MUTANT MEAT

Will Australia deregulate genetically modified animals?

Friends of the Earth Australia

Contents

Executive summary

Australia is poised to become the first country in the world to deregulate the use of a range of new genetic modification (GM) techniques in animals that are being collectively referred to as 'gene editing'.

These new genetic engineering techniques, such as CRISPR, are being used, for example, to try to develop more muscular and disease resistant livestock that can be housed in intensive conditions without getting sick; and to produce animals that don't reach sexually maturity so they eat less food. Scientists are also attempting to develop 'gene drives' - a GM technology that is deliberately designed to spread, with the aim of suppressing populations of mosquitoes and driving invasive species to local extinction.

There has been a great deal of media hype surrounding CRISPR applications in animals, with some scientists claiming this technology offers a new degree of precision and therefore doesn't need to be regulated.[1] However, the use of this technique in animals raises serious animal welfare, environmental and food safety concerns. The technique is not as precise as has been claimed and results in high levels of unexpected genetic mutations in mammals.[2] Gene editing techniques can inadvertently cause very low live-birth rates; abnormal sizes - rendering animals incapable of natural movement; and respiratory and cardiac problems.[3] Recent studies also suggest that editing cells' genomes with CRISPR might increase the risk that the altered cells will trigger cancer.[4]

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.[5] Our key agricultural competitor New Zealand will also be regulating these techniques as GM. Even the US Food and Drug Administration, which is not known for its precautionary approach to gene technology, has proposed that gene edited animals be assessed for food safety.[6]

In stark contrast to overseas regulators, the Office of the Gene Technology Regulator (OGTR) and Food Standards Australia New Zealand (FSANZ) have both recommended that a number of these new GM techniques be deregulated. Furthermore, they have relied on advice from biotechnology scientists with clear commercial conflicts of interest in making their recommendations.

Research shows that the majority of Australians are not comfortable with the idea of eating GM animals.[7] Yet if these techniques are deregulated anyone would be free to use them in animals and the resulting animal products would enter our food chain with no labelling and no safety testing.

There is zero tolerance for unapproved GM content in many of Australia's major export markets. That makes it essential to have prior assessment of not just the environmental and human health impacts, but also the economic impacts of any use of GMOs. As a major agricultural exporter, if Australia were to exempt any of these techniques from regulation it could result in serious trade implications.

Gene edited animals pose novel risks to human health and the environment and raise a raft of ethical issues. It's vital that we have a robust regulatory system in place to assess these risks. Products derived from these techniques also need to be labelled so that the choices of consumers, farmers and the food industry are protected.

Australia's GMO regulations should be interpreted as they were initially intended, to encompass all modern biotechnological processes that directly modify genomes.[8] Otherwise, the Australian Government will be failing its citizens.

Friends of the Earth is calling for:

- These new GM techniques and the products derived from them to be subject to a comprehensive case-by-case risk assessment, including full molecular characterisation and independent safety testing to minimise any potential risks to human and animal health and the environment;
- All products derived from these new GM techniques to be labelled to protect choice for farmers, producers and consumers;
- The precautionary principle to be enshrined in both the Gene Technology Act and the Food Standards Australia New Zealand Act, given the experimental nature of these technologies and the risks associated with them;
- A moratorium on the development of gene drives until our regulatory system for GMOs is adapted to deal with the potential risks posed by them.

1. What is gene editing?

The term gene editing refers to a variety of new GM techniques including CRISPR[9] TALENs[10] and zinc finger nucleases (ZFNs).[11] The biotechnology industry is arguing that these techniques only make small precise changes to the genome and so don't need to be regulated. However, more and more evidence is coming to light about the potential environmental and human health risks posed by these techniques, belying the biotechnology industry's claim that they are precise and predictable. For example, a recent study in *Nature Biotechnology* looking at mice and human cells found that in around a fifth of cells, CRISPR causes deletions or rearrangements more than 100 DNA letters long.[12]

Reviews commissioned by the Austrian[13] and Norwegian[14] Governments concluded that there is insufficient knowledge regarding the risks posed by these techniques and that products derived from them should 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 as GMOs.[15]

2. How are these new GM techniques being used in animals?

2.1 Livestock

Research institutes and private companies around the world are working to create a wide variety of gene edited livestock.[16] CRISPR in particular has received a great deal of hype in the past few years for its ability to make genetic engineering faster, easier, and cheaper.[17]

CRISPR has been suggested as a means to increase the muscle mass of animals, render farmed animals less susceptible to disease, enhance nutritional content, or create hornless cattle that are easier to handle.[18]

Maximising productivity

Much of the gene editing research that is being conducted on animals is focusing on increased productivity. A number of different institutions have developed 'double-muscled' cows, sheep and pigs to produce leaner meat and a higher yield of meat per animal.[19] CRISPR is also currently being used to try to increase wool length in sheep. [20]

Scientists at the biotechnology company Recombinetics have also applied for a patent on genetically modified animals to produce animals that don't reach sexually maturity - since "sexually immature animals generally consume less food per pound of weight than mature or maturing animals."[21] Others are working on chickens that produce only females for egg-laying and cattle that produce only males, since females are less efficient at converting feed to muscle.[22]

Some gene-edited animals are being presented as animal welfare solutions. For example, Recombinetics has created hornless cattle to avoid the need for de-horning when cattle are kept in close proximity.[23] Claims of an animal welfare benefit are questionable since alternatives to dehorning already exist (see section 3.2).

Disease resistance

Another focus for gene editing in livestock has been to genetically modify disease resistance into animals so they can be housed intensively without getting sick. For example, using CRISPR, scientists have developed pigs that are resistant to Porcine Reproductive and Respiratory Syndrome Virus (PRRSV).[24] Scientists have also created pigs with resistance to African Swine Fever Virus – which occurs in Africa and Eastern Europe[25] - using ZFNs.[26]

ZFNs have been used to generate mastitis resistance in cows.[27] Similarly, TALENs and CRISPR have been used to engineer cattle with increased resistance to tuberculosis.[28]

Recombinetics has created hornless cattle to avoid the need for de-horning when cattle are kept in close proximity.

Scientists are gene-editing pigs so they can be housed intensively without getting sick.
Image courtesy of the Humane Society of the United States

Hypoallergenic products

In a bid to tackle our increasing allergy epidemic, scientists are also attempting to genetically engineer chickens that lay hypoallergenic eggs[29] and cattle that produce hypoallergenic milk.[30]

'Farmaceuticals'

Gene editing is also being used to create animal 'bioreactors' for the production of biomedical products, such as human lactoferrin (hLF) in goats[31]; interferon beta – an antiviral protein - in chicken eggs[32]; and human serum albumin (a widely used human blood product) in pigs and cows.[33]

Scientists are also considering replacing the milk protein genes of livestock to 'humanise' the milk for human consumption.[34]

2.2 Gene drives

A gene drive is a GM technology that can rapidly spread a particular gene throughout a population. CRISPR gene drives work by copying and pasting themselves into chromosomes from both parents, ensuring they get passed on more often.[35]

Some scientists are proposing to use gene drives to permanently alter the gene of species in order to prevent disease or to control invasive species.

For example, scientists at Imperial College London are attempting to use gene drives to spread a female sterility gene through *Anopheles* mosquito populations.[36] The aim is to significantly reduce mosquito numbers to try to eliminate malaria.

DARPA are funding CSIRO and the University of Adelaide to develop gene drive mice

Researchers at CSIRO and the University of Adelaide are being funded by Defence Advanced Research Projects Agency (DARPA – the US military's research arm) to develop gene drive mice that only produce male offspring. The plan is to release them on islands off the coast of Western Australian with the aim of driving the local mouse populations to extinction.[37]

CSIRO are also investigating the potential for gene drives and other new GM techniques to be used to eliminate cane toads, fruit flies, carp and feral cats.[38]

2.3 De-extinction

There are several research groups working on plans to use CRISPR to 'resurrect' extinct species such as the woolly mammoth and passenger pigeon by editing the elephant and pigeon genome respectively.[39]

3. What are the concerns associated with gene edited animals?

"Can off-target effects of CRISPR—unanticipated mutations leading to undesirable phenotypes—be controlled? What are the effects on animals or humans who eat genetically edited insects or animals? Will wiping out an entire species—albeit invasive, or diseasebearing, such as mosquitos or ticks—upset the ecological balance? Will edited organisms be able to survive in natural environments, and if so, for how long? Addressing these questions requires far more regulatory oversight than currently exists anywhere in the world."

Caplan et al. (2015)[40]

3.1 Ethical issues

The gene editing of animals raises complex ethical questions about animal welfare, who benefits from these technologies, and the evolving, contradictory relationship between humans and animals. Unfortunately, these questions have so far been largely ignored.[41]

There are several research groups working on plans to use CRISPR to 'resurrect' extinct species such as the woolly mammoth.

A better animal welfare solution than gene-edited animals is to not farm animals intensively.

Image by Jim Champion - Own work, CC BY-SA 3.0

3.2 Animal welfare concerns

There has been a great deal of media hype surrounding CRISPR applications in animals, with some scientists claiming this technology offers a new degree of precision.[42] However, the technique is not as precise as has been claimed, and results in high levels of unexpected genetic mutations in mammals - raising serious potential animal welfare concerns.[43]

Our understanding of how DNA controls different traits is still limited, and new functions of previously known DNA sequences are still being discovered. A 'simple genetic tweak' could therefore have unpredictable repercussions on many aspects of an organism's development. [44] For example, two recent studies published in *Nature Medicine* suggest that editing cells' genomes with CRISPR might increase the risk that the altered cells will trigger cancer.[45]

Gene editing in animals often involves somatic cell nuclear transfer (cloning). Wei *et al.* observe that this is "often hampered by a high incidence of developmental abnormalities that are associated with substantial welfare concerns."[46] Kurome *et al.* (2013) reviewed 274 studies that produced GM pigs using this technique. Out of 318 cloned piglets, 243 (76%) were alive, but only 97 (40%) were clinically healthy and showed normal development. The proportion of stillborn piglets was 24% (75/318), and another 31% (100/318) of the cloned piglets died soon after birth[47]

In 2015, the European Parliament took animal welfare and ethical concerns into account and voted to ban the cloning of all farm animals and imports of food from cloned animals, although this has yet to come into force.[48] In Australia there is no prohibition on the use of cloned farm animals in food production.[49]

Increasing productivity compromises health

Rauw *et al.* (1998) note that animals selected for high production efficiency seem to be more at risk of behavioural, physiological and immunological problems resulting in impaired animal welfare.[50] They note that "future application of modern reproduction and DNA-techniques in animal breeding may increase production levels even faster than at present, which may result in more dramatic consequences for behavioural, physiological and immunological traits."

For example, 'double-muscled' pigs gene edited to produce more meat had to be delivered by caesarian because of their large size. According to the scientists, of the 32 mutant pigs produced only two are still alive and only one is considered healthy."[51]

A boon for animal welfare?

Gene editing has been promoted by some scientists as an animal welfare solution. For example, TALENs has been used to produce hornless cattle, purportedly reducing the need for the painful dehorning process.[52] However, as Ishii (2017) points out, there are already alternative solutions to gene editing cattle including "enriching the rearing environment to prevent accidents, the use of horn covers...and performing the dehorning of cattle under anesthesia."[53] Cattle can also be selectively bred to be hornless, although industry has argued that this is time consuming.

Similarly, gene editing has been proposed as a method of combatting the increasing disease incidence within livestock populations. However, in reality there are simpler, more cost effective methods of disease control.[54] Diseases such as Porcine Reproductive and Respiratory Syndrome Virus (PRRSV) occur when animals are housed in inhumane conditions. A better animal welfare solution than genetically modifying animals so that they don't get sick under these conditions would be not to house them under these conditions in the first place.

3.3 Perpetuating a broken system

Gene editing in livestock is frequently touted as a solution to ensure food security for a rapidly growing human population in a world of decreasing resources and a changing climate. However, the economic interests involved create a powerful disincentive to consider the welfare, food safety and other concerns associated with GM animals.[55]

Animal production is incredibly resource intensive. According to the United Nations Environment Program report "more than half of the world's crops are used to feed animals, not people. Land and water use, pollution with nitrogen and phosphorus, and GHG emissions from land use and fossil fuel use cause substantial environmental impacts."[56] The report concludes that "a substantial reduction of impacts would only be possible with a substantial worldwide diet change, away from animal products."[57]

Instead, of encouraging this much needed global shift, gene-editing animals focuses on even more extreme forms of business as usual. It is yet another attempt to maintain a fundamentally broken system.

More than half of the world's crops are used to feed animals, not people

Gene edited animals are symptomatic of a much larger problem in agriculture. The over-emphasis on productivity has too often achieved higher yields at great expense to human health, animal welfare and the environment.

Rather than genetically engineering animals so that they can survive in inhumane conditions without getting sick, we should focus on creating ethical and regenerative and farming systems that don't create these problems in the first place. Gene edited animals have no place in our food system or in the environment.

3.4 Environmental concerns

If GM animals are released or escape into the wild, they could potentially become invasive species, outcompeting wild populations, or contaminating wild gene pools though cross breeding.[58] In this way GM animals could eradicate or fundamentally and permanently alter wild populations and ecosystems. This is not only of concern for wild animals (e.g. mosquitoes), but also of farm animals or fish, who may not be adequately contained and escape.

For example, a study published in *Proceedings of the National Academy of Sciences* found that a release of just 60 genetically modified fish in a population of 60,000 could lead to the extinction of the wild population in less than 40 generations.[59]

The risks are even more pronounced in the case of gene drives, which are deliberately designed to spread through populations (see section 3.6).

3.5 Human health risks

Selecting for increased growth and productivity in livestock can have serious consequences for animal health, with corresponding implications for food safety.[60] For example, selective breeding for increased milk production in cows has been tied to increased rates of mastitis - an infection of the udder.[61] Increased disease incidence in livestock poses significant threats to human safety because some diseases can pass from livestock to humans. Increased disease incidence can also encourage antibiotic overuse, further exacerbating our current antibiotic resistance crisis.[62] Since gene editing is anticipated to further increase the ability to select for productivity traits, these trends should be cause for considerable concern.[63]

Many GM livestock are produced though somatic cell nuclear transfer (SCNT), a type of cloning associated with low embryo survival rates and adverse health effects.[64] Because of these health issues, cloned animals tend to have high loads of harmful pathogens that can make their way into the final meat product.[65]

Gene editing could result in unintentional alterations to the composition of animal products, including the production of novel toxins or allergens.[66] It would be highly irresponsible to bring gene-edited livestock to market without extensive independent safety assessments and regulatory oversight.

GM animals as bioreactors

The use of GM animals as 'bioreactors' to produce pharmaceutical products is ethically questionable and also poses potential human health risks. It is difficult for transgenics producers to produce 'nature identical' proteins in milk and they typically vary in subtle ways that may affect their toxicity.[67] These products pose particular risks to individuals allergic to products produced by those animals. For example, an anticoagulant drug produced by a GM goat was approved in the US and EU despite concerns regarding its potential allergenicity in people who are hypersensitive to goats milk.[68]

The use of GM animals as bioreactors for producing pharmaceutical products poses additional risks in the event that these products accidentally end up in the food chain. Between 2001-2005 there were at least four unauthorised instances of experimental GM pigs entering the food or feed supply. These were either accidentally comingled with non-GM livestock at the abattoir, sometimes due to mislabelling - or in one case they were deliberately stolen.[69]

3.6 Gene drives

There has recently been a great deal of media hype around the potential to use gene drives to eliminate diseases such as malaria and to drive invasive species to local extinction.[70] However, gene drives are a highly risky unproven experimental technology that will cost millions of dollars to develop and have no guarantee of success. Moreover, studies suggest that resistance is likely to develop quickly in genetically diverse wild populations.[71]

There is too little knowledge about the long-term effects of this new technology to make any robust predictions about whether gene drives would work or what adverse effects might arise. However, there is no doubt that the environmental release of gene drive organisms would be irreversible. Furthermore, the effects of releasing gene drives into the wild could

Vaccines are being developed for malaria and Lyme disease.

be potentially catastrophic. Leading proponents of gene drives have now said that they are too risky to release in the wild.[72] Because of their serious and potentially irreversible threats to biodiversity – as well as national sovereignty, peace and food security over 160 global groups have called for a moratorium on the environmental release of gene drives.[73]

Even if the technology is not effective in eradicating diseases and disease vectors, it could still have profound impacts on the environment if it were released intentionally or unintentionally.

Diverting funds towards researching risky new technologies such as gene drives also comes at an opportunity cost. There are already proven strategies for eliminating malaria,[74] in fact Paraguay successfully eliminated the disease this year.[75]

There are also other promising alternatives to gene drives for disease vector control. Vaccines are being developed for malaria and Lyme disease, and research is being conducted on *Wolbachia*, a type of natural bacteria that, when present inside mosquitoes, prevents dengue fever from developing or being transmitted.[76]

3.7 De-extinction

> *"Technofixes for environmental problems are band-aids for massive haemorrhages…De-extinction suggests that we can technofix our way out of environmental issues generally, and that's very, very bad."*
>
> Daniel Simberloff, Ecologist[77]

Apart from the obvious impact of wholesale ecosystem disruption if synthetically produced versions of extinct species are introduced into the wild, there are a number of other reasons why de-extinction is a really bad idea.

As Paul and Anne Ehrlich from Stanford University argue "it is much more sensible to put all the limited resources for science and conservation into preventing extinctions, by tackling the causes of demise: habitat destruction, climate disruption, pollution, overharvesting, and so on. Spending millions of dollars trying to de-extinct a few species will not compensate for the thousands of populations and species that have been lost due to human activities, to say nothing of restoring the natural functions of their former habitats."[78]

4. How have regulators responded?

Currently, there is international debate about how gene-edited animals should be regulated.[79]

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.[80] New Zealand has also said it will regulate these techniques in all organisms.[81] Even the US Food and Drug Administration, which is not known for its precautionary approach to gene technology has proposed that gene edited animals be assessed for food safety.[82]

4.1 The Australian Government response

There are two main Government agencies that oversee the regulation of genetically modified organisms in Australia – the Office of the Gene Technology Regulator (OGTR) which regulates live organisms and Food Standards Australia New Zealand (FSANZ) which regulates the use of GMOs in food. In stark contrast to overseas regulators, both agencies have recommended that a number of these new GM techniques be deregulated. 83 Furthermore, they have relied on advice from biotechnology scientists with clear commercial conflicts of interest in making their recommendations.[84]

> *"Investigations by anti-corruption commissions in Australia "have repeatedly shown that agencies with regulatory functions…are particularly vulnerable to corruption and misconduct, especially where a high degree of discretion is combined with close relationships with the industry"*
>
> Adams *et al.* (2007).[85]

4.2 FSANZ attempts to deregulate these techniques by stealth

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. Two workshops were held which were chaired by Professor Peter Langridge, who was then Director and CEO of Australian Centre for Plant Functional Genomics.

FSANZ is very aware that good governance requires disclosure and management of actual and potential conflicts of interest.[86] The Board of FSANZ, for example, is required to register pecuniary and other potential or actual conflicts of interest. The Register makes clear the broad scope of actual and potential conflicts of interest that FSANZ works to.[87]

Similarly, the FSANZ tendering process, which involves the engagement of external interests, includes a requirement that any potential conflict of interest by a tenderer must be reported to FSANZ. FSANZ defines a conflict of interest as a personal, professional or commercial relationship with FSANZ or with an organisation that would affect the performance of the contract or would bring disrepute to or embarrass FSANZ.[88]

Remarkably in 2015 when FSANZ was asked by Senator Rachel Siewert about the conflicts of interest on the panel they claimed:

> *"FSANZ is not aware that any members of the expert panel have potential conflicts of interest such as a commercial interest or patents in any of the listed breeding techniques. Some members of the panel have been, or are currently, engaged in research using some of the listed techniques."*[89]

However, under Freedom of Information laws Friends of the Earth obtained email correspondence between Peter Langridge and FSANZ in which he stated "I'm happy to chair the meeting if you don't feel my potential conflict of interest is a problem."[90]

When Senator Janet Rice pointed out the contradiction between FSANZ's previous testimony and the Langridge email in Senate Estimates in March this year FSANZ, reversed its position, stating that:

> *"It is acknowledged that they all had potential conflicts of interest, but there is a difference between a potential conflict—it would be very hard to find an expert who did not have a potential conflict of interest."*[91]

Disturbingly it appears FSANZ intended to adopt the conflicted advice it received from this expert panel in full. Correspondence between FSANZ and the Minister obtained by Friends of the Earth 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."*
>
> *"Foods derived using oligo-directed mutagenesis, zinc-finger nuclease technology used to introduce small, site-specific mutations involving one or a few nucleotides, and seed production technology are not captured by the standard and therefore do not require pre-market approval."*[92]

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 doesn't need to regulate or legislate.[93]

In the workshop FSANZ relied on the conclusions of the expert panel but did not disclose its conflicts of interest. FSANZ stated that:

> *"From a scientific and safety perspective, we are quite comfortable with foods derived from those types of techniques not having to undergo premarket assessment and approval, given their similarity to conventional food products."*[94]

These conclusions are notably at odds with reviews commissioned by overseas regulators. [95]

In other words, FSANZ attempted to make a *de facto* decision not to regulate these techniques in food that is completely unaccountable, unchallengeable and hasn't been subject to any Parliamentary scrutiny or public consultation.

Presumably this attempt to avoid public consultation failed, because in May 2018 FSANZ released a discussion paper on 'new breeding techniques' –a biotechnology industry term for these techniques - for public consultation.[96] FSANZ has convened a new expert committee which again is stacked with scientists with commercial interests in these techniques. These include:

Dr Allan Green

Dr Allan Green is CSIRO's Innovation Leader for Bio-based Products and is currently involved in the team commercialising GM safflower[97] He was on FSANZ's initial expert panel and was Deputy Chief of CSIRO Plant Industry when the workshops took place. He has a background in plant breeding and genetics, and his main research activities have been the genetic modification of oilseed crops.[98] The CSIRO has numerous gene technology related patents, including patents in gene silencing, and is conducting field trials with genetically modified cotton, safflower, wheat and barley.[99] The organisation also has strategic partnerships with the GM crop companies Monsanto and Bayer CropScience the details of which remain confidential.[100]

Dr Mark Tizard

Also from CSIRO, Dr Tizard is a member of Genetic Biocontrol of Invasive Rodents Program (GBIRd) which is being funded by the US military to conduct gene drive (genetic extinction) experiments in mice.[101] He is also one of the four expert advisors on the Government's 2017 Gene Technology Scheme Review Expert Advisory Panel. This review is examining gene drives and other synthetic biology applications.[102] According to the Department of Health "his current interests are in gene editing in the cane toad and exploring the possibilities of the new gene drive technology for fish and rodent pests."[103] On 28th November 2017 he co-chaired the Department of Health's public engagement webinar on the Review of the Scheme.[104] Dr Tizard recently publicly stated that people with serious conflicts of interest shouldn't be on government advisory committees.[105]

Dr Goetz Laible

Is a senior scientist at AgResearch in New Zealand. He presently specialises in the use of gene editing and other GM techniques to express pharmaceutical products in the milk of cows.[106]

4.3 The OGTR breaches its own conflict of interest regulations

In 2016, the OGTR released a discussion paper canvassing a number of regulatory options for these new techniques – most of which involved not regulating them.[107]

FOI documents obtained by Friends of the Earth reveal that the OGTR had been inviting submissions from industry for over a year beforehand. The OGTR also stated in a presentation to Institutional Biosafety Committees in April 2015 that there is a:

> *"Challenge, role, opportunity for YOU – scientists and regulated organisations to 'make the case'"*[108] i.e. for deregulation.

The OGTR also consulted its Gene Technology Technical Advisory Committee (GTTAC) on the issue.[109] The rules around conflicts of interest are clearly outlined in the Gene Technology Regulations 2001 (paragraph 20). These clearly state that GTTAC members with "interests that could be perceived to represent a possible conflict of interest" must not "take part in any decision of the Committee about that matter.

A number of the members of the GTTAC at this time have clear conflicts of interest regarding these new GM techniques. These include Dr Ian Godwin from the University of Queensland who is using these techniques to develop GM cereal crops and whose school collaborates with Monsanto; and Ross Barnard who is the Biotechnology Program Director at the University of Queensland.[110] However, all of these members were present during the discussion of this topic.[111] Furthermore, Dr Godwin and Dr Barnard advised that "the risks posed by organisms altered by SDN-1[112] are unlikely to be any different to naturally mutated organisms."[113]

Hardly surprisingly, GTTAC advised the Regulator that:

> *Risks posed by organisms altered by SDN-1 are unlikely to be different to naturally mutated organisms.*[114]

This advice formed the basis of the OGTR's discussion paper and the whole way it was framed. The OGTR also repeated the claim in its Regulation Impact Statement: "Because the changes brought about through SDN-1, including off-target effects, are no different to natural mutations, they do not give rise to any different risks to natural mutations."[115] Again this conclusion is notably at odds with reviews commissioned by overseas regulators. [116] The OGTR has now recommended that these techniques be deregulated.

5. Conclusion

Whilst biotechnology industry is racing to commercialise the use of these new GM techniques in animals, scientists are only just beginning to assess their potential risks to animal welfare, human health and the environment.

Meanwhile our regulators are failing to protect our safety and right to know. Both the OGTR and FSANZ seem all too happy to accept industry claims of safety and to deregulate these techniques without any kind of public debate.

Those government agencies overseas that have considered the biosafety risks posed by these techniques have concluded that there is insufficient knowledge regarding their risks. On this basis, they argue that products derived from new GM techniques should be regulated in the same way as those created using older GM techniques and require a comprehensive case-by-case risk assessment. [117]

There is zero tolerance for unapproved GM content in many of Australia's major export markets. That makes it essential to have prior assessment of not just the environmental and human health impacts, but also the economic impacts of any use of GMOs. As a major agricultural exporter, if Australia were to exempt any of these techniques from regulation it could result in serious trade implications.

Products derived from these techniques also need to be labelled so that the choices of consumers, farmers and the food industry are protected.

Australia's GMO regulations should be interpreted as originally intended - to encompass all modern biotechnological processes that directly modify genomes.[118] Otherwise, the Australian Government will be failing its citizens.

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