To: Food Standards Australia New Zealand
NBTConsultSubmissions@foodstandards.govt.au

Submission on: Food derived using new breeding techniques consultation paper

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Submitter:

Mark Ross
Chief Executive
Agcarm – representing NZ's animal medicine and crop protection industries
111 The Terrace
Wellington

Phone: 04 499 4225
Email: mark.ross@agcarm.co.nz

Submission on: Food derived using new breeding techniques

1. Introduction

Agcarm welcomes the opportunity to comment on the 'Food derived using new breeding techniques' consultation paper, released in February 2018.

As one of our key objectives Agcarm supports the principle of sound science based risk assessment. On this basis we have assessed the questions outlined within the consultation document.

We have concluded that there is no scientific reason that a genetic change that relies on existing inherent diversity in a plant or animals gene pool, would be more or less likely to present a new or novel food safety risk. Foods derived from new breeding techniques therefore, present no greater food safety risk than foods derived from traditional methods.

As a nation we need to embrace new technologies to ensure that we continue to produce high-quality food and fibre into domestic and global markets. Agcarm encourages FSANZ to develop robust risk assessment processes that are based on objective science, thus ensuring that whatever method is used to produce our food, we remain confident that it is safe for consumption.

2. Summary of the submission

i. In relation to the question 'that food derived from organisms containing new pieces of DNA should be captured for pre-market safety assessment and approval', Agcarm does not support this principle. Rather, Agcarm is supportive of the principle that scientifically based risk criteria are used to assess the safety and approval of food, whether it is derived from new pieces of DNA, or not.

ii. Agcarm submits that much of the technological advances in food production cannot be predicted. Hence, regulatory control must be short to medium term focused, with the ability of the new Code to have reactive elements to novel processes in the longer term.

iii. As per CropLife Australia, Agcarm recommends that if FSANZ can make a risk-based distinction for food obtained from null segregants, they should be able to make the same risk-based distinction for food obtained from gene-edited organisms. In addition, as it is impossible, or extremely difficult to measure of detect such foods, then there is no point in attempting to include them in pre-assessment and approval.

iv. Agcarm submits that food derived from genome edited organisms should be treated no differently than food produced through conventional techniques. There is no scientific reason that a genetic change that relies on existing inherent diversity in a plant or animals gene pool, would be more or less likely to present a new or novel food safety risk.

v. As a nation we need to embrace innovation and new technology. Agcarm remains supportive of new methods of breeding food, and encourages the FSANZ to develop robust assessment processes that ensure our food remains safe and of a high-quality.

3. General comments

Agcarm has provided commentary under each question. As a general theme we are supporting and re-emphasising the key points put forward within the **CropLife Australia** submission.

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?

Agcarm submits as a leading statement that any regulation developed by government must be based on the principles of objective and credible based science, along with the assessment of risk. With this in mind, the assumption that food derived from organisms containing 'new' pieces of DNA have a greater risk than food derived from organisms developed using 'conventional' breeding methods is challenged.

Many of the protein expressed from inserted DNA are already common within the food chain. Whether they are new pieces of DNA is irrelevant. The focus in this instance is on ensuring that the risk is ascertained as to the safety of the food.

In relation to the question 'that food derived from organisms containing new pieces of DNA should be captured for pre-market safety assessment and approval', Agcarm does not support this principle.

Rather, Agcarm is supportive of the principle that scientifically based risk criteria are used to assess the safety and approval of food, whether it is derived from new pieces of DNA, or not.

As per the CropLife Australia submission, food derived from conventional breeding methods, such as those that harness spontaneous or induced mutagenesis to generate large amounts of genomic variation are not subject to pre-market safety assessment. Food with a similar genetic variation, when produced using newer plant breeding innovations, should not be subject to pre-market regulation purely on the process through the technique that it was created.

In considering the different outcomes of plant breeding innovations, genetic changes can range from small nucleotide changes, deletions or additions; re-creation of an allele from a wild relative in a commercial variety; to introducing a transgene in a site-specific manner. Genome editing techniques such as SDN1, SDN2, ODM, cisgenesis and intragenesis produce plant varieties that are indistinguishable from those produced by conventional breeding methods or by nature. Genome editing techniques that introduce a gene from an unrelated species, are similar to 'foods produced using gene technology' and are currently captured by current regulations.

Several of these products of genome editing applications could also be accomplished, albeit more slowly and with less precision, through more traditional plant breeding methods, such as crossing a commercial variety with a wild relative, or mutation breeding. This is an important point to bear in mind when considering the potential for any new food safety risks.

The CropLife Australia submission provides detailed analysis on mutagenesis – Agcarm is supportive of the context and points that have been raised around spontaneous and induced mutagenesis, targeted mutagenesis and cisgenesis.

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?

Agcarm submits that food from null segregant organisms should be excluded from pre-assessment and approval. Given that it would be impossible to detect the difference between food derived from mutation breeding and gene editing, placing additional controls does not have a strong basis in risk.

In reiterating the principle of sound science based risk assessment, Agcarm submit that here is no scientific basis to regulate food obtained from organisms that are derived from GMOs that have not

inherited traits that occurred because of gene technology. Such organisms have lost the transgenic event (insert) due to normal segregation following conventional breeding with an organism that did not contain the transgenic event.

Food derived from these organisms does not contain any elements of the transgenic event, and therefore should not be subject to pre-market safety assessment and approval as a genetically modified food.

Agcarm is supportive of CropLife, who have identified some logical inconsistency within the Consultation Paper in Section 3.1.2 on null segregants and in Section 3.1.3. In these sections FSANZ have implied that they are to consider and look at factors not related to definitional interpretation, but based on potential risk. For example:

> "*The question for this category is whether there is sufficient justification (based on risk) to require pre-market assessment and approval for food obtained from null-segregants.*"

As per Croplife, Agcarm recommends that if FSANZ can make a risk-based distinction for food obtained from null segregants, they should be able to make the same risk-based distinction for food obtained from gene-edited organisms. In addition, as it is impossible, or extremely difficult to measure of detect such foods, then there is no point in attempting to include them in pre-assessment and approval.

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?

Agcarm submits that food derived from genome edited organisms should be treated no differently than food produced through conventional techniques. There is no scientific reason that a genetic change that relies on existing inherent diversity in a plant or animals gene pool, would be more or less likely to present a new or novel food safety risk.

Agcarm submits that it is not scientifically justified to regulate the process by which food is produced based on the fact that they are new methods. As the outcome of gene editing can be equivalent to those of more traditional non-regulated breeding methods, the presumption of history of safe use should logically extended to gene edited food products.

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?

Agcarm submits that much of the technological advances in food production cannot be predicted. Hence, regulatory control must be short to medium term focused, with the ability of the new Code to have reactive elements to novel processes in the longer term.

As a nation we need to embrace innovation and new technology. Agcarm remains supportive of new methods of breeding food, and encourages the FSANZ to develop robust assessment processes that ensure our food remains safe and of a high-quality. At all times any risk assessment of new techniques must remain robust and based on credible science.

Agcarm submits that food derived via DNA methylation techniques is not regulated as these changes can already readily be induced in traditional breeding. When it comes to other techniques, these need to be assessed on an individual basis using sound risk assessment criteria.

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?

Agcarm supports the positon taken by CropLife in its submission as outlined below.

Agcarm **agrees** with the statement in the Consultation Paper that as a mechanism for capturing foods with new DNA inserted, the process-based approach has generally worked well over nearly 20 years of application. However, Agcarm **submits** that the current process-based definitions are no longer fit for purpose and no longer deliver appropriate risk-based outcomes in terms of what foods are captured for pre-market safety assessment.

As stated previously, the final characteristics of the new plant variety are the best indicator as to whether a new plant variety will present a food safety risk.

This review provides the opportunity to improve the definitions used by FSANZ, particularly that of 'gene technology'. For example, CropLife proposed the following amendment to the definition of 'gene technology' in the *Gene Technology Act 2000*:

gene technology means any technique for the modification of genes or other genetic material, but does not include:

(a) sexual reproduction; OR

(b) homologous recombination; OR

(c) techniques that do not result in the integration of one or more genes in a defined genetic construct into the genome; OR

(d) any other technique specified in the regulations for the purposes of this paragraph.

The inserted text (underlined) above would exclude upfront from regulatory scope foods derived from organisms developed using the techniques of ODM, SDN-1 and SDN-2. It also does not change the regulatory status of food derived from organisms that are currently, and have historically been within regulatory scope of the Food Standards Code.

3.4 Questions
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?

The main issue is to ensure that foods derived from new breeding techniques are regulated commensurate with risk and regulated consistently between regulatory agencies.

As an example in New Zealand the Hazardous Substances and New Organisms (HSNO) Act regulates the release into the environment of live and viable GMOs. Releases are prohibited unless approved by the EPA. Although there is workable legislation in place and risk assessments are science based, the

current government's policy is inhibitive to innovation. The current legislation and a High Court interpretation decision mean that all NBTs are currently considered to be GMOs. Agcarm submits that looking to the future our legislation, and the role of GMOs in New Zealand is reviewed.

As per the Crop Life submission, Agcarm also supports the following policy development.

Development of an 'unstacking' policy
Gene stacking refers to the process of combining genes of interest into a single plant line. Plants with stacked genes now form a significant part of GM crops grown throughout the world. FSANZ does not require separate approval or safety assessment for foods derived from a stacked GM line that is the result of traditional breeding between several GM parent lines for which food has already been approved.

As per CropLife, Agcarm requests that FSANZ may consider clarification regarding the 'unstacking' of genes through conventional breeding. For example, if you have a plant with three unlinked GM events (i.e. insect resistance, herbicide tolerance and drought tolerance) that had been approved by FSANZ (as a stack, no individual approvals sought); then if a new plant variety is brought to market containing one or two or those events segregated by conventional breeding, would it be subject to separate regulatory oversight?

4. About Agcarm

Agcarm is the industry association for manufacturers and suppliers of crop protection and animal health products. For further information and a full list of members, see www.agcarm.co.nz.

Agcarm member products protect public health, improve animal welfare and help environmental management. They:

- Play a pivotal role in growing high yield, sustainable food and fibre products;
- Help supply healthy, nutritional and affordable food;
- Keep New Zealand's agriculture, horticulture and forestry sectors internationally competitive.

Our members are committed to safety, innovation and product stewardship.