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To: NBT Consult Submissions <NBTConsultSubmissions@foodstandards.gov.au>
Subject: New Breeding Tech

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

Because each event varies, it is vital to regulate, monitor and research unintended consequences.

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".

Without case by case 'omic' profiling it cannot be assumed that these foods or any newer techniques are safe for commercial use.

There is insufficient knowledge of the risks of these techniques and all of them should be regulated.

New Zealand legislation has ruled they are Genetic Modification and therefore need regulation. They cannot be used in organic food says the International Organic Federation IFOAM.

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.

FSANZ must not withdraw from the public-service role under pressure from industry, or promotion of 'innovation'.

The following responds to FSANZ questions

3.1.1 Genome contains new DNA

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

There should NOT be any exceptions to this general principle.

3.1.2 Genome unchanged by gene technology.

Null segregant organisms must NOT be excluded from pre-assessment and approval.

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 Genome changed but no new DNA

Foods from genome edited organisms are NOT the same in terms of risk to foods derived using chemical or radiation mutagenesis? It cannot be assumed. 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 Other techniques

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

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 Regulatory Trigger

A process-based definition is appropriate as a trigger for pre-market approval in the case of NBTs. Genetically modified organisms pose unique risks and a process based trigger is appropriate for assessing these risks.

Retain Standard 1.5.2 defining "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.

Since Australia is a major food exporter we in a sovereign nation NZ (or even New Caledonia who may import Australian wheat for their bread) are all going to wind up eating this stuff, if it is deregulated . We demand all newer GM & CRISPR food be assessed for safety. Australia & NZ may become the first food safety authority to rubber stamp this less than four years old GMO biotech' via FSANZ who again won't independently test the GM food and crop experiments. This perpetuates the repetition of the introduction of GM by stealth as 'accidentally' occurred in the NZ Corngate saga.

Please listen and respond to the public opinion as well as the worlds independent scientists. We must heed the reality not the commercial hype under international trade deals

such as the TPP-11.

yours sincerely ,

M.T.