

December 20, 2018

"The Hon Jenny Mikakos MP - Minister for Health Vic 9096 8561"  
<minister.health@health.vic.gov.au>, <jenny.mikakos@parliament.vic.gov.au>

**Re: proposed deregulation of CRISPR SDN1 GM techniques and products**

Dear Minister:

**There are compelling reasons to continue regulating new Genetic Manipulation techniques such as CRISPR and their products.** Please advise a suitable time to brief you and/or your advisors and department officials, prior to your final decision on the Federal Government's proposal to amend the Gene Technology Regulations, to deregulate SDN1 (Site-Directed Nucleases 1).

**We ask you to:**

- **Not approve any SDN1 deregulation until all the economic, social, ethical, biosecurity and technical hazards and risks are identified, publicly discussed and fully resolved;**
- **Commission research and a public review to fully consider the trade and market implications of the proposed SDN1 deregulation for your state and its economy;**
- **Co-operate with other states to ensure that the rights and interests of all are protected.**

Hasty and premature deregulation of a whole category of new GM techniques and all their products - living GM animals, plants, micro-organisms, human therapeutics and even humans - would be reckless and undermine the spirit and integrity of the national Gene Technology Scheme.

The Gene Technology Act 2000 and its Regulations were designed and approved by all Australian parliaments, to robustly review and regulate all new GM processes and products. The Act and its Regulations enable the Office of Gene Technology Regulator (OGTR) to operate a comprehensive and precautionary regulatory process on behalf of all Australians. It remains fit for purpose and its integrity must not be compromised by the blanket deregulation of SDN1.

Market and trade questions are the responsibility of State and Territory governments under the national Gene Technology regulatory scheme. Your constituents are entitled to know if there is a sound business and public interest case for the SDN1 deregulation that the Federal Government proposes.

Yet the Federal Department of Health's Regulation Impact Statement for the Gene Technology Regulation review explicitly rules these matters out of consideration. It says:

"no changes will be recommended that relate to topics outside of the current scope of the GT regulations. For example, any issues raised through the consultation process which relate to the regulation of genetically modified food, marketing and trade issues, ... cannot be considered further through this process."<sup>1</sup>

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<sup>1</sup> OGTR, Updating Gene Technology Regulation in Australia, Regulation Impact Statement for consultation, 2017.

So, to ensure that the regulatory review is complete, all State and Territory governments must undertake their own reviews to thoroughly consider the trade and market implications of the proposed SDN1 deregulation. Without such reviews, there can be no compelling business or public interest case made for the proposed SDN1 deregulation.

Deregulated, SDN1 processes and products are almost certain to profoundly disrupt markets and trade in food, beverages and other commodities. This would affect State and Territory governments' capacity to meet their responsibilities to their own communities, to protect trade and markets, as the shared responsibilities require under the national Gene Technology Regulatory Scheme.

We therefore ask you to commission your own studies and hold a public inquiry into key unanswered questions that the new SDN1 GM techniques raise for markets and trade. For example, would your state's markets and trade benefit or suffer from SDN1 deregulation? How will major trading partners and purchasers respond to inadvertently importing unapproved GM products? Would SDN1 organisms entering food and feed, therapeutic goods, or the environment without assessment, regulation or labelling adversely affect public trust and confidence?

There is evidence from past experience with GM product recalls and rejections that unassessed and unregulated SDN1 organisms may pose unacceptable challenges to the orderly marketing and trade in food and beverages, and other commodities. So it is important to pro-actively resolve market and trade uncertainties before any new GM techniques are deregulated.

Please delay consent to the proposed SDN1 deregulation until you have undertaken a business, trade and marketing review in consultation with public and private stakeholders in your own jurisdiction. Encourage state parliament, Cabinet, industry and the interested public in all jurisdictions to participate. Please also accord us an opportunity to brief you and/or your staff.

Yours sincerely,



**Executive Director**

PS: Precautionary regulation of heritable human germline genetic manipulation may have prevented the recent use of CRISPR techniques that appears to have led to the birth of genetically engineered twin babies. Research team leader Dr He moved his experiments from the USA where they would have been refused ethics approval, to secretly conduct his work in China, breaching a voluntary global moratorium among scientists on such clinical use. Scientists alone must not decide the fate of the human genome. A robust and comprehensive regulatory framework like Australia's may have restrained him and others, also eager to proceed with human GM. The Federal Government's proposal to deregulate all SDN1 procedures is the sort of schism through which unacceptable projects may slip, unbeknown to policy-makers and the public. Selected comment.<sup>2 3 4 5</sup>

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<http://ogtr.gov.au/internet/ogtr/publishing.nsf/Content/reviewregulations-1>

<sup>2</sup> The road to enhancement, via human gene editing, is paved with good intentions, The Conversation, November 27, 2018.

<https://theconversation.com/the-road-to-enhancement-via-human-gene-editing-is-paved-with-good-intentions-107677>

<sup>3</sup> Why we are not ready for genetically designed babies. The Conversation, November 28, 2018.

<https://theconversation.com/why-we-are-not-ready-for-genetically-designed-babies-107756>

<sup>4</sup> Super-smart designer babies could be on offer soon. But is that ethical? The Guardian, November 19, 2018.

<https://www.theguardian.com/commentisfree/2018/nov/19/designer-babies-ethical-genetic-selection-intelligence>

<sup>5</sup> China's win-at-all-costs approach suggests it will follow its own dangerous path in biomedicine, The Conversation, December 17, 2018. <https://theconversation.com/chinas-win-at-all-costs-approach-suggests-it-will-follow-its-own-dangerous-path-in-biomedicine-108658>

PPS: Similarly, there is a consensus among Parties to the Convention on Biological Diversity that gene drives, which may be designed to drive whole species to extinction, are too dangerous to deploy. So our robust and uncompromised regulatory regime is necessary to ensure that open trials or general release are not allowed without due process and the exercise of rigorous precaution. A comment on the risks and need for regulation of gene drives.<sup>6 7</sup>

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<sup>6</sup> Gene Drives on the Horizon: Advancing Science, Navigating Uncertainty, and Aligning Research with Public Values. US National Institutes of Health, 2016. <https://www.ncbi.nlm.nih.gov/books/NBK379271/>

<sup>7</sup> United Nations Hits the Brakes on Gene Drives, ETC Group, November 29, 2018. <http://www.etcgroup.org/content/united-nations-hits-brakes-gene-drives>