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Subject: Submission re. Consultation paper on Food derived using 'new breeding techniques'

Re: gene editing, CRISPR, GM rootstock grafting, cisgenesis, intragenesis RNA interference and null segregants. There is insufficient knowledge of the risks of these techniques and all of them should be regulated. 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. They 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.

We have a right to know what we are eating and growing. If these techniques are safe and valuable then pre-market testing, full labelling and follow up monitoring will confirm this.

FSANZ Questions to answer

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.

Yours sincerely, Nicole Leonard