

September 25, 2018

The Hon Jill Hennessey MP
Vic Minister for Health and Ambulance Services

Email: <minister.health@health.vic.gov.au>, <jill.hennessy@parliament.vic.gov.au>

Re: proposed deregulation of SDN1 (new GM techniques and products)

Dear Minister:

We ask you, as a member of the Legislative and Governance Forum on Gene Technology, to say 'no' to deregulation of the new Genetic Manipulation (GM) Site Directed Nuclease 1 (SDN1) techniques and their living products. These techniques include CRISPR, zinc finger nucleases and TALENS.

The federal government has sought to rush you into accepting radical changes to the national Gene Technology Regulatory Scheme and its Regulations without due process or public notice. Your decision ought to be fully informed and precautionary, after full discussions with your parliament, your Ministerial colleagues, and the interested public in your jurisdiction.

Deregulating a whole category of new GM techniques and all the living GM animals, plants, micro-organisms and human therapeutics that they may produce would be reckless. It is not rigorously evidence-based, as a number of these new GM techniques have only been invented over the past five years. Their products have scant history of safe use in the environment, food supply or human therapeutics¹ and their well-documented flaws may never be fixed.

Deregulation would also run counter to trade, biosecurity, bioterror and other key policies. Those pushing hardest for deregulation are global industries that want to progress their work with farm crop plants and animals, unhindered by any regulation. But SDN1 techniques may be used to manipulate the genome of any living organism so you should consider much broader policies and issues.

The Gene Technology Act 2000, the national Gene Technology Regulatory Scheme, and the Gene Technology Regulations are robust. They were well designed to provide a suitably precautionary, science-based regime for the notification, assessment, licensing and monitoring of the dealings with all GM organisms of all sorts, and have done so for 18 years.

The Federal Government is trying to move the goalposts with claims that the Gene Tech Act and its Regulations cannot keep pace with new discoveries. However, the Act is still fit for purpose as its provisions fully anticipated the technical innovations that would inevitably emerge. It was designed to robustly accommodate all such changes.

¹ Burgio, Gaetan, CRISPR/Cas9 gene editing scissors are less accurate than we thought, but there are fixes, The Conversation. July 17, 2018. <https://theconversation.com/crispr-cas9-gene-editing-scissors-are-less-accurate-than-we-thought-but-there-are-fixes-100007>

For instance, the Gene Tech Scheme already includes provisions for the selective exemption or reclassification of dealings that are found to be low risk, but only after accumulated scientific evidence shows them to be safe. The OGTR has exercised these discretions with appropriate diligence.

But now it is proposed to make a blanket exemption for all SDN1 techniques and their living products with little of the requisite evidence to support any exemption, let alone a blanket one.

Scientific, corporate and informal users of the SDN1 techniques will be able to completely bypass any regulation of their dealings or products, now generally managed through an Institutional Biosafety Committee (IBC) which refers to the OGTR, FSANZ, APVMA or TGA.

Among those enabled to create new SDN1 organisms without any regulatory oversight at all would be unskilled and untrained biohackers and start ups, often working in poorly equipped, unlicensed and substandard premises. The OGTR already allows them to operate without reference to an IBC or the regulators. This flaw in the regulatory system also requires repair.

US authorities have repeatedly warned that the risk of bioterror has increased with the availability of the dual-use CRISPR GM techniques, especially in deregulated environments where materials and equipment are cheaply available on the internet. For instance, the 2018 Worldwide Threat Assessment of the US Intelligence Community noted that:

“Biological and chemical materials and technologies — almost always dual-use — move easily in the globalized economy, as do personnel with the scientific expertise to design and use them for legitimate and illegitimate purposes.”²

Australia’s present GM regulatory scheme would appropriately require every new GM technique and the organisms it produces to be notified, assessed, licensed and monitored. So exempting all SDN1 techniques and the insects, fish, trees, microbes, etc. they may be used to produce will profoundly compromise the integrity of the whole regulatory scheme and undermine its reputation.

If SDN1 were deregulated, State and Territory powers to effectively assess GM animals, plants, microbes and human therapeutics for their potential impacts on markets and trade would end. New GM organisms would be released without your government’s knowledge or consent and your jurisdiction would be unable to exercise its important discretion - to consider market and trade impacts on the economy. The government would have no means of even knowing what research or commercial use of SDN1 or its GM organisms was going on within its jurisdiction.

Since the Federal Government’s review team made its deregulatory proposal the European Union’s Court of Justice has ruled that all new GM CRISPR techniques will be regulated.

Deutsche Wella said: “The ruling states:

- New mutagenesis techniques such as "molecular scissors" carry the same risks to humans, animals, and the environment as traditional genetic engineering
- Food produced by these cutting-edge technologies must be subjected to the same risk assessments, tracing and labelling systems required of traditional GMOs.
- Only mutagenesis tools that **"have conventionally been used in [a] number of applications and have a long safety record"** will be able to receive exemptions in the future.”³

² Daniel R Coats, Worldwide Threat Assessment of the US Intelligence Community, 13 February 2018. <https://www.dni.gov/files/documents/Newsroom/Testimonies/2018-ATA---Unclassified-SSCI.pdf>

³ News, Deutsche Wella, Top EU court rules new breeding tech counts as GMOs. July 25, 2018. <https://www.dw.com/en/top-eu-court-rules-new-breeding-tech-counts-as-gmos/a-44820835>

This is an appropriately precautionary stance that Australian governments should also adopt.

New Zealand has also resolved that SDN1 techniques will be regulated as GM under the Hazardous Substances and New Organisms Act (*HSNO Act*) 1996.⁴

Thus, deregulating SDN1 in Australia would put us out of step with major trading partners and would very likely hinder access to markets for any products made using the new GM techniques.

For example, China has a policy of zero tolerance for existing GMOs which its regulators have not approved, and China, South Korea and Japan have rejected various commodity shipments contaminated with unapproved GM events. These include corn,⁵ wheat,⁶ and alfalfa (lucerne) hay.⁷

We were assured that new scientific and other evidence could alter federal government proposals for SDN1 deregulation. Yet substantial new peer-reviewed scientific evidence has been published this year that questions the accuracy,⁸ precision,⁹ and predictability^{10 11 12} of CRISPR techniques and the OGTR has failed to revisit its assertion that SDN1 techniques pose no greater risk than traditional breeding. On safety, Kosicki's paper concludes:

"The observed genomic damage in mitotically active cells caused by CRISPR–Cas9 editing may have pathogenic consequences."¹³

Everyone relies on the OGTR to be the public's referee, to ensure that all GM techniques and their living products are notified, assessed, licensed and monitored for manageable safety and environmental impacts. Yet this deregulatory proposal would exclude the OGTR from supervising the substantial body of research and commercial dealings with SDN1 where the agreed rules would not apply. This would create a free for all for industry and science, and sideline the public interest.

Science and industry had an unfair advantage throughout the review process. They were able to unfairly influence the Health Department's review team as their experts were in the privileged position of preferential access as advisors to the process. Their undeclared conflicts of interest in deregulation were undisclosed, yet independent experts were excluded.

⁴ Nick Smith. GMO regulations clarified, April 6, 2016. <https://www.beehive.govt.nz/release/gmo-regulations-clarified-0>

⁵ Britt E. Erickson, Farmers Sue Syngenta, Agriculture: U.S. corn prices plunge after China rejects shipments. Chem and Eng News, Oct 10, 2014. <https://cen.acs.org/articles/92/i41/Farmers-Sue-Syngenta.html>

⁶ Jane Chung, South Korea rejects Argentina feed wheat after GMO strain found. Reuters, July 26, 2016.

<https://www.reuters.com/article/us-southkorea-wheat-argentina/south-korea-rejects-argentina-feed-wheat-after-gmo-strain-found-idUSKCN1060HD>

⁷ Jesse Newman, China's Hard Line on Biotech Burns U.S. Hay - Traces of GMO Alfalfa, Unapproved by Beijing, Wreak Havoc With a Formerly Booming U.S. Crop, Wall Street Journal, Dec. 15, 2014. <https://www.wsj.com/articles/u-s-hay-exports-to-china-shrivel-up-1418598477>

⁸ Rusk, N. Surprising CRISPR roadblocks. Nature Methods, 15(8), 569, 2018. https://www.nature.com/articles/s41592-018-0097-9.epdf?no_publisher_access=1&r3_referer=nature

⁹ Kosicki, M, et. al. Repair of double-strand breaks induced by CRISPR–CAS9 leads to large deletions and complex rearrangements. Nature Biotech, Volume 36, pages 765–771 (2018) 16 July 2018. <https://www.nature.com/articles/nbt.4192>

¹⁰ Liam Mannix, We can change human DNA. We're just not sure which bits, The Age, August 9, 2018.

<https://www.theage.com.au/national/we-can-change-human-dna-we-re-just-not-sure-which-bits-20180808-p4zw83.html>

¹¹ Adikusuma, F, et al. Large deletions induced by Cas9 cleavage. Nature, Brief Communications Arising, August 8, 2018. <https://www.nature.com/articles/s41586-018-0380-z>

¹² Nicole Rusk, Surprising CRISPR roadblocks. Nature Methods, Volume 15, page 569 (2018)

<https://www.nature.com/articles/s41592-018-0097-9>

¹³ Kosicki, et. al. Op Cit.

In contrast, the interested public had some opportunity to participate in early rounds of the GT Scheme and GT Regulations reviews but we had no role in the final processes, after the review team, on the advice of its advisors picked the deregulatory winner.

Such exclusions unfairly skewed the results and we regard this as unfair to the public interest. We rely on you to redress this at consultations and hearings in your jurisdiction.

The Regulatory Impact Statement on the proposed deregulatory changes has not been published and, in fairness, should have been available to everyone before you were asked to make your decision on deregulation.

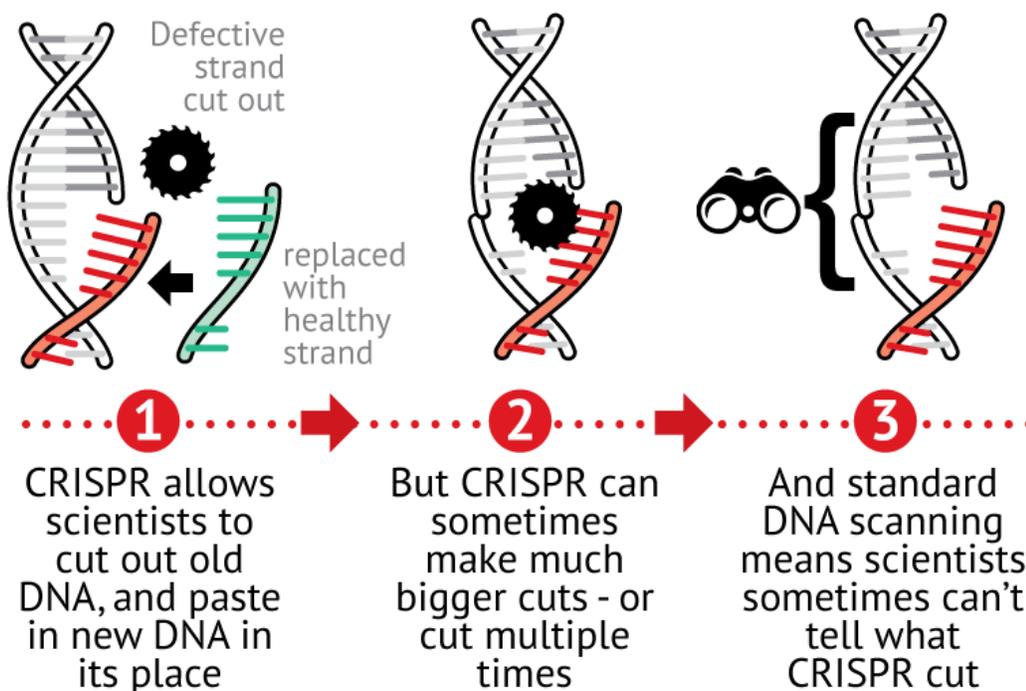
Please ensure that you and your government do not approve the deregulation of dealings with SDN1.

Yours sincerely,



Executive Director

CRISPR-Cas9 can chop DNA, rather than precisely cutting and mending it. Cuts may also be made unpredictably, and in unintended and unidentified places on a target genome.



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¹⁴ [Adikusuma, F, et al. Large deletions induced by Cas9 cleavage. Nature, Brief Communications Arising, August 8, 2018. https://www.nature.com/articles/s41586-018-0380-z](https://www.nature.com/articles/s41586-018-0380-z)