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Submission

Proposal P1055. Definitions for gene technology and new breeding techniques

Deadline: December 3, 2021 6pm (Canberra time)

submissions@foodstandards.gov.au

1. The Soil and Health Association (hereafter the Association) welcome the opportunity to submit to this proposal to revise and update the definitions in the Australia New Zealand Food Standards Code (the Code) for 'food produced using gene technology' and 'gene technology' to make them clearer and to better reflect existing and emerging genetic technologies, including new breeding techniques (NBTs).'[1]
2. Pre-market risk assessment must continue to be the critical control point.
3. The Association ***disagrees with the proposal to adopt the United States Department of Agriculture (USDA) revised definition for 'genetic engineering'.***[2]
    a. Harm may occur via other pathways that do not occur via changes in nucleic acids. A focus on nucleic acids constrains the regulatory scope.
    b. Increasing derogations result in risk creep (as opposed to regulatory creep). Small shifts reduce transparency and result in an erosion of regulatory oversight over time.
4. The Association ***agree that it is important to regulate NBT foods in a manner that recognises their risk***.
    a. NBTs retain similar characteristics to so-called older techniques – they are tools for guided or site directed DNA modifications. NBTs are new generation technologies.
5. The Association proposes that **NBT food and refined ingredients should remain designated as GM food for Code purposes.**
    a. NBTs must not be given exemptions and must be subject to case by case safety evaluations.
    b. Commercialisation incentives increase the potential for NBT's to scale up rapidly throughout the global food chain. These incentives are not present in conventional commodity foodstuffs.
6. The Association ***agrees with the proposal to revise and expand the process-based definition*** for 'gene technology' to capture all methods for genetic modification other than conventional breeding.

[1] 1st Call for submissions – Proposal P1055. Definitions for gene technology and new breeding techniques

[2] Ibid p. 24 *'techniques that use recombinant, synthesised or amplified nucleic acid to modify or create a genome'*

7. The Association ***emphasise that process-based definition must remain.*** Subsection 18(1) of the FSANZ Act reminds us that the standards must be 'based on risk analysis using the best available scientific evidence'

    a. In fast-paced technological environments the 'best available evidence' can shift very quickly. Transparency is important to identify change in use patterns over time which might increase health risk.

    b. Off-target effects may be difficult to identify. While some NBT foods may contain equivalent characteristics to conventional food, the potential for off-target or adverse effects cannot be dismissed[3] [4] [5], indeed 'some off-target activity must be expected.[6]

    c. Changes are often not fully understood by developers and future risk scenarios cannot be easily anticipated, and regulators must not rely on industry claims alone.

        i. For example, Recombinetics' cattle, where manufacturer claims of no off-target effects of hornless cattle were found to be inaccurate.

        ii. For example, early approvals of glyphosate tolerant crop species have not adjusted for to recognise risk from quintuple applications that alter the risk profile for consumers and surrounding environments exposed to these pesticide emissions.[7]

8. The Association ***proposes that process-based definition is expanded*** to recognise the increase in risk arising from the global acceleration in research and development and commercialisation of gene technologies.

9. Investment, commercialisation & rapid R&D advancement mean that ***gene technology scales risk not safety.***[8]

    a. As technologies improve, financial and technological barriers to gene technology are substantially reduced, accelerating R&D and commercial deployment of engineered organisms.

    b. The potential for off-target modifications and unanticipated effects remain a challenge for developers and regulators, and that risk scales up with increased R&D efforts.

    c. There are properties in modified organisms that are not in naturally derived organisms including conventional foods. There are commercial incentives that gene technology offers that do not exist in conventional foods, due to the fact that gene technologies are patented and that use of these technologies will result in rent/royalties to the licensee.

    d. Increased releases increase the potential 'expected' off target effects – but the scale of deployment amplifies the potential for harm as a consequence of an unintended/adverse effect.

2. ***The capacity for risk at scale is a defining feature of the Anthropocene***. Regulation of genetic technologies are essential to retain transparency and accountability and to maintain and promote trust in the

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[3] Modrzejewski, et al. What is the available evidence for the range of applications of genome-editing as a new tool for plant trait modification and the potential occurrence of associated off-target effects Environ. Evid. 2019:8;27

[4] Eckerstorfer, M.F.; Dolezel, M.; Heissenberger, A.; Miklau, M.; Reichenbecher, W.; Steinbrecher, R.A.; Waßmann, F. An EU Perspective on Biosafety Considerations for Plants Developed by Genome Editing and Other New Genetic Modification Techniques (nGMs). Front. Bioeng. Biotechnol. 2019, 7, 31

[5] Höijer I et al (2021). CRISPR-Cas9 induces large structural variants at on-target and off-target sites in vivo that segregate across generations. bioRxiv. doi: https://doi.org/10.1101/2021.10.05.463186. https://www.biorxiv.org/content/10.1101/2021.10.05.463186v1

[6] Rostoks, N. Implications of the EFSA Scientific Opinion on Site Directed Nucleases 1 and 2 for Risk Assessment of Genome-Edited Plants in the EU. Agronomy 2021:11;572.

[7] E.g. maize engineered for dicamba, glufosinate, quizalofop, and 2,4-dichlorophenoxyacetic acid resistance with tissue-specific glyphosate resistance facilitating the production of hybrid maize seed. Bayer application for nonregulated status. US Department of Agriculture. Docket No. APHIS-2020-0021

[8] Heinemann et al. Differentiated impacts of human interventions on nature: Scaling the conversation on regulation of gene technologies. Elementa: Science of the Anthropocene (2021) 9 (1): 00086. DOI 10.1525/elementa.2021.00086

development of new technologies. Effective regulation is critical to safeguarding and stewarding both human and environmental health.

a. Will Steffen and colleagues have highlighted that pressure from novel entities has potential to threaten the planetary boundaries of earth systems and emphasised the potential for these to be persistent and/or harm at scale.[9] This group recognised the absence of research commitment to 'identify the insights from previous experience to new applications.

b. Professor Toby Ord[10] proposed that the rapid acceleration of technologies including genetic engineering amounted to a potential existential risk for humanity, noting:

'Measures of this progress suggest it is accelerating, with the cost to sequence a genome falling by a factor of 10,000 since 2007 and with publications and venture capital investment growing quickly. This progress in biotechnology seems unlikely to fizzle out soon: there are no insurmountable challenges looming; no fundamental laws blocking further developments. Here the past offers almost no reassurance. Increasing efforts are made to surpass natural abilities, so long-run track records need not apply. It would be optimistic to assume that this uncharted territory holds only familiar dangers.' [11]

10. Currently, despite this international recognition of risk at scale, no regulatory mechanism exists that can identify critical control points arising from the scalability of these technologies. The definition provided by the FSANZ does not include risk that arises from the characteristics or patterns of use.

11. Steffen, Ord and colleagues iterate and emphasise Nobel laureate Sydney Brenner's 50 year old observation:

'there is now available a method which allows us to cross very large evolutionary barriers and to move genes between organisms which have never before had genetic contact" and the "*essence is that we now have the tools to speed up biological change and if this is carried out on a large enough scale then we can say that if anything can happen it certainly will.'*[12]

12. Scalar effects increase the potential for gene technologies to produce unanticipated, adverse effects inside the food system – the effect is that ***risk scales for food derived from NBTs also***.

13. Previous substantial equivalency claims rest on a current state of knowledge idea. For example, claims of gene edited crops not being substantially different from naturally bred (conventional) crops were later found to be substantially altered as biomarker technology to track those differences improved. [13] [14]

14. The less regulation, the less barriers to entry, this increases the potential field, but not necessarily in a good way. There is less public-sector oversight, less understanding of developments and the increased risk from the growth of the field scales up risk once out of containment.

15. ***When there is less regulation – there are fewer incentives for safe innovation.*** Regulation is a critical control point that keeps innovation moving forward with one eye on the public interest.

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[9] Steffen et al. Planetary boundaries: Guiding human development on a changing planet. Doi 10.1126/science.1259855
[10] Ord T. The Precipice: Existential Risk & the Future of Humanity. Bloomsbury Publishing.
[11] Ord T. The Precipice: Existential Risk & the Future of Humanity. Bloomsbury Publishing.
[12] Brenner, S. 1974. Evidence for the Ashby working party. Cold Spring Harbor Laboratory Library. In Heinemann et al. Differentiated impacts of human interventions on nature: Scaling the conversation on regulation of gene technologies. Elem Sci Anth , 9: 1. DOI: https://doi.org/10.1525/elementa.2021.00086
[13] Mesnage et al. An integrated multi-omics analysis of the NK603 Roundup-tolerant GM maize reveals metabolism disturbances caused by the transformation process. Sci Rep. 2016; 6: 37855.
[14] Zanatta et al. Stacked genetically modified soybean harboring herbicide resistance and insecticide rCry1Ac shows strong defense and redox homeostasis disturbance after glyphosate-based herbicide application. Env Sci Europe 2020:32:104

16. The Association advocates for increased financial and scientific support for the FSANZ. Under-resourcing is a form of regulatory capture. The international pressure on regulatory agencies to deregulate is significant.[15] [16] [17] Without adequate resourcing for research and to assist with risk evaluation, industry lobbying tactics seeking reduced regulation of their activities are more likely to work, as deregulation reduces resources required for risk assessment. Where there is less resourcing to both risk-assess and both demand and produce the science required for long-term stewardship of new technologies, regulation is much more likely to move in the direction advocated by much more powerful industry groups. We suggest that this requires rectification in 2 ways:

    a. There needs to be an increase in financial resourcing to enable FSANZ to carry out their duties. This is a numbers game, and without adequate resourcing the authority cannot 'keep up' and will advocate for deregulation.

    b. Public sector scientists working on commercial development of technologies cannot be described as 'independent' and many will have part ownership of

    c. FSANZ must advocate for dedicated public interest science to research the cause and effect of these technologies in vivo and in vitro, which are then required to feedback into the regulatory system as independent advice that can confirm or counter industry claims. Without independent science to contest regulatory claims there is no effective check and balance that can protect human and environmental health.

17. In conclusion, noting that risk but not safety scales with deregulation, the Association requests that:

    a. the USDA definition of gene technology is not applied by the FSANZ.

    b. NBT food and refined ingredients should remain designated as GM food for Code purposes and regulated on a case by base basis.

    c. process based definitions must remain and be expanded.

    d. in addition to chemical and biological risk, that definitions of risk integrate the potential for organisms to be deployed at scale.

    e. The FSANZ recognises that scalar risk of new technologies, including modified organisms is a global challenge and that norms of transparency and accountability – regulation that can take account of this specific Anthropogenic risk - will support this

[15] Friends of the Earth Citizens' concerns and already-proven farming solutions to climate change are dismissed November 25, 2021. https://friendsoftheearth.eu/press-release/commission-gives-in-to-big-biotechs-tactics-to-deregulate-new-gmos/

[16] Nicolas E. Revealed: the new lobbying effort to deregulate GMOs. March 29, 2021. https://euobserver.com/climate/151375

[17] CEO. CRISPR-Files expose lobbying tactics to deregulate new GMOs. March 29, 2021. https://corporateeurope.org/en/2021/03/derailing-eu-rules-new-gmos

The Soil & Health Association of New Zealand Inc.

The Soil & Health Association of New Zealand is an incorporated society founded in 1941. Its primary purpose is to promote the production and consumption of organic food. Our motto is:

This includes an obligation to:

- Ensure the perpetuity of the soil's sustainable fertility, which is the foundation for the existence, the prosperity and health of all life on the earth;
- Promote organic methods of gardening, farming and other natural production and processing methodology, and the conservative sustainable use of all natural resources in order to foster:
  - An awareness of the interdependence of all life on earth;
  - The need to live in harmony with the natural environment