

Email Submission: Jonathon Singleton

"And politics is prior to the vagaries of science..." The Sweetest Girl -- Green Gartside (1981)

12 November, 2016

Dear New Zealand Environment Minister Dr Nick Smith,

Re: OGTR's Review of the Gene Technology Regulations 2001 - call for submissions.

Using the above lyric excerpt from a classic Scritti Politti single from my teen years, I sincerely commend the New Zealand government on its pragmatic and precautionary decision regarding the recent April, 2016, clarification of GMO regulations -- what is and what is not a genetically modified organism.

Press Release <https://www.beehive.govt.nz/release/gmo-regulations-clarified-0>

The final paragraph of your Press Release reads in contrast with Australia's Office of the Gene Technology Regulator discussion paper proposal canvassing options for regulating new technologies. Presently up for public consultation.

OGTR: "The primary aim of this review is to provide clarity about whether organisms developed using a range of new technologies are subject to regulation as genetically modified organisms (GMOs) and ensure that new technologies are regulated in a manner commensurate with the risks they pose..."

While the Regulator will consider all [public] submissions and proposals put forward, those that are not well supported or raise policy issues are unlikely to be addressed in this technical review... All proposals must be supported by a rationale and, where possible, a science-based argument."

This letter is my public submission. Minister Smith, one would logically assume there is significant "policy issue" weight -- in both Australia and New Zealand -- for our governments to ensure export market perceptions are not needlessly shaken. As you write, "The rationale for our cautious approach is that New Zealand is an exporter of billions of dollars of food products and we need to be mindful of market perceptions as well as the science."

This new science... OGTR's difficult to comprehend discussion paper appears written by those same "frustrated" scientists you refer to in your Press Release. Folk whose passions and careers are staked in biotechnology and molecular editing. Minister, I'm not a retro Luddite with this science. From a healthcare perspective, I comprehend the benefits of new time efficient approaches to say, animal and human vaccination e.g. safe, non-replicating genetically engineered consensus antigens based on the different disease variants or strains -- DNA vaccine immunotherapy.

Orwellian Doublethink is the cognitive dissonant act of simultaneously accepting two mutually contradictory beliefs as correct. Are gene editing techniques other versions

of genetic engineering? The bizarre fact the OGTR is even considering not regulating them as such demonstrates how captured the agency has become by certain industry interests.

Using an American company, Inovio Pharmaceuticals, Inc. as a longitudinal common sense consistency exemplar. This archive data excerpt from the U.S. Securities and Exchange Commission shows two important realities. Inovio Pharmaceuticals, Inc. clearly and logically accepts the experimental nature of these technologies -- "This synthetic consensus DNA sequence does not exist in nature (and is consequently patentable)." Secondly, years of regulated animal and human clinical study data has demonstrated a favorable safety profile (some of these studies took place in Australia).

<https://www.sec.gov/Archives/edgar/data/1055726/000119312514069728/d685397dex991.htm>

Minister Smith, we're all still learning. But I couldn't glean basic knowledge about CRISPR/Cas9 or TALENs from OGTR's incomprehensible discussion paper. So I turned to the science journal, Nature. Interestingly, David Cyranski's October 2015 article identified the aforementioned "Doublethink" in spades. Evident in the article title, "CRISPR tweak may help gene-edited crops bypass biosafety regulation (Technique deletes plant genes without adding foreign DNA)".

Just letting the interviewed scientists talk, Cyranski demonstrates these folk don't appear to perceive their gene editing as exactly that... Editing -- altering or modifying the arrangement of genes. Instead, the scientists seem much more focussed on convincing regulatory agencies their synthetically edited plant DNA is not conventional GM when *Agrobacterium tumefaciens* is removed from the picture. Of course it's not conventional GMO, Minister. But ideology aside, it is artificial modification AWAY from the original plant genome. Literally.

<http://www.nature.com/news/crispr-tweak-may-help-gene-edited-crops-bypass-biosafety-regulation-1.18590>

Minister, obviously if the OGTR deregulates these new GM techniques there will be no monitoring or surveillance. They will enter our domestic and export food chain and environment with little to no safety testing. Certainly, there won't be any appropriate consumer product labelling. In conclusion, I fully share Friends of the Earth request for:

"These new GM techniques and the products derived from them to be subject to a comprehensive case-by-case risk assessment, including full molecular characterisation and independent safety testing to minimise any potential risks to human health and the environment;

All products derived from new GM techniques to be labelled to protect choice for farmers, producers and consumers;

The precautionary principle to be enshrined in both the Gene Technology Act and the Food Standards Australia New Zealand Act, given the experimental nature of these technologies and the risks associated with them;

The Government to impose strict liability on all dealings with GMOs licensed by the OGTR, so that liability for GM contamination and the resultant losses and costs rests fully on the licensees and the owners of GM patents;

A moratorium on the commercialisation of these new GM techniques until our regulatory system for GMOs is adapted to deal with the potential risks posed by them."

Thank you for reading, Jonathon Singleton.