Submission on New Breeding Techniques

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AGEFC is a community network that represents the public concern for regulation and labelling of new approaches to genetic manipulation in order to allow people the choice to avoid them; for protection of a GE-free environment in Aotearoa New Zealand.

There is a social contract in place that requires regulation of the three new techniques being considered in this consultation.

The international concerns of civil society and independent scientists around emerging genetic techniques has resulted in the demand for an international system of regulation, testing and labelling.

Although countries like the US have followed industry lobbying and not required labels on novel foods the consumer demand has driven a huge non-GMO sector in the US.

The community-FSANZ- industry nexus is the basis for the industry 'license to operate' – regulation, testing, labelling, monitoring and capacity for emergency recall.

Deregulating the three new techniques would fundamentally destroy public confidence and trust.

There is an unmanaged risk in FSANZ's approach because of conflicts of interest and unintentional bias within the advisory panel used by FSANZ.

It is concerning that the panel may have been influenced by a view of consumers that is based on potentially misleading market research experiments. This includes creating models of consumer acceptance of novel foods based on misrepresenting benefits to consumers and which can be considered 'confusion marketing' or even unethical.

It is wrong to assume safety of any products from Crispr and the other techniques. There is a significant potential for unintended results and the integrity of the food supply requires regulation, omic profiling, labelling and oversight.

It is wrong to allow trade relations to influence the fundamental unwinding of food safety system that a failure to regulate the new techniques would be.

The US appears to not be regulating crispr. However this puts at risk food safety and monitoring and should not be followed, but a policy change urged by other governments.

The risk to trade is much greater from a loss of global consumer confidence by FSANZ not regulating. A major food safety event is a high risk to global trade and made more likely if safety of any of the techniques is just assumed but not tested for in each case.

To answer the questions FSANZ:

3.1.1 Questions - Genome contains new DNA,

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. All new genetic modification techniques should be assessed for safety before being allowed in our food. They should also be labelled for consumer choice. This includes gene editing, GM rootstock grafting, cisgenesis, intragenesis RNA interference and null segregants.

Should there be any exceptions to this general principle? NO

3.1.2 Questions - Genome unchanged by gene technology.

Should food from null segregant organisms be excluded from pre-assessment and approval? NO.

If no, what are your specific safety concerns for food derived from null segregants - The assumption that there have been no unintended genetic changes needs to be tested before products derived from these techniques are allowed in our food. Hence the need for a full safety assessment.

3.1.3 Questions - Genome changed but no new DNA

Are foods from genome edited organisms likely to be the same in terms of risk to foods derived using chemical or radiation mutagenesis? NO.

If no, how are they different? - While chemical and radiation mutagenesis can increase the rate of random DNA point mutations, gene editing techniques cause DNA double strand breaks and can be used sequentially to make dramatic differences to DNA. They are also prone to additional unexpected mutations. They therefore carry a greater risk and warrant pre-market safety assessment and approval.

3.2 Questions - Other techniques

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?

RNA interference which can result in DNA methylation and gene silencing and has the potential to be used in the future for the development of food products. It poses unique risks such as gene silencing in non-target species that need to be assessed before it is allowed in food. Products produced using RNA interference should also be labelled as genetically modified for consumer choice.

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

Yes. DNA methylation is quite clearly a genetic modification technique and can result in heritable

genetic changes. It therefore needs to be assessed for safety before being used in our food.

3.3 Questions - Regulatory Trigger

Do you think a process-based definition is appropriate as a trigger for pre-market approval in the case of NBTs? - YES, genetically modified organisms pose unique risks and a process based trigger is appropriate for assessing these risks.

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

All genetic modification techniques should be assessed for safety and these new GM techniques are quite clearly genetic modification techniques under -The Hazardous substances and New Organisms Act (HSNO) 1996 includes all new GM techniques including RNA interference.

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

Standard 1.5.2 defines "food produced using gene technology" as "a food which has been derived or developed from an organism which has been modified by gene technology." It states that "gene technology means recombinant DNA techniques that alter the heritable genetic material of living cells or organisms." This definition clearly includes gene editing techniques. The intent of the Gene Technology Act and Standard 1.5.2 was to capture all new GM techniques. Since RNA interference can also "alter the heritable genetic material of living cells or organisms" through DNA methylation the definition of gene technology in Standard 1.5.2 would be better changed to "gene technology means in vitro techniques that alter the heritable genetic material of living cells or organisms" for clarity.

SUMMARY

AGEFC ask for regulation of: gene editing, CRISPR, GM rootstock grafting, cisgenesis, intragenesis RNA interference and null segregants.

Why? Because the research simply hasn't been done to show there are no unintended consequences and that these foods or techniques are safe for commercial use.

The public expectation underpinning FSANZ's legitimacy is a social contract.

These techniques are required to be regulated under the Gene Technology Act 2000. This defines gene technology as "any technique for the modification of genes or other genetic material".

It clearly includes all new GM techniques including RNA interference.

Please keep us informed.

We would like to be heard if any community consultation or public hearings are held