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### **Submission to FSANZ – new breeding techniques**

*Deregulating oversight of these new techniques would fundamentally destroy public confidence and trust.*

*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.*

*This is what I, and I believe most members of the public EXPECT and deserve. Without case by case 'omic' profiling it cannot be assumed that these foods or techniques are safe for commercial use.*

*It is unreasonable for authorities to withdraw from the public-service role under pressure from industry.*

*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.*

*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.*

*In Australia and New Zealand the industry 'license to operate' is founded on regulation, testing, labelling, monitoring and capacity for emergency recall.*

*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.*

*Please do not betray the public trust.*

*It appears there is a risk in FSANZ's approach because of conflicts of interest and unintentional bias within the advisory panel used by FSANZ. This may include experimental research misrepresenting benefits to consumers in ways which can be considered 'confusion marketing' or even unethical.*

*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.*

*It would be disastrous to allow trade relations, or a policy objective to make innovation 'easier' to influence the fundamental unwinding of food safety system that a failure to regulate the new techniques would be.*

*The US authorities appear to not be regulating crispr, putting at risk food safety and monitoring. A policy change should be urged by our governments.*

### 3.1.1 Questions - Genome contains new DNA,

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.

There should NOT be any exceptions to this general principle

### 3.1.2 Questions - 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 Questions - 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 Questions - 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 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.

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 should retained and 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.