

Email Submission: Sam Statham

Dear Regulator,

Thankyou for the opportunity to present the below facts before a final decision is made on the proposed changes to the regulation of GMOs in Australia.

According to the the review papers, "Under existing provisions, it is not clear whether or not organisms that have undergone several site-directed nuclease techniques , oligo-directed mutagenesis (ODM) and some RNAi techniques are within or excluded from the scope of regulation under the GT Act. The draft amendments would implement option 3 from the Discussion Paper under which organisms modified using site-directed nucleases without templates to guide genome repair (i.e. SDN-1) would not be regulated as GMOs. Organisms modified using the template-guided techniques SDN-2 and ODM would continue to be regulated as GMOs."

May I remind the Regulator that the object of the Gene Technology Act 2000 (section 3) is:

"... to protect the health and safety of people, and to protect the environment, by identifying risks posed by or as a result of gene technology, and by managing those risks through regulating certain dealings with GMOs."

The Regulator must concede that the proposed changes are **contrary to the spirit of the objective of the Act** because they avoid managing the risks posed by GMOs by simply redefining certain GMOs as not being GMOs. In fact, the proposed changes are nothing short of ivory tower scientific obfuscation and avoidance of the Regulators Duty of Care!

Why not use the same definition as the World Health Organisation? "Genetically modified (GM) foods are foods derived from organisms whose genetic material (DNA) has been modified in a way that does not occur naturally, e.g. through the introduction of a gene from a different organism."

http://www.who.int/topics/food_genetically_modified/en/

Isn't simpler better? Of course, the proposed new generation GMOs would still be classed as GMOs.

The fact that these definitional changes are being proposed shows that the risks envisaged 17 years ago by the Australian Government's own Science, Technology, Environment and Resources Group are coming true:

"The genetic engineering era has coincided with a trend to smaller government and increased encouragement for the private sector to fill the void through mechanisms such as contracting out or self regulation. There is a trend towards reduced employment of experts, namely, scientists and technical specialists in government agencies. This is happening when the products of sophisticated technologies require extensive scrutiny so as to prevent health and environmental mistakes. **There has been a corresponding adoption of the concept 'acceptable risk' rather than 'zero risk' in public policy design**, e.g. in quarantine policy. Containment of escalating

scrutinising costs has been a major driver of this policy direction. Lack of concrete data to assess risk in a scientifically adequate manner is a significant problem." Research Paper 17 2000-01, Genetically Modified Governance Issues, Rosemary Polya, Science, Technology, Environment and Resources Group, 6 February 2001 https://www.aph.gov.au/About_Parliament/Parliamentary_Departments/Parliamentary_Library/pubs/rp/rp0001/01RP17

The Regulator must also concede that the proposed definitional changes are contrary to the **Precautionary Principle**. As a signatory to the Convention on Biological Diversity, Australia has an obligation, moral at least, to use the Precautionary Principle as a guide in decisions such as this.

To label products that to a layman are clearly GMOs as not being GMOs is dangerous and negligent whilst the jury is still out on the safety of any GMOs, let alone the newest forms, the risks of which the Regulator has **the least knowledge**.

Although conveniently placed outside the scope of the Gene Technology Act, the definitional change has important implications for Trade from the point of view of the Cartagena Biosafety Protocol. As also pointed out in the above-cited report, the Protocol makes it clear that products from new technologies must be regulated based on the Precautionary Principle and let countries ban imports of a genetically modified organism if they feel there is not enough scientific evidence the product is safe. https://en.wikipedia.org/wiki/Convention_on_Biological_Diversity

Although Australia is not a signatory, the Regulator should note that **ALL of Australia's neighbours are parties to the Protocol**, as are some of our major trade partners (Japan, China, India, the EU, the UK, and many others!) <https://www.cbd.int/countries>

Therefore, to deregulate certain GMOs must have an impact on trade, but more relevant to the Regulator, however, is the fact that the Protocol defines GMOs as follows:

"The protocol defines a 'living modified organism' as any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology, and 'living organism' means any biological entity capable of transferring or replicating genetic material, including sterile organisms, viruses and viroids. 'Modern biotechnology' is defined in the Protocol to mean the application of in vitro nucleic acid techniques, or fusion of cells beyond the taxonomic family, that overcome natural physiological reproductive or recombination barriers and are not techniques used in traditional breeding and selection. 'Living modified organism (LMO) Products' are defined as processed material that are of living modified organism origin, containing detectable novel combinations of replicable genetic material obtained through the use of modern biotechnology."

https://en.wikipedia.org/wiki/Cartagena_Protocol_on_Biosafety

Even under this broader definition, the proposed changes to Australian definitions are clearly avoidance of the Duty of Care of the Regulator and contrary to the object of the Act.

In conclusion I urge the Regulator to reject any definitional changes that will open the doors to new technologies that Australian consumers like myself **do not wish to consume**, and due to which the Australian economy risks losing export markets due to a lack of regulation of organisms defined in the **majority of other countries** as being GMOs.

Yours sincerely,

Sam Statham