZ might be seen as simply seeking to clarify the boundaries between what is, and is not, subject to Standard 1.5.2 of the ANZ Food Standards Code, with the goal of providing certainty and regulatory clarity to industry. Such an answer, though, is predicated on the foundation that Standard 1.5.2 itself solves a problem where government action is needed, and this is a far more complicated question.

[2] REGULATION OF BREEDING TECHNIQUES

Figure 1 on page 5 of the Consultation Paper well illustrates the AFGC's point about the need to consider wider issues. Selective animal and plant breeding is millennia old, as humans have sought ever better nutrition and yield since farming was

established. Cross breeding, mutagenesis and tissue culture are in relative terms more recent, but even recombinant DNA techniques have now been used for a generation in food production. All these techniques have the same goal - to create better or more food to meet the demand for human nutrition – and yet only the latter is regulated in terms of the food that is produced. It has certainly not been established that there is a clear scientific basis for the regulatory distinction between techniques such as mutagenesis, which brought the world canola oil, and gene technologies which have included Australian inventions such as the CSIRO's *Arctic Apple*, and yet the regulatory gulf between the two is vast, not the least of which being the latter must be labelled as being a product of gene technology, playing to consumer fears, uncertainty and doubt.

The AFGC is not naïve to the concerns that have been raised in the past regarding GM foods and their regulation. And the the food sector does not seek to hide information from consumers. However, there are social costs of current GM regulation, for example in that CSIRO's *Arctic Apple* is not available on Australian shelves. Australian consumers miss out on such innovation, and the Australian manufacturing industry misses out on the opportunity to commercialise Australian technology.

A further issue to consider is that current regulations drive innovation into older, less predictable technologies. A researcher seeking to achieve a particular outcome, such as a banana with improved vitamin and mineral content, might well use recombinant DNA techniques to develop a 'target' tree, and then use other, non-regulated techniques such as mutagenesis to selectively breed banana trees, using the target tree DNA as the basis for selection, until a sufficiently close match has been developed without using recombinant DNA. The problem for regulators is that the use of recombinant DNA is a far more precise means to that end than mutagenesis, with fewer potential risks, but regulations commercially compel the latter over the former.

It is against this background that the AFGC recommends FSANZ be very cautious about extending the current regime in Standard 1.5.2 to breeding techniques outside its current scope.

That is not to suggest that clarity around the operation of Standard 1.5.2 should not be improved, but rather that the role of government in relating one or more breeding techniques and leaving others untouched carries significant perils for unintended outcomes as well as social costs to the Australian community.

[3] SPECIFIC CONSULTATION PAPER ISSUES

3.1.1 Questions

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?

Should there be any exceptions to this general principle?

This question highlights the difficulty in terminology when seeking to distinguish between breeding techniques. All of the techniques in Figure 1 of the Consultation Paper result in organisms that contain new pieces of DNA – indeed that is the whole purpose of the exercise, to develop new and better foods for human consumption. Further, new DNA appears all the time through natural mutation, and this evolutionary fact of life too has seen new foods emerge from old ones.

The question as phrased does not reflect the existing Standard 1.5.2, where it is the means of introduction of new DNA that triggers application of the regulations, rather than the fact of new DNA.

As with all regulation, including food standards, there is an onus on the regulator to demonstrate risk. This returns to the comments earlier - what exactly is the problem that FSANZ is seeking to address? The AFGC is not aware that any significant risks to health and safety have emerged through the commercial use of any of the breeding techniques identified in Figure 1, and so is suspicious of very generalised questions of the sort posed here.

3.1.2 Questions

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

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

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

Again, this question appears to jump ahead of the discussion. Null segregant organisms, by definition, do not contain novel DNA or novel protein (novel in the sense of being derived from recombinant DNA techniques) and so are not likely caught by the existing regulation. In effect, they have been breed using conventional breeding techniques, albeit using a plant with altered DNA as an intermediate step to improve on random mutagenesis. This is a key point – to regulate a food on the basis of the use of recombinant DNA techniques at some point in the organisms ancestry

but where the relevant DNA coding is deliberately then bred out, is to regulate the process and not the outcome. To regulate null segregants would be similar to regulating animals raised on GM feedstock, something that is explicitly excluded from Standard 1.5.2.

There are no safety concerns in relation to null segregants that do not also arise in relation to mutagenesis and conventional breeding. The Food Standards Code needs to remain focussed on food outcomes, not farming practices.

3.1.3 Questions

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?

The AFGC considers that foods from genome edited organisms in commercial production are likely to be of the same of less risk than foods derived from any of the other breeding techniques identified in Figure 1 of the Consultation Paper, because in the case of genome edited organisms the intended effect is precisely identified rather than randomly approximated. In other words, there is a greater risk in the case of other breeding techniques that the desired outcome may be accompanied by unwanted and unintended co-mutations or traits due to the random nature of inheritance and mutation. In practice, such unwanted or unintended traits are bred out by further breeding, but this goes to the essential point that genome editing is simply a faster way to the same outcome as conventional breeding.

3.2 Questions

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?

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

The question required to be asked of regulators is not whether new techniques should be subject to pre-market regulation, but whether there exists a problem, whether government action is needed to address the problem, and whether regulation is the best means to address that problem. This is the key message of the GGR. The immediate leap from the existence of technology to proposals for regulation is precisely the thinking that the GGR is seeking to eradicate.

3.3 Questions

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

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

Again, the leap from the existence of NBTs to the sort of regulation that should apply does not accord with the Government's policies on regulation. The first question is not whether process-based definitions be a trigger for regulation, but what is the evidence that regulation is needed at all? What is the problem? The fact that Standard 1.5.2 regulates foods derived from organisms bred using recombinant DNA techniques is not justification for extending such regulation to other breeding techniques, whether new or millennia old.

3.4 Question

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. The Consultation Paper does not address the social costs that arise from regulatory changes that favour on approach to breeding over another, an issue discussed above where there are identifiable disadvantages to the Australian public flowing directly from Standard 1.5.2.

The Consultation Paper further should address the fact that Australia is only a small player in international markets, indicate how comparable economies are looking to deal with the issue and the opportunities to develop an integrated understanding of, and response to, the risks (if any) posed by these new technologies.

[4] SUMMARY AND RECOMMENDATIONS

There may be appropriate grounds to clarify the scope of existing Standard 1.5.2 as to what is, or is not, a food produced using gene technology.

With the emergence of NBTs it is important to understanding the regulatory consequences of breeding decisions, and if one path leads to regulation and labelling while another does not, investment decisions will need to take that into account.

In accordance with the intent of the Consultation paper, the AFGC does not seek to use this consultation to reopen to debate about whether Standard 1.5.2 and the regulation of recombinant GM technology remains appropriate. Given that it exists,

though, its scope needs clear boundaries especially when innovation in food technology has moved on and, in the new context, the older language of the regulation creates uncertainty as to what is, or is not, captured.

The Government Guide to Regulation requires regulators, prior to considering regulatory intervention, to identify a specific problem, for which government intervention is required to solve, and for which regulation is the most effective option.

The AFGC directs the attention of FSANZ to the assessments of the WHO and the US National Institute of Health. The number of people consuming GM and new technology foods without identified adverse effects significantly exceeds the size of the Australian population.

The GGR is not a statement of political aspiration but a means to deliver best practice regulation that serves the national, political, social and economic welfare of the country. The suggestion that new technology needs to be regulated simply because it is new does not meet this touchstone.

The AFGC is mindful of the fact that NBTs have already attracted the attention of some stakeholders who believe that the NBTs do introduce new risks to health requiring a new tranche of regulations. The AFGC is unaware of any factual foundations to these beliefs. Irrespective of that, however, the agrifood industry, and individual food companies, are very aware that there is already regulatory oversight of foods derived from NBTs in that all foods must be 'safe and suitable' as required by the ANZ FSC, and Australian consumer law also demands it.

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