Email Submission: P Wilson

Regulations Review,
Office of the ***Gene Technology*** Regulator (MDP 54),
GPO Box 9848, Canberra
Dear Health Ministers,

Thank you for the opportunity to comment.
We strongly urge you to retain current GM rules and regulations, just as we expect and require a high level of integrity and expertise in the handling of all matters relating to public and environmental health in Australia.
We oppose the proposed Gene Tech deregulation of key new GM techniques (Eg CRISPR (SDN-1) and GM products.. Such a proposal is totally unacceptable in view of known off-target impacts and lack of sufficient evidence of safe use.
GMOs pose an existential risk.
Scientific American June 2015, Extract from Advances, page16, Martin Rees, founder of the Center for the Study of Existential Risk
http://www.scientificamerican.com/article/meet-the-co-founder-of-an-apocalypse-think-tank/

Question to Martin Rees: What are the major risks to humanity as you see them and how serious are they?
Answer: 'I'm personally pessimistic about the community's capacity to handle advances in biotech. In the 1970s the pioneers of molecular biology famously formulated
guidelines for recombinant DNA at the Asilomar conference. Such issues arise more starkly today. There is current debate and anxiety about the ethics and prudence of new techniques: “gain of function” experiments on viruses and the use of so-called CRISPR gene-editing technology. As compared with the 1970s, the community is now more global, more competitive and more subject to commercial pressures. I'd fear that whatever can be done will be done somewhere by someone. Even if there are formally agreed protocols and regulations, they'll be as hard to enforce as drug laws.
Bioerror and bioterror rank highest on my personal risk register for the medium term (10-20 years)'.

Though the OGTR recommends deregulation of CRISPR and other new GM techniques, to fast-track projects in medicine and agriculture, Clovis Palmer director of research into Immunometabolism and Inflammation at the Burnett Institute in Melbourne says, “... current claimed benefits are perhaps over-emphasised. The technology is still in its infancy and should continue to be highly scrutinized under rigorous federal authorities that govern GMOs.”

There is no public imperative to market GM products in Australia. There is no proven long term benefit to Australian producers. Indeed the imperative is NOT to approve this product. The Precautionary Principle should be exercised.

* We support repeal of item 1 in Schedule 1. All organisms altered by gene technology must be regulated as GMOs, whether ‘foreign nucleic acid’ is introduced, or not.;

* We oppose the proposed deregulation of GM techniques (g CRISPR (SDN-1),, even when used to cause DNA breaks that are claimed to repair naturally;

- Because neither safety testing nor labelling would be required if new GM techniques ere to become deregulated, necessary monitoring and surveillance would be bypassed. Security

issues are immediately raised since amateur biohackers, industry, terror groups or the military could misuse these to produce harmful animal or plant forms,or microbes, against the public interest.

- CRISPR has only been trialled for 5 years, leading Austrian and Norwegian government reports to conclude that too little is known of the risks. They recommend risk assessment.on a ;case-by-case basis.
- Deregulation implies the Precautionary Principle would be ignored, despite it being central to the Gene Technology Act and the regulatory scheme. Without precaution, they fail;
- We are right to be concerned. Even small genetic changes in microbes can make them highly pathogenic so deregulation poses big biosafety risks; GM vaccines should be a great concern. Viruses reproduce very fast and therefore evolve very fast and are always at least one step ahead of humans. They can swap over to infecting different species made easier by humans coming more into contact with e.g. chickens with intensive husbandry involving feather plucking etc. Deletion vaccines may be a good idea but nothing is completely foolproof for the reasons we have just given. Use of live GM viruses even though attenuated is unacceptably high risk.
- *Deregulation of use in animals and humans raises major ethical issues which require a regulatory forum for debate, regulation and resolution. Where is the broad public debate? ;*
- *New GM techniques used sequentially could significantly change the genome of any organism over time, so must be regulated;*
- *OGTR inappropriately likens many GM-like mutations to those that might be expected to naturally occur, giving this as a reason for deregulation, However evidence shows natural mutation rates in plants are low, and generally take place over long periods of time in the slow course on evolution, often as an adaptive response to a change in the external environment.;*
- All new genetic modifications can result in bacterial or synthetic DNA becoming incorporated into chromosomes, and without regulation, timely evidence of these would be missed.
- Claims that new GMOs cannot be identified from natural organisms so are difficult to regulate are false and misleading. E.g. non-browning CRISPR mushrooms are characterised to enable patent enforcement;
- We oppose the deregulation of ‘null segregants’ – the offspring of GMOs. The claim that these do not contain GM DNA requires rigorous scientific testing.through the regulation process. Traceability to the GM parents - difficult or not to accomplish - is necessary for health and safety.reasons. In the interests of the scientific classification of all living organisms, the definition of 'GMO' must include organisms derived from GMOs;
- We strongly oppose the proposal to deregulate RNA interference and gene silencing. The Gene Technology Act 2000 defines gene technology as “any technique for the modification of genes or other genetic material” which clearly includes RNA interference and gene silencing. The fact that such a proposal has been put forward is cause for distrust. There are valid concerns that non-target species could be adversely affected, eg if RNAi is sprayed on crop insects. All applications of RNAi must have a risk assessment and be regulated;
- The intention for gene drives to be potentially used to make whole species extinct, means that any such research must be in PC level 4 laboratories, and they must not be released to the environment.

Sincerely,

P Wilson