



Dow AgroSciences

Dow AgroSciences Australia Ltd ABN 24 003 771 659

www.dowagrosciences.com.au

Level 5, 20 Rodborough Road, Frenchs Forest N.S.W. 2086 Australia

Telephone: 61 + 2 9776 3400 Fax: 61 + 2 9776 3435 Toll Free +1800 700 096

Postal Address: Locked Bag 502, Frenchs Forest N.S.W. 2086 Australia

18th April 2018

Food Standards Australia New Zealand

Level 4, 15 Lancaster Place

MAJURA PARK ACT 2609

Re: Comment on the FSANZ New Breeding Technologies Consultation Paper

Corteva Agriscience™ the Agriculture Division of DowDuPont™, a business division of DowDuPont (NYSE: DWDP), combines the strengths of DuPont Pioneer, DuPont Crop Protection and Dow AgroSciences. Together, Corteva Agriscience™ provides growers around the world with the most complete portfolio in the industry, developed through a robust research pipeline across germplasm, biotech traits and crop protection. Corteva Agriscience™ is committed to delivering innovation, helping growers increase productivity and ensuring food security for a growing global population. We appreciate the opportunity to provide comment on the *FSANZ Consultation Paper – Food derived using new breeding techniques*. Gene editing is one of the plant breeding tools that allows scientists to more precisely and efficiently improve a plant that could be also obtained using conventional breeding methods or found in nature, helping farmers produce more and better food, with fewer resources. It is important that the food produced from these plant breeding innovations to be afforded the same regulatory regime as all similar plant foods, irrespective of the techniques used to develop them. If plant foods could be developed by a new plant breeding technique or by a conventional breeding technique, they should be regulated no differently.

**3.1.1 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?**

Corteva Agriscience™ the Agriculture Division of DowDuPont expects that any regulations be consistent with the following regulatory principles:

- Regulation should protect health and the environment while promoting innovation.
- Decisions should be based on the best available scientific and technical information.
- Regulation should be cost-effective and commensurate with the risk.
- Regulation should accommodate new evidence and learning.
- Regulation should be consistently applied and enforced.
- Regulation should be adopted through a public and transparent process.

Specifically regulation of food should be applied based on the level of risk associated with the food derived from the breeding technique. The need for a pre-market safety assessment ought to be driven by the characteristics of the plant and thereby the safety profile of the end food product in the context of the long history of safe use. Plant varieties produced using SDN1, SDN2, ODM, cisgenesis or intragenesis, are similar or indistinguishable from varieties that could be found in nature or could have been produced through earlier breeding methods should be treated in the same manner.

When considering the food safety risks of food it is important to address the characteristics of the plant producing the food rather than the specific plant development method. This concept is supported by the US FDA's statement in the 1992 "Statement of Policy: Foods Derived From New Plant Varieties"¹ which is applicable to gene edited plant foods: *"The method by which food is produced or developed may in some cases help to understand the safety or nutritional characteristics of the finished food. However, the key factors in reviewing safety concerns should be the characteristics of the food product, rather than the fact that the new methods are used."*

Mutations and genomic changes are inherently occurring in plants and represent an important source of genetic diversity utilised by plant breeders to develop new and improved varieties. Technical abilities and dramatically increased affordability of genome sequencing technologies now allow in-depth whole genome sequencing and provide an undisputable source of information about the rate of inherent genetic variability of plants within a single generation, across different generations, and across different varieties of the same species.

Genomic changes occur in nature via various processes, for example, UV radiation, reactive oxygen species, or the action of transposable elements which can disrupt, restore, or modulate gene function^{2,3}. Helitrons, a superfamily of transposable elements, can capture and mobilize gene fragments, further contributing to genomic diversity and polymorphism⁴. Single base pair changes (SNPs – Single Nucleotide Polymorphism), indels (short insertions or deletions) and complete gene deletions are now known to frequently occur in plant genomes^{5,6}. SNP frequency is one of the intensively studied phenomenon; for example, in maize SNPs may occur, on average, every 100 bp^{7,8}. It can be estimated that a one-hectare field of soybeans may contain 1.8 million novel SNPs⁹. An example of retrotransposon-mediated genomic changes is duplication of the SUN gene in tomato that increased gene expression and resulted in elongated fruit shape¹⁰. A study on the two well-known maize inbred lines, B73 and Mo17, revealed an impressive rate of the gene copy number variation (CNV) and gene presence/absence variation (PAV): the two maize inbreds were different by several hundred CNVs and several thousand PAVs¹¹.

These and other numerous examples illustrate that a range of inherent genetic variability within a plant species is much broader than previously understood^{12,13}. Many of such genetic changes are 'silent' and do

¹ Food and Drug Administration. 1992. "Statement of Policy: Foods Derived From New Plant Varieties; Notice" Federal Register, Vol. 57, May 29, 1992, pp. 22984-23005.

² Pacher, M and Puchta, H. (2017) The Plant Journal 90: 819-833. Doi:10.1111/tpj.13469.

³ Glenn, C. et al. (2017). Crop Science, 57: 2906-2921

⁴ Lal, S et al. (2009) Plant Science 176: 181-186.

⁵ Glenn, C. et al. (2017). Crop Science, 57: 2906-2921

⁶ Swanson-Wagner RA, et al. (2010) Genome Research 20:1689-1699. Doi:10.1101/gr.109165.110

⁷ Ching A. et al (2002) BMC Genetics 3: 19

⁸ Tenaillon M.I. et al. (2001) PNAS, 98,16: 9161-9166.

⁹ Parrot WA et al. (2012) Nature Biotech 30(9): 825-826.

¹⁰ Xiao et al. (2008). Science, 319: 15227-1530.

¹¹ Springer NM, et al. (2009) PLoS Genetics 5: e1000734.doi:10.1371/journal.pgen.1000734.

¹² Weber N, et al. (2012) Plant Physiology 160: 1842-1853 doi:10.1104/pp.112.204271

¹³ Jiao Y, et al. (2017) Nature doi:10.1038/nature22971

not result in a novel phenotype, however some may favourably change the plant phenotype and be useful for crop diversification or improvement. For example, the “Green Revolution” genes conferring the dwarf phenotype in wheat are a result of spontaneous mutations in genes involved in gibberellin biosynthesis¹⁴. White grapes and blood oranges are a result of the transposon activity¹⁵. The commercial grapevine cultivar Tannat, known for its high level of polyphenolic compounds, contains 1873 genes not shared with the grape reference genome. These cultivar-specific genes contribute substantially to the overall expression of enzymes involved in the synthesis of phenolic and polyphenolic compounds and thus, unique characteristics of the Tannat berries¹⁶.

Conventional breeding methods, also including hybridization and classical (chemical or radiation) induced mutagenesis are tools used by plant breeders to create significant, often unpredictable, genetic rearrangements or variability and search for desired phenotype through extensive and time consuming phenotypic screens^{17,18}. Classical mutagenesis is broadly used in modern plant breeding, with over 3200 mutants registered in the FAO/EAEA mutant variety database¹⁹. The history of safe use of conventionally bred varieties demonstrates that a multitude of spontaneous or induced mutations are unlikely to impact plant safety. The outstanding track record of conventional plant breeding provides a baseline for safety comparisons.

The more recent plant breeding methods, including cisgenesis, intragenesis and genome editing, allow plant breeders to make these same genetic changes in a much more targeted (hence, precise) and efficient manner. Irrespective of how plant varieties are developed, be it conventional breeding methods, *in vitro* recombinant DNA, cisgenesis, intragenesis, genome editing or any other methodology, all plants undergo extensive field evaluations before commercialization where any non-desirable changes can be selected out throughout the breeding.

Cisgenic plants are developed by adding a gene’s native expression cassette from the same species or a cross compatible species. The introduced DNA is plant’s sequence of genomic DNA that contains the gene of interest with its native regulatory sequences, i.e. promoter, coding region including its introns, terminator sequences, and 5’ and 3’ untranslated regions in the normal (“sense”) orientation²⁰. The tool of cisgenesis allows plant breeders the ability to access a broader range of traits found in the gene pool and wild relatives, increasing genetic variability; introgress traits in crops/varieties that are clonally propagated or sterile and overcome linkage drag.²¹

The knowledge of the genetic sequences used in cisgenesis includes position and function enabling this methodology to produce plants with comparable compositional safety, equivalent fitness and analogous effects to non-target organisms to plants produced utilising conventional breeding methodologies^{22,23}. Cisgenic plants contain native and unmodified genetic sequence from the same (or cross compatible) species. As discussed above, the gene CNV and PAV phenomena are common in plants. We believe that

¹⁴ Peng J. et al. (1999) Nature 400: 256-261.

¹⁵ Lisch D. (2013). Nat. Rev. Genetics, 14: 49-61.

¹⁶ De Silva C. et al. (2013). The Plant Cell, 25: 4777-4788.

¹⁷ Fehr, WR. (1987) General Principles. In WR Fehr, ed, Principles of Cultivar Development, Vol 2: Crop Species. Macmillan Publishing Company, New York, pp1

¹⁸ Nuffield council on Bioethics (2016) Section 5 – Food. In Genome Editing; an ethical review, pp 56-72, <http://nuffieldbioethics.org/wp-content/uploads/Section-5-Food.pdf>

¹⁹ <https://mvd.iaea.org/>

²⁰ Holme, IB, Wendt, T, Holm PB, Plant Biotechnology Journal 11: 395- 407.

²¹ Andersen, MM et al (2015) Trends in Plant Science 20: 426-434.

²² Cardi, T (2016) Plant Breeding 135: 139-147

²³ Schouten, HJ, Krens FA, Jacobsen E (2006) EMBO Reports 7: 750-753

FSANZ ought to apply the same regulatory process to plants produced using conventional breeding methodologies and cisgenesis as the potential risks posed to the resultant food products are commensurate with each other. This would be consistent with the conclusion reached by the European Food Safety Authority stating that similar hazards can be associated with cisgenic and conventionally bred plants²⁴.

Intragenesis technique differs from cisgenesis in that it involves the insertion of a reorganized, full or partial, coding region of a gene frequently combined with a promoter and/or terminator from another gene of the same species or a cross compatible species²⁵. The coding region may be arranged in a sense or antisense orientation compared to the orientation in the donor organism. Similar to cisgenesis plants, intragenic plants contain genetic material solely from the same or cross compatible species. 'Intragenic plants' can also occur in plants spontaneously due to the inherent process of a transposon (helitron)-mediated relocation of genetic material, as discussed earlier.

Gene editing is a technique that allows plant breeders to obtain plants that could be also possible through conventional breeding and includes Site Directed Nuclease (SDN) techniques, SDN-1 (gene - delete) and SDN-2 (gene-edit) applications, and oligo-directed mutagenesis (ODM).

Examples of SDN-1 that have produced a food product that could also be obtained via conventional breeding include:

- Targeted mutagenesis of *FAD2* and *FAD3* genes in soybean using TALENs^{26,27} resulting in a high oleic soybean oil. *FAD2* and *FAD3* mutants, both spontaneous and X-ray induced, have been described in soybean as well as other plant species²⁸.
- Natural (spontaneous) or transposon induced mutations in maize *MS* fertility genes have been a subject of discovery and classical genetic studies for decades²⁹. Most recently, targeted mutagenesis of *MS* genes in maize and several other monocots was achieved using CRISPR-Cas and meganuclease techniques^{30,31}.
- TALEN-mediated mutation of three *MLO* genes in hexaploid wheat resulting in resistance to powdery mildew³². The experiment was based on a prior knowledge about the loss-of-function *mlo* alleles existing in barley, Arabidopsis and tomato and shown to lead to resistance to fungal pathogens causing powdery mildew^{33,34,35}.
- Next Generation Waxy Corn, generated using CRISPR-Cas technology to delete the endogenous *Wx1* gene³⁶. The *Wx1* gene encodes the granule-bound starch synthase, responsible for amylose biosynthesis. Mutations in the *Wx1* gene that result in a non-functional starch synthase lead to the disruption of amylose biosynthesis and a relative increase in amylopectin content in starch – i.e., the waxy corn phenotype. The *Wx1* gene is regarded as a “classical” maize gene and one of the most

²⁴ European Food Safety Authority Panel on Genetically Modified Organisms (2012) EFSA Journal 10: 2561.

²⁵ https://corporateeurope.org/sites/default/files/attachments/36._nbt_platform_multilateral_meeting_25_06_2014_steering_note._registered_version_0.pdf

²⁶ Haun W. et al. (2014) Plant Biotechnology J. 12: 934.

²⁷ Demorest Z.L. et al. (2016) BMC Plant Biology 16: 225.

²⁸ Pham A.-T. et al. (2010) BMC Plant Biology 10: 195.

²⁹ Mutants of Maize, Neuffer M.G., Coe E.H., and Wessler S.R (eds) (1997) Cold Spring Harbor Laboratory Press: 311.

³⁰ Svitashv S. et al. (2015) Plant Physiology 169: 931.

³¹ Cigan A.M. et al. (2016) Plant Biotechnology doi: 10.1111/pbi.12633.

³² Wang Y. et al. (2014) Nature Biotechnology 32(9): 947.

³³ Piffanelli P. et al. (2004) Nature 430: 887.

³⁴ Consonni C. et al. (2006) Nature Genetics 38: 716.

³⁵ Bai Y. et al. (2008) Molecular Plant Microbe Interaction 21: 30.

³⁶ https://www.aphis.usda.gov/biotechnology/downloads/reg_loi/15-352-01_air_inquiry_cbidell.pdf

rigorously studied^{37,38}. There are over 200 known mutations of maize *Wx1* gene that result in gene disruption and the waxy phenotype³⁹. These mutations include insertions or deletions of various sizes (from several base pairs to the entire gene). Waxy corn varieties have been grown in the U.S. since the 1940s. Therefore, the lack of a functional *Wx1* gene is common in traditionally bred waxy corn. As expected, deletion of *Wx1* gene in Next Generation Waxy Corn led to the waxy phenotype as in traditionally bred commercial waxy corn. Next Generation Waxy Corn is indistinguishable from a variety that could arise in nature or otherwise be developed via traditional breeding methods, such as the current waxy corn products. There is no reason to believe that the intended *Wx1* gene deletion would lead to a change in composition other than the intended kernel starch reduction in amylose and attendant increase in amylopectin. No new protein is expressed in Next Generation Waxy Corn; therefore, no new toxins or allergens are anticipated.

Examples of SDN-2 and ODM techniques that have produced a food product with equivalent risk to a conventional bred food product include:

- Various spontaneous and induced mutations in plant *ALS (AHAS)* genes leading to tolerance to sulfonylurea and imidazolinone herbicides have been described in several plant species^{40,41} and commercialized in a range of crops⁴². Herbicide tolerance is conferred by specific amino acid changes in the ALS protein sequence. The same changes could be generated in maize and rice using CRISPR-Cas and TALEN mediated SDN-2 approach, and though oligo-directed mutagenesis approach in canola and predictably resulted in plant's herbicide tolerance^{43,44,45}. Similar experiment was conducted in flax to generate two targeted amino acid changes in the native *EPSPS* gene resulting in glyphosate tolerance⁴⁶.
- Targeted replacement (swap) of unfavourable allele in a variety of interest with the favourable allele of the same gene from another variety is another potential application of SDN-2 technique^{47,48}. In this instance the homology directed repair involves a DNA template sequence that encodes the favourable allele. The favourable allele is brought into the recipient line at its native genomic location and replaces the current allele. Such an outcome is similarly achievable through conventional breeding by introducing the desired gene allele through a series of breeding crosses.

³⁷ Bennetzen, JL and Hake, SC. (2009) Handbook of Maize: Genetics and Genomics. Springer Science & Business Media, New York.

³⁸ Neuffer MG, et al. (1997) Mutants of Maize. Cold Spring Harbor Laboratory Press.

³⁹ www.maizegdb.org/data_center/stock

⁴⁰ Duggleby R.G. and Pang S.S. (2000) Journal of Biochemistry and Molecular Biology 33(1): 1.

⁴¹ Tan S. et al. (2005) Pest Management Science 61: 246.

⁴² <https://agriculture.basf.com/en/Crop-Protection/Clearfield-Global.html>

⁴³ Svitashv S. et al. (2015) Plant Physiology 169: 931.

⁴⁴ Li T. et al. (2016) Journal of Genetics and Genomics 43: 207.

⁴⁵ <http://www.cibus.com/technology.php>

⁴⁶ Sauer N.J. et al. (2016) Plant Physiology 170: 1917.

⁴⁷ https://www.aphis.usda.gov/biotechnology/downloads/reg_loi/17-076-01_air_inquiry_a1_cbidel.pdf

⁴⁸ Custers R (2017) The regulatory status of gene-edited agricultural products in the EU and beyond. Emerging Topics in Life Sciences. DOI: 10.1042/ETLS20170019

**3.1.2 Should foods 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?**

Corteva Agriscience™, the Agriculture Division of DowDuPont™, supports that foods from null segregant organisms should be excluded from pre-assessment and approval, and it is appropriate that they are excluded. This is supported by the notion in the document that it has been already common practice at FSANZ to use null segregants as non-GM comparators for compositional analysis of GM foods. Implementation of such an exclusion would align FSANZ with the current proposal by the OGTR, as a part of the review of the Gene Technology Regulations, to classify null segregants as not GMOs⁴⁹. Alignment of OGTR and FSANZ positions would drive towards more clear, predictable and aligned regulatory status of seed and derived food products developed with new breeding techniques in Australia which is important to commercial product developers for business planning.

**3.1.3 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?**

Corteva Agriscience™, the Agriculture Division of DowDuPont, believes that a plant variety produced via genome editing, as defined in Appendix A of the *FSANZ Consultation Paper – Food derived using new breeding techniques*, is unlikely to present food safety risks that differ to or are greater than those developed by conventional methodologies, including chemical and radiation mutagenesis. An increase of genetic diversity beyond spontaneous mutations can be accomplished for the purpose of breeding through classical (chemical, irradiation) mutagenesis. Unlike a targeted mode of gene editing by oligo-directed mutagenesis or SDNs, unintended mutations caused by classical mutagenesis are abundant, random and not possible to predict. Depending on the mutagen concentration and/or duration of exposure, mutation frequencies were estimated to reach as high as 1 per 40 kb in rice, 1 per 24 kb in wheat, 1 per 322 kb in tomato, etc.⁵⁰ As acknowledged by the European Food Safety Authority (EFSA), the frequency of mutations is predicted to be higher after mutation breeding⁵¹. With that, conventional mutagenesis is a universally deployed tool in modern breeding, with over 3200 mutants registered in the FAO/IAEA mutant variety database⁵² and no verified reports raising safety questions⁵³. This justifiably supports the safety baseline for plant breeding. Thus, the potential for unintended changes in the genome is not a unique feature of the new techniques and furthermore, any potential imprecision of the new techniques is expected to be significantly less than the rates of mutations from classical mutagenesis for which there is an established history of safe use.

An important factor to consider is that common practices of plant breeding involve extensive evaluations of new plant varieties before their release on market; these assessments are designed to eliminate plants

⁴⁹ [http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/39DB72B3BB9AA790CA25823B00812B73/\\$File/Regulation%20Impact%20State%20for%20consultation.pdf](http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/39DB72B3BB9AA790CA25823B00812B73/$File/Regulation%20Impact%20State%20for%20consultation.pdf)

⁵⁰ Citations from: ²Sikora et al (2011) Intl. K. Plant Genomics doi:10.1155/2011/314829

⁵¹ EFSA (2012) EFSA Journal 10(10): 2943.

⁵² <https://mvd.iaea.org/>

⁵³ Parrot WA et al. (2012) Nature Biotech 30(9): 825-826.

with unintended, unfavourable characteristics from further advancement⁵⁴. Such breeding practices would similarly apply to the gene edited varieties⁵⁵. While gene editing facilitates trait development, commercial product development typically involves several years of breeding and field evaluations according to the common breeding practices.

As discussed in our response to Question 3.1.1, the need for a pre-market safety assessment ought to be driven by the characteristics of the plant and thereby the safety profile of the end food product in the context of the long history of safe use of traditional breeding methods. Plant varieties that are similar or indistinguishable from varieties that could be found in nature, that do not present a food safety risk or could have been produced through earlier breeding methods should be treated in the same manner, thereby exempt from pre-market safety assessment.

3.2 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?

As outlined in our response to Question 3.3, Corteva Agriscience™, the Agriculture Division of DowDuPont™, believes that by employing a system that regulates on a food products characteristics, rather than the process by which it was developed, FSANZ will be able to ensure appropriate risk management of food products into the future. As new techniques will continue to arise, it is important that FSANZ remains technique neutral and flexible otherwise they will be practicing in a constantly outdated regulatory environment. Utilising the food product characteristics as the driver for a pre-market assessment will help to future-proof FSANZ to work in the rapidly developing scientific space.

Corteva Agriscience™, the Agriculture Division of DowDuPont, believes that a plant variety produced via DNA methylation (an NBT), is unlikely to present food safety risks that differ to or are greater than those developed by conventional methodologies, including chemical and radiation mutagenesis. Similar to null segregants, organisms created using DNA methylation are absent of any genetic material modified by gene technology, they do not contain “new DNA”, and it is appropriate that they ought to be excluded from pre-market safety assessment. Additionally important to consider is that methylation is an inherent process within plants, making the risk of a conventional methylated food product equivalent to that of a food product achieved through an NBT. As a result, there should be no difference in the regulation of the food products.

3.3 Do you think a process-based definition is appropriate as a trigger for pre-market approval in the case of NBT's?

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?

The *FSANZ Consultation Paper – Food derived using new breeding techniques* states that the process-based approach has worked well for the last 20 years as a method of capturing novel foods with new DNA

⁵⁴ Glenn, C. et al. (2017). Crop Science, 57: 2906-2921

⁵⁵ Scheben and Edwards (2017) Science 355: 1122

inserted. Corteva Agriscience™, the Agriculture Division of DowDuPont™, agrees with this statement but feels the definition of gene technology used in this process is no longer suitable.

gene technology means recombinant DNA techniques that alter the heritable genetic material of living cells or organisms.

As outlined in our response to Question 3.1.3, it is important to assess risk based upon the characteristics of the final food product, rather than the tools used to develop said food product. Again, this concept is supported by the US FDA's statement in the 1992 "Statement of Policy: Foods Derived From New Plant Varieties"⁵⁶ which is applicable to gene edited plant foods: *"The method by which food is produced or developed may in some cases help to understand the safety or nutritional characteristics of the finished food. However, the key factors in reviewing safety concerns should be the characteristics of the food product, rather than the fact that the new methods are used."*

The way to best define Gene Technology has been under consideration in the two other reviews around NBTs in Australia, The Department of Health Review of the Gene Technology Act and the OGTR Review of the Gene Technology Regulations. In our submission to the review of the Gene Technology Act we suggested that the following definition be adopted:

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 result in a modified organisms where such modification could also occur in nature or be obtained using conventional breeding

If FSANZ too adopted this definition, they would be taking into account current scientific knowledge, be future-proofing their definition and as well allowing for the regulation of foods based upon their characteristics and not the process by which they were designed. Adoption of this definition style would also align FSANZ with the Department of Health and the Gene Technology Act.

3.4 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?

Currently within Australia there are three separate yet related reviews on the subject of gene technology and new breeding techniques:

1. 2016 Technical Review of the Gene Technology Regulations
2. 2017 Review of the National Gene Technology Regulatory Scheme
3. 2018 FSANZ Review of Food Derived Using New Breeding Techniques

Having these three reviews running somewhat concurrently provides an opportunity for consistency of regulation within Australia. Consistency of regulation would avoid instances where, for example, a product may be regulated as gene technology for environmental release purposes but not for food purposes, as well as providing regulatory clarity for those working within the space of new breeding

⁵⁶ Food and Drug Administration. 1992. "Statement of Policy: Foods Derived From New Plant Varieties; Notice" Federal Register, Vol. 57, May 29, 1992, pp. 22984-23005.

techniques. Although the risks being considered by FSANZ and the OGTR are different, and the legislation under which the two authorities function is also different, seeking to identify and implement potential areas of harmonisation would be beneficial to both the scientific community, product developers, and more broadly, the Australian people. As discussed in our submissions to the OGTR^{57, 58, 59} and throughout this response, gene editing is one of the plant breeding innovations that allows scientists to more precisely and efficiently improve a plant that could be obtained using traditional breeding methods or found in nature, helping farmers produce more and better food, with fewer resources. It is important that for these plant-food breeding innovations to be afforded the same regulatory regime as all similar plant foods, irrespective of the techniques used to develop them; if plant foods could be developed by a new improvement technique and by a conventional breeding technique, they should be regulated no differently.

Yours sincerely,



Sarah Russell French ANZ Seeds Regulatory and Product Stewardship

Corteva Agriscience™

Agriculture Division of DowDuPont™

Dow AgroSciences Australia Ltd
Level 5, 20 Rodborough Rd
Frenchs Forest, NSW, 2086

⁵⁷[http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/9B13B7BBB593A606CA2582570017DAB7/\\$File/Agriculture%20Division%20of%20DowDuPont.PDF](http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/9B13B7BBB593A606CA2582570017DAB7/$File/Agriculture%20Division%20of%20DowDuPont.PDF)

⁵⁸[http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/8884A10B0BA5CF42CA2580B10016087D/\\$File/Dow%20Agrosciences%20Australia.pdf](http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/8884A10B0BA5CF42CA2580B10016087D/$File/Dow%20Agrosciences%20Australia.pdf)

⁵⁹ [http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/8884A10B0BA5CF42CA2580B10016087D/\\$File/DuPont%20Pioneer.pdf](http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/8884A10B0BA5CF42CA2580B10016087D/$File/DuPont%20Pioneer.pdf)