



February 21, 2018

## **Submission to OGTR on Review of Gene Technology Regulation**

**Bill Gates** has warned of the existential risks of genetic engineering, although an investor himself through the Bill and Melinda Gates Foundation.

<https://www.businessinsider.com.au/bill-gates-op-ed-bio-terrorism-epidemic-world-threat-2017-2>

Similarly Cambridge University's **Centre for the Study of Existential Risk** (CSER) has identified biotechnology as a 'global catastrophic risk'.

<https://www.businessinsider.com.au/7-existential-risks-that-could-bring-an-end-to-humanity-2017-3>

Because genetic engineering has both potential for good but also is a potential threat to our existence, all techniques must be regulated.

**All gene-editing bioengineering techniques such as CRISPR and RNAi must be regulated.** Whether silencing or removing genes, swapping or adding genes, or waking dormant genes, whether intragenic or transgenic, these DNA manipulation techniques must be regulated. And claims of beneficial effects such as consumer health benefits from these techniques that are put before the Regulator must be provable and proven.

**Professor Julian Savulescu** from Oxford University Institute for Science and Ethics, has concluded, "The biggest threat that we face ahead of climate change, ahead of nuclear war, is the intentional or unintentional misuse of advances in biology." He speaks of the runaway likelihood, once we start messing with genetics, as they have a life of their own. Genetic pollution is worse than chemical pollution. Genetic pollution propagates and so, absolutely, rather than lifting regulation, we actually need to improve the regulation that we have and really try and keep pace or put the brakes on the pace at which these things are coming out. Please refer to my submission to the Productivity Commission Review on Agricultural Regulation at the public hearing in Perth 16 August 2016.

<https://www.pc.gov.au/inquiries/completed/agriculture/public-hearings>

When is a GMO not a GMO? It is too soon to draw an arbitrary distinction between the organisms created by some GM techniques and not others, especially when the monitoring and testing through to final consumption has not been done. It is not ok to have some GMOs regulated, while others are released 'under the cover of darkness'. Whether transgenic or intragenic, all GMOs must be regulated with full traceability through to the final consumer so that safety over time can be proven. Anything less will mean problems might be hidden from the public in the short term but if left unaddressed, the problems cannot be hidden in the long term as health & environmental harm cannot be suppressed forever. Lax regulations around leading-edge bio initiatives, will surely drive the demise of the bioengineering industry ... and ourselves.

I can understand the will of industry and researchers to bypass the second step of the two-step process of regulation as a fast-track to market, but this is not necessarily in the public interest. We need the regulators to assess risk to the public and put appropriate mechanisms in place to minimise and mitigate those risks.

The first step of regulation is in the private interest. This is the application by industry & researchers to patent the bioengineered product to ensure the investors get a return on their investment.

The second step of regulation is in the public interest. It is an independent risk assessment of the consequences of releasing the bioengineered product to the wider world outside the strict security of the laboratory. It is an essential step and must not be bypassed.

Most of us can't cut-and-paste a Word document without making errors, possibly leaving out just one word such as "not" to completely reverse the functional intent of the creation. Technology aids and editorial reviews by peers and publisher help to achieve confidence before release of the final product. Book reviews provide post-release feedback. Post-implementation reviews of bioengineered products are vital to assess success or failure. Unintended consequences must be predicted pre-release, and then post-release monitoring and feedback is required. New science without a feedback mechanism is not science.

Gene-editing DNA within or across species must be included in the Gene Technology Regulations, without exception.

Shirley Collins

**Contact details not for publication:**