



An Australian company has bred from genetically modified (GM) hornless cattle

A Victoria based company - Total Livestock Genetics - has bred dairy cows from 'gene edited' bulls whose genomes have since been found to unintentionally contain bacterial DNA. The US Food and Drug Administration (FDA) have argued this example illustrates the risks posed by these techniques and why they need to be regulated.¹ European countries will also be regulating these new genetic modification (GM) techniques and their products.

However, in Australia the Office of the Gene Technology Regulator (OGTR) is allowing a number of these techniques to be used in animals with no regulation at all. And Food Standards Australia New Zealand has proposed regulatory changes that mean that milk from these cows could enter our supermarkets with no safety assessment or labelling.²

An unknown risk

The bacterial genes found in the bulls confer resistance to three different antibiotics – ampicillin, neomycin and kanamycin.³ These are commonly used in both cattle and humans. There is a risk that these resistance genes could be transferred to disease causing bacteria in either cattle or humans – potentially rendering them immune to treatment by these antibiotics. The World Health organisation considers antibiotic resistance “one of the biggest threats to global health, food security, and development today.”⁴

No research has yet been carried out on the possible consequences for animal health, or whether these additional genes are biologically active.

It is also not clear if there have been other unexpected changes as a result of the genetic engineering process. For example, a recent study in mice shows that gene editing can result in multiple copies of genes being inserted that can't be detected using standard detection techniques.⁵ Other research has found that gene editing can cause large genetic rearrangements such as DNA deletions and insertions that could lead to important genes being switched on or off.⁶

Genetically modifying animals raises serious ethical issues

Genetically modifying animals poses serious ethical and animal welfare concerns that no authority has properly discussed or assessed. Gene editing is less precise than claimed and results in many unexpected and unpredictable genetic mutations in mammals.⁷ Gene editing techniques can inadvertently cause very low live-birth rates; abnormal sizes - rendering animals incapable of natural movement; and respiratory and cardiac problems.⁸ Recent studies also suggest that editing cells' genomes with CRISPR might increase the risk that the altered cells will trigger cancer.⁹

Genetically modified animals are often clones. Cloning poses serious animal welfare concerns including high rates of miscarriage, birth defects and premature death. For this reason the EU voted to ban cloning in 2015. In the case of these GM bulls, only 2 of the 26 original embryos that they implanted survived. Most were aborted by the cows and 3 were euthanised at birth because they were 'unviable'.¹⁰



Industry self regulation clearly won't work

The bacterial DNA in the bulls was found by US FDA scientists.¹¹ Importantly, the developers of the cattle did not detect these potentially dangerous genetic inserts.¹² The study demonstrates how risky the Australian Government's deregulation of a number of these new genetic modification techniques in animals, plants and microbes is.¹³ The Government's decision is based on advice from the OGTR that certain gene editing techniques "present no different risk than organisms carrying naturally occurring genetic changes."¹⁴

The discovery that bacterial DNA was accidentally incorporated into cattle clearly demonstrates that the OGTR's position is wrong. As the experts from the FDA point out, the errors caused by the genetic engineering technique are unlikely to be individual cases. Unexpected integrations of foreign DNA through the gene editing process have been observed in many other species.¹⁵

Since the developers of these cattle did not detect these potentially dangerous genetic inserts, had they been deregulated they could have entered our fields and food chain with no safety assessment and no labelling.¹⁶

Gene editing is imprecise and need to be regulated

More evidence¹⁷ is coming to light about the potential environmental and human health risks posed by these new GM techniques, belying the biotechnology industry's claims that they are precise and predictable. Given these risks, a recent peer-reviewed study concluded that assuming these GM processes are safe "lacks a robust scientific basis".¹⁸

In July 2018, the European Union's top court ruled that new GM techniques such as CRISPR pose similar risks to older GM techniques and need to be assessed for safety in the same way.¹⁹ This ruling is consistent with the findings of reviews commissioned by the Austrian²⁰ and Norwegian²¹ Governments. These concluded there is insufficient knowledge regarding the risks posed by these techniques and products derived from them, so they require a comprehensive case-by-case risk assessment. Because of these risks, over 60 international scientists have signed a statement calling for these techniques to be strictly regulated.²²

Other countries have taken a more precautionary approach than Australia's. In 2016 our key agricultural competitor New Zealand announced it will regulate organisms derived from these techniques as GMOs.²³

Our regulators are failing us

Both the OGTR and FSANZ relied on advice from scientists with serious conflicts of interest when arriving at their recommendation to deregulate these techniques.²⁴

The OGTR consulted its Gene Technology Technical Advisory Committee (GTTAC). The Gene Tech Regulations clearly state that members of GTTAC with possible conflicts of interest in a topic must not participate in any Committee decision on that matter. However, FOI documents reveal that scientists with serious conflicts of interest led the GTTAC discussion of these techniques and advised the OGTR that they



posed risks no different to conventional breeding. This opinion is starkly at odds with those of government agencies overseas.²⁵

In 2012 and 2013 FSANZ convened an expert panel – comprised almost entirely of genetic engineers with gene technology patents – to look at whether these new GM techniques should be considered genetic engineering. Not surprisingly, the panel concluded that the majority of these methods did not pose food safety concerns, and could either be deregulated or undergo a simplified form of food safety assessment. Furthermore, FSANZ appears to have deliberately mislead the Senate when it claimed it was “not aware that any members of the expert panel have potential conflicts of interest.” From subsequent statements it is clear that FSANZ was aware of these potential conflicts of interest and simply chose to ignore them.²⁶

Disturbingly FSANZ appears to have adopted the advice it received from this expert panel in full. Correspondence between FSANZ and the Minister obtained by FoE under Freedom of Information laws stated that:

“We have considered the key findings of the expert panel and concur with their conclusions regarding which foods should be regarded as GM food, and which should not.”²⁷

In August 2016, FSANZ held a workshop with states and territories where it proposed adopting this interpretation of the current legislation and definitions in full, so that it didn’t need to regulate or legislate.²⁸ In other words the agency attempted to make a *de facto* decision not to regulate these techniques in food that was completely unaccountable and hadn’t been subject to any Parliamentary scrutiny or public consultation.

We can only surmise that FSANZ was concerned about a potential legal challenge regarding its decision, as it subsequently initiated a review of ‘new breeding techniques’ (a biotechnology industry term for these techniques). FSANZ has said it will conduct public consultation on its proposed regulatory changes in mid 2020.²⁹

It’s time our regulators stopped letting industry write the rules for them and put public health and our environment before private profit.

What needs to happen?

Friends of the Earth is calling for:

- A moratorium on the environmental release of genetically modified animals.
- Products derived from all GM techniques to be subject to a comprehensive case-by-case risk assessment - including full molecular characterisation and independent safety testing - to ensure they are not harmful to human health or the environment;
- All products derived from GM techniques to be labelled to protect choice for farmers, producers and consumers.



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- ¹² Carlson, D.F. *et al.* (2016)
- ¹³ Gene Technology Amendment (2019 Measures No. 1) Regulations 2019. <https://www.legislation.gov.au/Details/F2019L00573>
- ¹⁴ OGTR (2019) *Questions & Answers on the Technical Review of the Gene Technology Regulations 2001* [http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/A0E750E72AC140C4CA2580B10011A68E/\\$File/Technical_Review_QA_July_2019.pdf](http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/A0E750E72AC140C4CA2580B10011A68E/$File/Technical_Review_QA_July_2019.pdf)
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