

## **Email Submission: Julie Pratt**

To The Regulator, OGTR,

If the OGTR's proposals to amend the Regulations are adopted, new GM techniques (e.g. CRISPR; RNAi) and living GM products will be deregulated, despite off-target impacts and lack of a history of safe use.

I support some, but not all, of the draft amendment proposals in Option 3.

I support the repeal of item 1 in Schedule 1. All organisms that have been altered by gene technology should be regulated as GMOs, irrespective of whether any 'foreign nucleic acid' has been introduced.

*I oppose the proposed deregulation of GM techniques such as CRISPR (SDN-1), even when used to make DNA breaks that are claimed to naturally repair.*

New GM techniques could be used sequentially to greatly change the genome of any organism, so it must be regulated.

I oppose the deregulation of 'null segregants' – the offspring of GMOs. It is claimed they do not contain GM DNA but this assumption needs testing via regulation. The definition of GMO must include organisms derived from GMOs; or those that include temporal GMOs, as is the case in the EU.

I oppose the proposed deregulation of 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. It raises concerns that non-target organisms could be adversely affected if, for example, RNAi is sprayed against insects on crops. All applications of RNAi must have a risk assessment and be regulated

No safety testing or labelling will be required if new GM techniques are deregulated and monitoring and surveillance are bypassed. So amateur biohackers, industry, terror groups or the military could use them to make harmful plants, animals or microbes. If these techniques are deregulated there will be no monitoring or surveillance and that could lead to the creation of entirely new diseases and poisons, which could enter our food chain and our environment, with no safety testing and no labelling. The risks are huge and the results could be beyond our ability to contain.

CRISPR is only 5 years old so Austrian and Norwegian government reports conclude not enough is known of the risks. They recommend full case-by-case risk assessment. Deregulation ignores the Precautionary Principle which is central to the Gene Technology Act and the regulatory scheme. We should not go against this principle when we are unaware of the full consequences of this technology.

Even small genetic changes in microbes can make them highly pathogenic so deregulation poses big biosafety risks.

All consumers have the right to know how the safety of their environment may be altered by scientists and what risks are being posed by new technologies. Therefore all new gm techniques should be individually assessed by the regulator.

Regulating and labelling of all genetically modified foods is especially important so that consumers can make a choice about what they are eating. Deregulation of use in animals and humans raises major ethical issues which require a regulatory forum for public debate, regulation and resolution. The public has a right to input on this issue. Use of GM in animals and humans certainly needs to be fully regulated. Animal welfare is of major concern to a majority of Australians.

OGTR claims many GM-like mutations may also occur naturally so need not be regulated, but evidence shows natural mutation rates in plants are low. The OGTR's argument that these mutations could occur naturally and therefore don't need to be regulated is not supported, since the natural mutation rate is extremely low. One plant study found that the probability of any letter of the genome changing in a single generation is about one in 140 million. In contrast these new GM techniques can cause hundreds of unwanted mutations in some organisms.

Claims that new GMOs can't be identified from natural organisms, so are difficult to regulate, are false. GMO's are patented and have characteristics that distinguish them from their natural counterparts. There are a number of techniques that can be used to identify organisms produced using SDN-1.

All new GM can result in bacterial or synthetic DNA incorporation into chromosomes but without regulation, these unexpected effects won't be found in advance; Case by case regulatory oversight is therefore essential for each GM application

It is intended that gene drives may be used to make whole species extinct so any research must be in PC level 4 level labs and must not be released to the environment. It is of grave concern that this is even being contemplated as there could be major disruptions to food chains in the wild and other unintended effects, for e.g. if mosquitos were wiped out: their larvae are very important in aquatic ecology. Many other insects and small fish feed on them and the loss of that food source would cause their numbers to decline as well. Anything that feeds on them, such as game fish, raptorial birds, etc. would in turn suffer too

Though the OGTR recommends deregulation of CRISPR and other new GM techniques, to fast-track projects in medicine and agriculture, Clovis Palmer, head of 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." <https://cosmosmagazine.com/society/gene-edit-deregulation-proposal-draws-mixed-response>

All of these techniques result in unpredicted mutations that can result in the production of toxins and allergens. The OGTR's argument that these techniques create similar results to chemical and radiation mutagenesis which have a history of safe use does not stand up to scrutiny. Neither of these techniques have been safely used in animals or microbes. Unlike chemical and radiation mutagenesis which increase the rate of random mutation, all of these techniques can be used sequentially to make dramatic changes to the genome.

Arguing that new techniques such as CRISPR should be deregulated because of the Government's failure to regulate other potentially risky techniques sets a dangerous precedent.

All of these techniques rely on older GM methods such as protoplast creation, biolistics, viruses, electroporation tissue culture, and Agrobacterium-mediated gene transfer.

These can all cause unexpected mutations that would be extremely unlikely to occur in nature. This is a major reason why organisms produced using them need to be assessed for safety.

If Australia deregulates these new GM techniques it may damage our ability to prove that our export produce is safe. We may not be able to meet the requirements of the zero GM tolerance policies of our key trading partners like the EU. If we don't regulate them on a case by case basis, they will be untraceable and therefore unacceptable as imports to those trading partners. The EU is likely in 18 months time to regulate the new techniques as GM's and already has a zero tolerance policy for unapproved GMO's.

This is not a small change to existing rules; the proposed deregulation changes have many serious ramifications for all of society. Those benefiting most from these changes would be the big biotech companies and it will give them more control over our global supply of seeds, plants and animals which is not good for agricultural biodiversity.

All negative intended, and unintended, consequences of any GM technique should be the responsibility of the biotech companies and not the taxpayer, or other organic and conventional farmers. There needs to be transparency and accountability for all GM techniques introduced into our world. Regulation of all GMO's is the safest way forward.

Julie Pratt