

VIEWS ON DISCUSSION PAPER FOR REGULATION OF NEW TECHNOLOGIES

<http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/regs-process-1>

1) AUSTRALIA MUST RETAIN ITS FULL REGULATORY SOVEREIGNTY.

(a) A STRONG, COMPREHENSIVE, HIGH STANDARD AND TRANSPARENT REGULATORY PROCESS IS VITAL, ONE WHICH ALWAYS GIVES PRECEDENCE TO THE PUBLIC INTEREST, AND TO PUBLIC AND ENVIRONMENTAL HEALTH.

[**Please note** : our discussion does not involve biomedical / healing applications of gene technology where only selected individuals are affected. This topic needs to be raised separately].

(b) We, like all Australians, are key stakeholders. We all bear the risks directly and indirectly; we are all potentially the victims when these experiments go wrong. Who would be accountable? Genetically Modified Organisms (GMOs), and Synthetically Modified Organisms (SMOs) produced by radical / extreme technologies have the potential to cause profound and unexpected results, and carry significant and unacceptably high risks. See APPENDIX A ..

(c) We do not accept these risks. Why should we? A whole generation is being sacrificed for the sake of excessive profits for a very few.

(d) Like many, we do not trust our governments at either federal or state level.

Long experience with OGTR and APVMA , has shown us that under the current system, we can have little faith in our regulators. The federal government appears to be weakly bowing down under external mega-corporate pressure. As a result Australia faces a real and present danger of losing its regulatory sovereignty. At the same time as it is planning to force an influx of radical new gene technologies and techniques, government is also planning to heavily deregulate the agricultural sector. (Productivity Commission 2016). But among the regulations to go would be those designed to protect human health and the environment. This is reflected in a recent, serious weakening of Australia's biosecurity in an era when the country's biosecurity urgently needs strengthening. (Biosecurity Act 2015, effective since 16 June 2016). Our home state, Western Australia, has erred down the same path. (Western Australian Biosecurity Strategy 2016). Seemingly to suit commercial interests, other policies and procedures designed to protect human and environmental health are being ignored.

Many people sense all is not right, and the government needs to listen to this.

(e) Question to Martin Rees, founder of the Center for the Study of Existential Risk
(Ref: *Scientific American*, June 2015, *Advances*, page16).

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).'*

2) TERMINOLOGY:

It is misleading to use the description "new technologies / techniques". These are radical / extreme *experiments* involving living GMOs and SMOs, taken out of the laboratory for release into the broad Australian community without its informed consent, and into a vulnerable, poorly understood, under appreciated and already stressed natural environment. Every day Australians are being used as guinea pigs.

Are the relevant gene tech corporations favouring an isolated continent like Australia to conduct such experiments, where bioerror could possibly be prevented from spreading to other countries? .If so, what does this say about about the kind of risks and degree of risks Australia would be exposed to? What does it say about the mindset and morality of those involved?

3) RATIONALE:

(a) Most important, the public first needs to learn the rationale of the gene tech industry. These new technologies are apparently an instrumental part of one or more commercial enterprises. What is the purpose What is the industry's business model? What is the business case in every instance? Full disclosure is needed. Transparency is needed.

(b)The government (through OGTR) needs to provide its rationale. Through OGTR, Government appears to be proposing handing over the power given to it by its citizens to corporate interests. That is dangerous. It is unacceptable. Transparency is needed .

(c)Below are reasons why we believe the Precautionary Principle should be applied. Otherwise, reasons why strict, fully comprehensive regulation of all new GM technologies such as CRISPR Cas9 and synthetic techniques would be imperative.

4) WHERE IS THE DEBATE?

(a) This is really a debate about the future of humanity. This very complex topic

requires public forums. Best Practice / due process is to hold a public debate. Instead it seems government and industry together have skipped that necessary step, and involved the OGTR. This avoidance of due process is viewed not only as wrong but also as arrogant and presumptuous.

(b) Government and industry are impoverishing even this limited OGTR “Discussion Paper”, by confining considerations to a narrow set of 'Options'. Presumably one such option would eventually dictate how OGTR is to treat a whole range of radical new of technologies / techniques.

(c) By omission in the scope of the Discussion Paper, the names of the industries pushing the new technologies are not disclosed as they should be. Actual 'products' of those new techniques - the GMOs and SMOs – are not disclosed at this point. No specific examples are given. This lack of transparency is unacceptable.

(d) Understanding the fundamental purpose of the new technologies is vital to this discussion but appears to escape the scope of this technical review. The purpose drives the technologies. Promised 'clarity' has yet to be provided. No alternative options are given. This is totally unacceptable. (See Point 6 (h), page 9, on the struggle to keep an ailing biotech industry alive).

(e) Who are the overlords behind these technologies, and what makes them tick?

As with robot technology, this background is also essential for the community to know and consider.

'If these technologies are transforming our future, wouldn't it be wise to know what makes their designers tick, and what roles they envisage for their human operators? What these roles turn out to be, argues *New York Times* science writer John Markoff, involves not only a technical but an ethical choice.'

.....there are 'urgent, compelling and relevant calls to consciously embed our values in systems we design, and to critically engage with our choices. Unless we design ourselves out, humans are part of any technical system that we commission, develop, use and hack.'

(Ref: '*Gods of tomorrow? To avoid techno-dystopia, we must act now.*', Regina Peldszus. *New Scientist, Culture Lab, 15 August 2015*).

(f) Because an Option is not provided of saying NO to involving Australia in these experiments, it appears :

(i) the technologies would be forced on Australia.

(ii) Australia would become a test- bed for the new technologies.

(iii) OGTR's limited list of Options is aligned with what the GM industry wants, not what is vital for the public's or the nation's best interests..

(iv) There is a public perception that this is another example of 'regulatory capture', with OGTR the 'captive agency'.

(g) Australian democracy continues to be seriously undermined. This is totally unacceptable. Swiss style referenda on these major issues are needed.

(h) People are forced to send submissions to an agency that has no knowledge of our communities and their aspirations, and that systematically ignores public concerns and objections. This process, though frustrating and senseless, is what we all must now engage in to secure our children's future. How can OGTR make findings against community representatives who point out any decisions to the contrary go against the very framework which is there to guide their decision-making?

(i) The Australian community is cast aside, metaphorically, along with other natural planetary life-forms, by empty policies at many levels, lip service and greed. OGTR has accepted every GM application up to now, seemingly attesting to this.

(j) Government subsidies to GM companies seem senseless, so why do we seem powerless to stop them? Why should taxpayers directly or indirectly subsidize GMO, SMO and other radical technologies without a net cost /benefit advantage over continual progress in traditional agronomy, traditional plant and animal breeding, and ecological agriculture?

Ref: 'The GMO Deception', Edited by S Krimsky & J Gruber, Skyhorse Publ. 2014.

(See Point 19 below, page 14, "Australia lacks adequate protection measures)

(k) OGTR's set of Options below is unbalanced and skewed towards the biotech industry. The regulator is not demonstrating its independence.

'Option 1: no amendment to the GT Regulations

Option 2: regulate certain new technologies

Option 3: regulate some new technologies based on the process used

Option 4: exclude certain new technologies from regulation on the basis of the outcomes they produce.'

(l) Options must include application of the Precautionary Principle. If not, why not?

(m) Options must include in explicit language, regulation of all new technologies, and of all the products and outcomes of those new technologies. If not, why not?

Any loss or undermining of Australia's regulatory sovereignty must not be an outcome of this OGTR technical review.

(n) It is essential that an option is available for the Precautionary Principle to be practiced, as it is in other countries, particularly when considering GM or SM microbes. OGTR must explain why this option is not given.

(o) If not through OGTR, how can the Precautionary Principle be called In?

(p) Since the Precautionary Principle has been excluded as an Option, we conclude the intention is to force these new unspecified technologies on Australians. This approach

is seen as bullying, as lack of respect and contempt for Australia. It is unacceptable. The OGTR is taxpayer funded, this Option should be included.

(q) A preventive approach is appropriate rather than a risk-based approach. Biotech manipulation of animal genetics is complicated and fraught with problems: It lacks long term evidence of its value and safety. It lacks ethical debate. We oppose the idea.

(r) Further to the Precautionary Principle, and using the list of OGTR options, we favour next Option 2. Responsibly our society requires total regulation of each and every new GM technology, and of ALL GMOs and SMOs produced by such technologies. We strongly urge OGTR not to exempt any new GM, SM or other new technologies / techniques from assessment, while properly informed debate is lacking, while there is insufficient independent scientific evidence of adverse impacts, short and long term, on health and safety of humans, animals and the environment.

(s) We require our regulator (OGTR) to assess, regulate and license ALL radical new GM techniques (CRISPR; ZFN; RNAi; etc.) and their living GM & SM products.

(t) We support the view that ALL of the following are genetic modifications:

- A - Adding a gene from another organism
- B - Inducing mutations with radiation or toxic chemicals
- C – Making a single precise change to an organism's genome.

All gene-edited plants and animals need safety testing. 'Zero oversight makes as little sense as draconian regulation'. (Ref: *New Scientist*, Michael Le Page, 30 April 2016, page 19).

To a degree we support the view that an added system of oversight is needed that focuses not only on how strains of plants and animals are created, but whether they have been changed in a way that could harm people or the environment. However the level of assurance needed would require independent long term studies and these are already lacking with existing GMOs, so trust and confidence remain at a very low ebb.

(u) RNAi is considered an inherently unsafe GM technique: "The potential hazards posed by RNA interference (RNAi)-based pesticides and genetically modified crops to non-target organisms include off-target gene silencing, silencing the target gene in unintended organisms, immune stimulation, and saturation of the RNAi machinery."

Ref: <http://bioscience.oxfordjournals.org/content/63/8/657.full>

(v) Option 3 and Option 4 are untenable.

Technology is a double-edged sword.

"History teaches us we simply cannot predict the ultimate costs and benefits of new technologies." "The entire history of technology is full of examples where immediate benefits were obvious, but the costs completely hidden and unpredictable *a priori*. If we can't anticipate what the effects will be, we don't even

know what to look for. I think as long as we get caught up in trying to marshal evidence from animal studies, epidemiology and other areas to show harmful effects, the potential consumer and eventual taxpayer are bound to lose.”

Ref: 'Inventing the Future: Reflections on science, technology and nature', Professor David Suzuki, Publ. Allen & Unwin 1990, Page 63.

5) THE MAJOR PROBLEMS ARE:

(a) implementation is coming from the Biotech industry, from companies like Monsanto. Government needs to take control.

(b) the biotech companies that fund the research and new techniques are also bankrolling political lobbyists (even former politicians) and others in an effort to dispel public fears. The public can't get the full story. Political factors are impacting on individual and community health.

(c) The gene tech companies cannot, must not, commission the research work, they must be twice removed from government – kept absolutely at arms length.

(d) handing power over to foreign biotech corporations is reducing our country to a state of infantile dependency, dangerously so. It removes the possibility and incentive to produce our own forms of scientific advancement, fitted to Australia's unique environment and values.

(e) the democratic process is being undermined. Much of the power Australian citizens give to government is being handed over to corporate interests. This is dangerous.

What's being implemented, and the way it's being implemented, makes no sense in civil society. The new kid on the block should not be enabled to bully it's way in. Never seen before is the way consumers are repeatedly ridiculed, shamed and bullied for questioning any aspect of new technologies and new GM products. These are concerning characteristics of authoritarian rule.

(f) 'new techniques' are likely to be a rehash of the patented system, so Australians would end up continuing to subsidize overseas mega corporations; with profits going off-shore.

(g) under the patenting system GM food production brings loss of sovereignty, especially food sovereignty, and threatens our food safety and food security. Government is allowing corporations to hijack our agriculture.

(h) so intent is government on providing “a level playing field” for imports that many of our own high quality Australian companies are bowled out of the game. Australia is throwing away its competitive edge and the basis of its successes, eg by undermining the Australia's organic and GE- free farmers. This is causing great unease, instability and vulnerability. It is not ensuring Australia's future prosperity, nor ensuring a healthy population or a healthy environment. On the contrary.

(i) just as the wheat industry and government are still not taking responsibility for the health impacts on millions of people of modern industrialised “wheat”, it would appear the food biotechnology industry in collusion with government is also doing the same. Such a diabolical state of affairs must not continue. Impacts on environmental health are not being monitored.

(j) There has been no widespread public agreement or debate about the risks and implications of the new gene technologies. Vital, extensive public involvement has not properly occurred. Views of what are “acceptable’ risks in the view of the assessing person(s), can differ dramatically from the views of the Australian public which bears the risk.

(k) The main reason GMOs are accepted into the country as low risk is because it's still too soon for any dangerous potential to be known to science and so they don't feature on our quarantine schedule. It's only when they reveal themselves that they can added to the list.

(l) Genetic contamination (eg arising from Roundup Ready GM Canola) is already happening in Western Australia but political factors appear to be preventing remedial action. Surely this is in breach of Section 3 of the Act.

The “negligible risk” identified by OGTR in its initial assessment has not only been realized, but that risk has also escalated and multiplied. An effective response is urgently needed to manage both the original risks and new emerging risks – why has that response not happened? This indicates a gross failure of regulation of “certain dealings” with GMOs, which urgently needs to be addressed by the *Gene Technology Act* to protect the health and safety of people, and to protect the environment.

(m) Australia would become a test-bed for GMOs.

(n) food biotechnology companies engage in increasingly harmful 'treadmill solutions'.

(o) Australia's priority is to save *existing* species and the irreplaceable role they have in human existence, from disappearing off the face of the planet.

(p) 'failure of technological advances to keep pace with pressures on biodiversity' is a likely major, current and emerging risk to biodiversity. (Ref: Australia State of the Environment report 2011, Commonwealth govt., page 676). This must be addressed.

(q) rules keep changing rapidly, the goal post keeps changing bringing instability and chaos. Underlying reasons need examining.

6) GOVERNMENT MUST ALWAYS GIVE PRECEDENCE TO THE PUBLIC INTEREST.

(a) If not, what is government for? “A task of government is to ensure society functions smoothly. It has already failed terribly through inaction on climate change, GM contamination supposedly on the OGTR's watch, and deep division over GMOs. Chaos ensues.

“It has failed to protect the weak against the strong, defending citizens against aggressors.’ (Ref: *“It seems a good time to ask : what are governments for? We give them power to meet our most basic needs, but they fail us through inaction”* , Anne Coombs, *The Guardian Weekly*, 24 June 2016, last page):

(b)The Australian public interest, human and animal health and welfare, and environmental security in Australia, must always have precedence. Protection of planetary well-being must always take precedence. This is not reflected in the government's actions.

(c)The wrong questions are being asked about introducing radical new technologies ... it is not a debate about the risks and safety of the practice. “it's impossible to know these until the technology is widely used by millions of people, and until the ecosystems on which we all depend have experienced the impacts over the long term. History shows there will be unexpected and deleterious effects”. (Ref: *Extrapolated from 'Inventing the future – Reflections on Science, Technology and Nature,' Prof. David Suzuki, Allen and Unwin Publ, 1996).*

(d)Do we need food biotechnologies, particularly radical / extreme kinds? Are these socially relevant and practical? There is no public imperative to market products of these gene technologies in Australia. There is no proven benefit to Australia. The Precautionary Principle should be exercised.

(e) Farmers want to keep things simple.

(f) No-one to our knowledge, fancies a future of self-inflicted overcomplexity and unpredictability.

(g) The government of Australia has yet to provide evidence justifying the need for new technologies and for the imposition of significant risks to farmers, human beings, animals and the environment, and for imposition of unnecessary added complexity of our Biosecurity, already seriously weakened federally in 2016, and in WA in 2016.

(h) As with the nuclear industry, it seems a major motivation for this radical biotechnology, is to keep an ailing biotech industry alive. That obscures the

fundamental question: do we need a biotechnology industry in this day and age? Is it merely a playing out of the fantasies of a privileged few? Is the innovation skewed towards first world problems? An Inquiry to reassess the role of biotechnology is long overdue.

(i) A major barrier for GM companies is public acceptance. This appears to be an attempt by industry via OGTR to "normalize" GM foods, to have them treated the same as naturally produced foods, and to try to conceal the GM origins by avoiding regulation as much as possible, as well as GMO labeling. Also an apparent attempt to avoid accountability. This is a totally unacceptable.

(j) The overall failure of gene tech companies to substantiate their claims, shows the experimentation and investment is unwarranted. eg The GRDC has remarkably little to show, despite its budget of over \$100 million per year from farmer levies and taxpayer subsidies, spent on GM Research and Development over the past 25 years.

(k) Definitive tests of impacts of GMOs for human health and safety are obviously human trials, but already these are not happening with existing GMOs. Very limited testing is done using laboratory animals ... "lab animals and humans have vastly different gut microbiomes". ((Ref: Glenn Gibson, *Uni of Reading UK*).

7) UNDERSTANDING THE FUNDAMENTAL PURPOSE, THE GOAL OF THE NEW TECHNOLOGIES, IS PIVOTAL. It is crucial to this discussion.

Why should industry's and government's goal of introducing a flood of entirely novel GM foods, foods that have never existed on the planet, be trusted by consumers ?

The grains industry in WA wants to expand GM food production. The overriding goal of the grains industry is to double profits over coming years through large industrial - scale production of a consistent commodity, on large broad-acre farms, with little or no apparent regard for consumers or landcare. Wheat is a prime example. Boosting yields and producing a product for the ease and benefit of manufacturers and retailers has been achieved through intensive hybridization that has given rise to thousands of varieties of modern wheat.

But modern wheat is markedly different to the product grown over the past 10,000 years, even over the past 5,000 years. Significant changes in wheat have occurred over the past 50 years, reflected by the four fold increase of coeliac disease(CD) over the same period, the rapid rise in gluten intolerance and wheat allergies and other wheat-related health issues. Yet deceptively this modern-day product is still called "wheat".

'Modern commercial wheat production has been focused on delivering features such as

increased yield, decreased production costs, and all the while no questions are asked about whether these feature are compatible with human health'. (Ref: 'Wheat Belly', Dr William Davis (cardiologist), Harper Thorsons, 2014). This needs to be urgently addressed. Dr William Davis describes modern wheat as "a perfect chronic poison".

Ref: The Dietary Intake of Wheat and other Cereal Grains and Their Role in Inflammation
<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3705319/>

The wheat industry needs to take responsibility for its role in apparently precipitating an epidemic in CD and other serious wheat-related health issues, yet does not appear to be doing so. All on the government's watch.

Proponents of GM wheat appear to be misleading the OGTR. Will the OGTR now mislead consumers?

8) THE SCIENCE DILEMMA :

The more we know, the more we know we don't know.

In this technical Review, OGTR asks submitters for “scientific evidence relating to risks posed as a result of using new technologies” . OGTR should know that this is an unrealistic request since either the necessary science hasn't yet been done, or isn't made available, especially to the public.

(a) Commercialization and shackling of science has become a serious problem [See Appendix A (Ref: 'State of the World's Science 2016' - “The Truth Brokers”, pages 42 -51 -Scientific American, October 2016). 'This exposes the insidious practice of manipulating the news in the US government and elsewhere; a culture of silence that discourages scientists from speaking out about their work; and the disconnect between what scientists do and what the public hears about'..

(b) OGTR seems forced at times to rely on low quality data from applicants. Most GM applications stem from USA or UK. Disturbingly our Australian regulators rely heavily on the information from US FDA which is “controlled and shaped” by an embargo system. Ref: 'State of the World's Science 2016' - “The Truth Brokers”, pages 42 -51 -Scientific American, October 2016. It seems a similar 'dysfunction' is happening here to control the press. This undermines communication and public confidence.

(c) The public is denied information:

'Virtually all of the university and government websites developed to promulgate information about ongoing animal biotechnology research activities have not been updated in this decade'. While expertise in the animal biotechnology exists, the information is 'thoroughly hidden from public view'.

(Ref: 'Gene technology in the animal kingdom,' Paul B thompson, *The GMO Deception*, S. Krimsky et al, *The Skyhorse Publ.* 2014, page 339).

(d) The public are locked out of access to scholarly articles needed to provide well-informed comment. Information is available only to institutions eg

<http://www.sciencedirect.com/science/article/pii/0378111988904258>

A simple and rapid method for the selection of oligodeoxynucleotide-directed mutants

•[Mark A. Vandeyara](#),

•[Michael P. Weinerb](#),

•[Carolyn J. Huttona](#),

•[Carl A. Batt](#), a

•a Department of Food Science, Cornell University, Ithaca, NY 14853 U.S.A. Tel. (607)255-7902

•b Department of Chemistry, Cornell University, Ithaca, NY 14853 U.S.A. Tel. (607)255-4737

Received 29 January 1988, Available online 16 January 2003

[http://www.annualreviews.org/doi/abs/10.1146/annurev.bb.24.060195.002251?](http://www.annualreviews.org/doi/abs/10.1146/annurev.bb.24.060195.002251?journalCode=biophys.3)
journalCode=biophys.3

'Site directed mutagenesis with an expanded genetic code', by D. Mendel et al, 1995, Dept of Chemistry, University of California, Berkley, USA.

Moreover, online sites are deliberately putting out unprecedented amounts of disinformation. People do not know what to read, as well as how. (Ref: *New Scientist*, 20 February 2016, "WORLD WIDE WARP" by Chris Baraniuk).

(e) 'It is the ultimate hubris of modern humans that we change and manipulate the genetic codes of another species to suit our needs.....

...Genetic modification and hybridisation of the plants we call food crops remain crude science, still fraught with unintended effects on both the plant itself and the animals consuming.' 'Earth's plants and animals exist in their current form because of the end result of millions of years of evolutionary coddling. We step in and, in absurdly brief period of the past half century, alter the course of evolution of a plant that thrived alongside humans for millennia, only now to suffer the consequences of our shortsighted manipulations.'

(Ref: 'Wheat Belly', Dr William Davis, Harper Thorson Publ. 2014, page 228)

(f) Each GM crop must be analyzed on a case-by-case basis, and improved testing methods need to be established and implemented before any product is brought to market (as post-marketing monitoring is significantly more expensive and thereby difficult).

(g) Greater support for our research institutions is urgently needed. Australia lags

markedly behind other countries.

(Ref: *Scientific American*, 1 Oct 2014, *Policy and ethics*, asks “How big is science ? ” globally – and looks at world leaders in science. Australia does not even appear ! This coincides with the sudden demise of CSIRO.

<https://www.scientificamerican.com/article/how-big-is-science/>

(h) Australia has fallen well behind in science literacy, while other countries like China and Singapore are rapidly educating their citizens to be well educated in science. The Biotech industry and government hangers-on appear to take advantage of this to win over as many people as possible. Dialogue and contact is superficial as with most interaction these days, and goes unnoticed. In WA in 2015 and 2016, calls for an urgent public forum on GMOs were ignored by the Minister for Agriculture.

(i) Because of this recently diminished science capacity, It is premature, improper and inappropriate for the Australian government to allow Australia to be targeted by overseas biotech companies for release of GMOs and SMOs. A cynical observer might wonder at the naivety, foolishness and lack of due diligence on the part of government. Australia is vulnerable to abuse and predation.

(j) OGTR professes to rely on “science”. Not everything or everyone can be right. “Science has the ability to be wrong – and with time and patience can do better.” (Ref: *'Inventing the Future: Reflections on science, technology and nature'*, Professor David Suzuki, Publ. Allen & Unwin 1990).

(k) Rule Number 1 : those who need advice are the least likely take it. Many overestimate their capacity to recognize eg a pest problem for humans. Some do not understand the problem. Extraordinary incompetence is not uncommon. Some think they are good at their subject but are not. Scientists are not perfect. Scientists do not have unified ideas. There is a lot of to-ing and fro-ing. Two steps forward; one step backward. There are a stream of scientists who want to publish. OGTR receives low quality data from applicants.

(l) This further emphasizes the need for much stronger, high standard regulatory powers.

(m) The important genuinely long term, independent, peer-reviewed medical and scientific testing for effects on human health and safety are not being done.

(n) Large gaps in knowledge are not being addressed in the rush by the biotech corporations to market their products. Plant genomes are highly complex. Despite rapid growth in the plant technology sector, understanding is in its infancy. Correspondingly the understanding of nutrition and of human and animal microbiomes are still very much in their infancy, so the effects of GM foods on human and animal health are barely explored.

9) THE PUBLIC ARE DENIED THE OPPORTUNITY TO BE PROPERLY INFORMED in the decision-making process.

(a) The low standard of science literacy in Australia is being exploited - inappropriate or biased / skewed decisions result. Any 'innovation' of a highly contentious nature should be open to full nationwide debate.

(b) Science itself is becoming poorly informed. As an example of the dangers of stifling information, the Dept of Agriculture and Food in WA, (DAFWA) has been stripped of some of its lead scientists at the same time as giant biotech corporation Monsanto appears to have gained control by funding a large part of the DAFWA's budget. (Monsanto also bought 26% shares in Intergrain which it apparently sold a short time ago). Notably among those to be removed from DAFWA was a top scientist with a long experience in sheep reproduction. Our guess at the time was that this is to make way for cloning of sheep in WA. By removing the top specialist on sheep reproduction, all knowledge of sheep is likely to be exclusively in the hands of the biotech companies – those responsible for producing the clones. The company acts in self-interest, not in the public interest, so disclosure of information that may be vital to the public interest and public health is likely to be suppressed or not made available to consumers at all. Accountability would be gone unless this situation is rectified. Some describe this as a hijacking of our food supplies. Consumers bear all the risks.

(c) Part of the process used by the biotechnology industry for the manufacture of genetically engineered plants and animals (GMOs) is based on the current extremely limited understanding of plant genomics and animal genomics and other complex interacting factors. Similarly microbial genomics leading to genetically modified microbes. It is far too premature to plan on release of new GMOs arising from new techniques at this point in time.

10) BIOCONTROL

(a) A potential is thought to exist in agriculture for genetic engineering (GE) techniques to improve biological control agents eg for Biosecurity purposes. _

As with naturally occurring organisms, the use of such GMOs would need to be based on a sound knowledge of the entire ecosystem in which the organism would be released, and of how the organism will interact in it.

(b) But with core science and funding now gone, eg in Western Australia which has highly complex and very valuable natural biodiversity, the WA government is unlikely to be capable of providing this necessary independent ecosystem research for a long time.

(c) The OGTR risk assessment frameworks in Australia are still immature.

(d) Both the benefits and serious risks of CRISPR-based gene drive are discussed in the attached publications:

1) (Ref: 'Opinion - Is CRISPR -based gene drive a bio-control silver bullet or a global conservation threat?', 'Land, water, health and biosecurity', CSIRO (WA) & CSIRO (Qld), PNAS, 25 August 2015, Vol 112, No 43).

“Drives

RNA-guided gene drives have the potential to merge the fields of genomic and ecological engineering. They may enable us to address numerous problems in global health, agriculture, sustainability, ecological science, and many other areas ...”

“Of these opportunities, perhaps the most compelling involve curtailing the spread **of vector-borne infectious diseases, controlling agricultural pests, and reducing populations of environmentally and economically destructive invasive species.**”

“Safeguards and control strategies:

Given the potential for gene drives to alter entire wild populations and therefore ecosystems, the development of this technology must include robust safeguards and methods of control (*Oye et al., 2014*).”

“Irrespective of how these biosecurity risks are perceived, we caution that without a regulatory framework that provides a mechanism to work through these issues with clarity and transparency for CRISPRCas9 gene drive, this putative silver bullet technology could become a global conservation threat. Biosecurity is just one of many areas in which CRISPR-Cas9 gene drive technology is being focused “

“Reversibility: The ability to update or reverse genomic alterations at the speed of a drive, not just a drive-resistant allele, represents an extremely important safety feature. Reversal drives could also remove conventionally inserted transgenes that entered wild populations by cross-breeding or natural mutations that spread in response to human-induced selective pressures. However, it is important to note that even if a reversal drive were to reach all members of the population, any ecological changes caused in the interim would not necessarily be reversed. “

(Ref:

EMERGING TECHNOLOGY

Concerning RNA-guided gene drives for

the alteration of wild populations

Abstract Gene drives may be capable of addressing ecological problems by altering entire populations of wild organisms, but their use has remained largely theoretical due to technical constraints. Here we consider the potential for RNA-guided gene drives based on the CRISPR nuclease Cas9 to serve as a general method for spreading altered traits through wild populations over many generations. We detail likely capabilities, discuss limitations, and provide novel precautionary strategies to control the spread of gene drives and reverse genomic changes. The ability to edit populations of sexual species would offer substantial benefits to humanity and the environment. For example, RNA-guided gene drives could potentially prevent the spread of disease, support agriculture by reversing pesticide and herbicide resistance in insects and weeds, and control damaging invasive species. However, the possibility of unwanted ecological effects and near-certainty of spread across political borders demand careful assessment of each potential application. We call for thoughtful, inclusive, and well-informed public discussions to explore the responsible use of this currently theoretical technology.

DOI: 10.7554/eLife.03401.001

KEVIN M ESVELT*, ANDREA L SMIDLER, FLAMINIA CATTERUCCIA* AND GEORGE M CHURCH*

(e) GM CONTROL OF PARASITES:

(Ref: David Pimentel, *Gene Watch*, Vol 2, Nos 4 & 6, Nov – Dec 1985. The author lists ecological procedures for reducing environmental risk).

'Parasite host systems in nature are well integrated genetically, host and parasite have evolved a balanced "demand / supply economy" '. 'Parasite and host coexist in relative stability or "natural balance" '.

..... 'altering the balance by genetic engineering.... could alter the dynamics of the entire natural system. Serious new environmental problems and even an increase in pest problems could result'. eg the "ice minus" bacterium *Pseudomonas syringae*. What if the GM form of *P. syringae* 'adversely effects honey bees, a major crop pollinator responsible for \$20 billion worth of crops, as well as diverse native plants?'

(f) GM CONTROL OF INSECTS:

'The international regulatory and risk assessment framework governing GM insects in general, and GM mosquitoes in particular, are still immature.' (Ref: S Krimsky et al, *The GMO Deception*, Skyhorse publ 2014, pages 254 – 256).

(g) **Release of GM insects** eg "GM mosquitoes raise many scientific, ethical as well as regulatory concerns. In US, public information, consultation and participation is lacking". This must not happen in Australia. Regulatory processes needed to govern the release of GM insects, and mosquitoes in particular, do not appear to exist. There is insufficient experience...and as in USA, there is a 'lack of rigorous risk assessment and robust investigation of unanswered questions and lack of effective and meaningful public consultation and participation". Therefore, any push to release GM mosquitoes at this point would be grossly premature.

(h) A set of protocols would need to be in place to prevent ecological catastrophes, including careful testing, regulation and monitoring prior to widespread release.

(i) GMO and SMO labelling would be essential. Food is increasingly flooded with GMOs and associated chemicals in that food, soil and water. It's important to learn as much as possible about what techniques are used to produce our food, by whom, under what conditions and what impacts are likely on health and the natural environment. Why is the Biotech industry so anxious to hide what it is doing by forbidding any reference to GM on food labels? It is insupportable to deny people the right to inform themselves, and make up their own minds. It is insupportable to deny people and the environment a surveillance system. (Ref: 'Inventing the Future: Reflections on science, technology and nature', Professor David Suzuki, Publ. Allen & Unwin 1990).

11) TECHNOLOGY ALWAYS COSTS. T

(a) While the gen tech corporations seek to gain financial benefits for themselves, the Australian public would be expected to bear not only costs of subscribing, but worst of all, to bear the risks and deleterious outcomes. **Highest costs are adverse effects on human and environmental health.** Children are the most vulnerable and are unwittingly being forced to unjustly bear the heaviest costs and risks.

(b) "A society that doesn't care for its children is a sick society", Harvard University's Nobel Laureate George Wald. "We don't inherit the earth from our parents, we borrow it from our children". (Ref: 'Inventing the Future: Reflections on science, technology and nature', Professor David Suzuki, Publ. Allen & Unwin 1990, page 66).

(c) "Human error is the one predictable but uncontrollable element in any new technology". "However clever we are, there will *always* be accidents involving our technologies." David Suzuki page 67. Accidental releases are inevitable. The Chernobyl and Fukushima nuclear accidents attest to this.

(d) Just as with man-made chemicals, many of which have never existed before and are highly toxic yet almost indestructible, GMOs and SMOs pose a whole new set of problems and cumulative risks everyone can well do without. Regulatory agencies are not adequately well structured, they do not have the capacity to assess the full nature and extent of new risks. All the possible long term "costs" of these new technologies cannot be anticipated because our knowledge of the biological and physical world into which they are being forced to enter is so incomplete.

(e) "When we choose the technological road, it takes us on a one-way route beyond constraints imposed by millions of years of evolution into strange territory where we have

to keep improving constantly". (Ref: *'Inventing the Future: Reflections on science, technology and nature'*, Professor David Suzuki, Publ. Allen & Unwin 1990).

(f) "Animals are miner's canaries, our environmental indicators, extinctions are a warning to us that something is wrong. Thanks to Evolution our complex nervous system informs us of immediate threats to our bodies. Existing species are integral to this warning process", and also serve as environmental indicators.. .

(g) "We can no longer afford to ignore ecological principles in everything we do. Ref: *'Inventing the Future: Reflections on science, technology and nature'*, Professor David Suzuki, Publ. Allen & Unwin 1990, Page 67). Before any new technology or technological process is allowed, long term environmental consequences of its outcome must be seriously considered. These costs must be an integral part of the market price of any new product derived from it. "

(h) "The sheer weight of human numbers and per capita consumption add up to a massive impact on all other life forms that share the planet with us. We lack biological controls, drain all life needs from other species and disperse our technological toxins throughout the biosphere." (Ref: *'Inventing the Future: Reflections on science, technology and nature'*, Professor David Suzuki, Publ. Allen & Unwin 1990, Page 68.). In a similar way genetic pollution from biotech experiments is likely to pose major risks to biodiversity and biosecurity.

12) PROPOSED INTRODUCTION OF CLONED and MUTANT ORGANISMS:

CLONED ANIMALS:

(a) Genetic manipulation of animals favours industrial scale production settings - exploitative use of animals on an industrial scale. This is not in the interests of the animals *per se*, nor the thinking farmer or GM contractor or consumer. .Any instrumental use that is contrary to the animal's interests we would expect to be prohibited. The concept and the conditions are abhorrent to most consumers.

(b) Industrial scale production of clones reinforces and expands monocultures which are notoriously more prone to large scale pest and disease outbreaks, sometimes causing total and permanent losses to farmers. GE companies would most likely seize these opportunities they themselves have created, to offer costly 'treadmill' GM solutions...Surely government leaders would not be gullible or foolish enough to lock Australia into such a monstrous practice. A practice which shows no respect for our country or its people.

(c) Standards of husbandry would be likely to decline. Would producing a cloned variety of animal that had a greater tolerance of poor living conditions in order to address welfare problems in industrial production settings, be something our society would accept? The argument against this is that farmers in Australia should respond to these problems by improving the animal's living conditions, rather than trying to produce an animal that is not adversely affected by existing poor conditions.

(d) Genetic technologies have the potential to impose suffering on animals. The governance framework for animal research should take this into account when contemplating introduction of cloned animals. It is unacceptable that this does not appear to be considered.

(e) With lower standards, the potential is significantly raised for diseases to take hold. GE companies then would no doubt seize the opportunity to offer costly 'treadmill' GM solutions...

(f) Weak regulation is noted for cloned animals and poor welfare – this is unacceptable. Unregulated genetic engineering of animals would provide further opportunities to raise the many animal welfare and rights concerns of which OGTR and the community should be made aware.

(g) 'Animals have a “nature” or an integrity to their being that biotechnology fails to respect. They have an evolutionary history of their own'. [Tom Regan, 'The case for animal rights' 2nd edition, Berkeley: University of California Press, 2004].

(h) The standard for animal integrity is unclear in the agricultural and veterinary chemicals code act 1994. Ethically-oriented critics of food biotechnology suggest traditional forms of livestock farming, and organic farming especially, set the standard for animal integrity. Specific GM and SM manipulations of animals determine that animal health and welfare is an ethical issue.

(I) Most US pedigrees require the cloning status of an animal listed in its pedigree. US and Chinese are producing the clones. Only US has specifically approved cloned animals for food. European Parliament has called for an outright ban on clones and their offspring.

(j) Tracking of clones and offspring is essential eg to ensure they will not enter the food chain. Government agencies in Australia lack authority (as well as funding) to certify

activity of the private sector . Ref: 'Paul B thompson, 'Gene technology in the animal kingdom', 'The GMO Deception', S Krimsky et al, pages 329 – 339).

(k) Just as agricultural biotechnology has so far produced a multitude of problems arising from GM plants, many believe the same will occur with animal biotechnology, including gene contamination and super pathogens.

CLONED PLANTS

(a) It is easy to exactly duplicate many plant species without genetic engineering techniques.. Plants capable of vegetative reproduction, grown under identical conditions, generally give rise to identical offspring. Vegetative reproduction evidently has an advantage for some. The success of *vines* provides an example how of this method of reproduction can be potentially helpful but often very troublesome to humans and the environment. Vines can also reproduce sexually, multiplying their invasive capabilities.

Eg Native Biocontrol - *Cassytha pubescens*, or devil's twine, is the first native plant to be investigated for use as a weapon against invasive weeds introduced to Australia by European settlers in the early 1800s. 'While the strategy makes sense ecologically, the success of biocontrols is very difficult to predict', says Roger Cousens, University of Melbourne.

Leslie Weston ,Charles Sturt University, NSW, agrees the strategy has potential. "The issue is how you manage the *Cassytha* itself once it's established because it's obviously not something you want to be extended past its natural range," she says. "Although *Cassytha* might not have an as adverse effect on the natives, it can still have an effect."

"Usually when you pick a biocontrol organism, you pick one that is incredibly specific to the host you're trying to decimate. **This is a non-specific option so it would have to be very carefully managed,**" says Weston.

(Ref: *New Scientist*, 'Vampire vine helps destroy alien European weeds in Australia', Alice Klein, 22 April 2016).

<https://www.newscientist.com/article/2085389-vampire-vine-helps-to-destroy-alien-european-weeds-in-australia/>

But many more introduced vines have attained pest status in Australia, and are difficult to eradicate.

(Ref: *New Scientist*, "Planet of the vines : Climbing plants are taking over", William Laurance, 2 Oct 2013).

<https://www.newscientist.com/article/mg22029370-900-planet-of-the-vines-climbing-plants-are-taking-over/>

(b) Artificially extending the capability of self-reproducing to other plants raises similar issues that would need to be approached with great caution, and closely investigated and monitored over the long term.

(c) Artificially cloned plants may not turn out identical as planned. A great many plants show a natural capacity for marked variation under differing conditions eg soil and climate, water availability etc.

(d) Selecting parent plants with no apparent capacity for variation would be unwise in view of climate disruption with its uncertain future. Obviously plants with a natural capacity for variation have an adaptation advantage.

A great deal of research remains to be done on this by CSIRO, Departments of Agriculture and our Australian university research institutions.

However for no sound reason, the research base of the WA Department of Food and Agriculture has been virtually decimated by the current government. This is a cause of great dismay and concern across the entire community.

13) BIOGENETIC WASTE ISSUES ARE INEVITABLE.

(a) A credible regulatory framework for dealing with GM biogenetic waste is essential. We know of none.

(b) With the new biotech industry has come a new form of waste which has the potential to spread disease or undergo genetic exchange. 'Both cloning and mutagenesis experiments involve discarding a lot of unwanted live outcomes. Genetic material can be transferred between organisms of different species, genera and even families. 'The rapid spread of antibiotic resistance among bacteria in clinical settings is an obvious example of the ease with which certain kinds of genetic exchange take place'. 'If something can happen in the lab, it can happen in a real world'. 'In considering biogenetic waste it is important to remember the major legacy the chemical industry has left untold billions of metric tons of toxic waste that poison our environment even today'.

(Ref: 'The GMO Deception', S Krimsky & J Gruber, Pages 202-203, Skyhorse Publishing, 2014).

(c) It seems likely the necessary consistent, high level preventive care and biosecurity checks would not be forthcoming, with inevitable harmful outcomes. The scope of national and WA biosecurity excludes GMOs. Would the biotech industry be given self-regulatory responsibility for storage and disposal of their GMOs and SMOs? Everyone knows a company cannot regulate itself. What audits or cross-checks would be made to ensure industry meets Australian safe standards of compliance? Evidently from the experience in WA of widespread genetic contamination arising from Roundup Ready GM Canola, supposedly on OGTR's watch, it' seems clear no safeguards, no security would be in place. This is unacceptable.

(d) If not our regulators, who would undertake ongoing monitoring and be given oversight at the taxpayer's expense? Who will be checking for environmental genetic contamination? The baseline for monitoring is no GMO presence and no pesticide residues.

14) KEEPING BASELINES IS A REQUIREMENT OF SOUND

SCIENCE. Our food sovereignty, food security and national biosecurity require baselines. Government must therefore ensure that at least South Australia and Tasmania remain GM-free in the long term. These can serve as baselines. WA provides a very suitable baseline but unfortunately 'the horse has already bolted' with the introduction of GM Canola, now contaminating farms, and private land across the southwest – all supposedly on the OGTR's watch.

The **Organic agricultural sector enables a baseline to be kept.** What other baselines does Australia keep?

15) AUSTRALIA WOULD BECOME A TEST-BED FOR GMOS:

There has been no widespread public debate and no agreement about the risks and implications of radical new technologies /techniques. Vital, extensive public involvement has not properly occurred. This in itself is unacceptable.

Views of what are "acceptable" risks in the view of the assessing person(s). (OGTR) can differ dramatically from the views of the Australian public which bears the risk.

16) FARMERS WOULD BE PERSUADED TO SUBSCRIBE TO STILL MORE 'TREADMILL SOLUTIONS' which on the best scientific advice is ill-advised.

17) SOCIETAL HEALTH

(a) In highly industrialised countries like ours, the understanding, and the sense of permanence and connection to nature is already unhealthily weakened, directly and indirectly leading to health and social problems. Introducing these "innovative new technologies" would be even more detrimental. Is account being taken of the benefits and rights of non-industrialised societies?

(b) Federal government has already committed a gross distortion of scientific truth and moral sensibility by wrongly classing animals as "goods" ; as another "commodity".

The accumulated history of life on Earth should never be rendered less important by commercial play.

(c) All societies and major religions of the world recognize that the role of all governments is sound stewardship of the planet and its naturally diverse life forms, its structural /ecological foundations and functionality, and its complex, interactive living systems.

Ref:

https://books.google.com.au/books/about/A_Guide_to_International_Environmental_L.html?id=I6H0uEQ_mv4C

Sound stewardship is lacking alarmingly in recent times in Australia.

(d) In matters of biosafety especially, Australia has international obligations and responsibilities relating to environmental protection, which have a role in national and local policies.

Ref: 'Guide to International Environmental Law', Alexandre Kiss & Dinah Shelton,

https://books.google.com.au/books/about/A_Guide_to_International_Environmental_L.html?id=I6H0uEQ_mv4C

'International Environmental agreements: politics, law and economics' , Ed by Joveeta Gupta ISSN-1553 (electronic version) Journal no 10784

<http://www.springer.com/law/environmental/journal/10784>

(e) THE CONFLICT BETWEEN ECONOMIC PRIORITIES, ENVIRONMENTAL PROTECTION AND SOCIETAL VALUES HAVE YET TO BE RESOLVED.

'Aboriginal people inform us of the reality and power of other values. Their relationship to their homeland is of far greater value than anything economic, it represents a value beyond price.'

“To all aboriginal people who are fighting for their identity and culture: Those of us who seek to live in balance with nature and leave some of the wondrous diversity of life for generations to come have much to learn from you ” (Dedication). .

(Ref: 'Inventing the future', Reflections on science, technology and nature', David Suzuki, Stoddart Publ, 1989, pages 246 -7) .

Aboriginal people hold a holistic view, lacking in western society: “The Earth is our mother and first friend”.

18) SYNTHETIC ENGINEERING OR EXTREME ENGINEERING TO

PRODUCE SYNTHETICALLY MODIFIED ORGANISMS (SMOs) HAS A DARK SIDE: -

(a) Releasing an SMO into the environment intentionally or unintentionally could have serious and irreversible effects on the ecosystem (Fuller, Page 138). SMOs may become the next invasive organisms, finding an ecological niche, displacing wild populations and disrupting entire ecosystems. (Ref: M. Rodemeyer, 'New Life, Old Bottles: regulating the first generation products of synthetic biology', Woodrow Wilson International Centre for Scholars, Synthetic Biology Project).

(b) It is thought SMOs will lead to genetic pollution, as commonly happens with GMOs, and create synthetic genetic pollution which will be impossible to clean up or recall.

(c) Using genes synthesized on a computer instead of those originally found in nature also raises questions about human safety and the possibility that SMOs could become a new source of food allergens or toxins. Cyber-hacking is a major threat..

(d) Possibly more hazardous is that DNA sequences and genes being used are increasingly different than those found in nature. Our ability to synthesize new genes is` fast outpacing our understanding of how these genes and the systems they are being inserted into actually work.

(e) The difficulty of assessing the safety of a single GE organism will be raised enormously by the use of Synthetic Biology. To date no scientific effort has been made to thoroughly assess environmental or health risks of any synthetic organism and these can have tens or even hundreds of entirely novel sequences.

(f) Biotechnology is already poorly regulated in the US and SMOs and new types of GMOs will only push the boundaries of this antiquated system. WA looks to US-derived regulation. The possibility is opened for the introduction of completely unregulated crops. This is totally unacceptable.

(g) How would the microbiomes of synthetically produced animals differ from those of natural animals? What issues does this raise for human and animal health?

19) SOME OF THE RISKS:

(a) Our current way of regulating GMOs as new animal drugs that do not require proper analysis of risks to human health, to the health of wild populations and to the environment is nonsensical. No estimations appear to have been done of the economic impact these GMOs might have when things go wrong. Nor estimations of the level of transparency needed to guarantee a reasonable level of public participation in decision making process, effective responses to, and management of, emerging pest or pathogenic

forms of GMOs.

(b) Likely major risks arise from slow progress on understanding the relationships between population, economy, technology and biodiversity, and communicating this to the public

(c) Genetic pollution from GMOs and SMOs represents a major risk to native species and biodiversity.

(d) Likely major risks are from failure of technological advances to keep pace with pressure of biodiversity.

(e) Failure to establish processes for collecting relevant data to provide early warning of threats and opportunity for biodiversity management poses possible major risks.

(f) Agricultural biotechnology so far has produced a multitude of problems, many of which would be exacerbated by synthetic biology, including gene contamination and super weeds.

(g) Major risks are market based approaches to managing biodiversity driving decline rather than sustainability. (Ref: *Australia State of the Environment Report 2011, "Current and emerging risks to biodiversity"*).

(h) Handing over CRISPR techniques to amateurs, is apparently proposed by GENSPACE, through children's SciTech Centre in Perth, 2016. GENSPACE appears to envisage the ability to genetically engineer new species becoming widely available and used by a range of skilled and unskilled people.

(I) Possible major risks to biodiversity are from major changes in food-production technologies reducing the numbers of people living in regional Australia and managing the land for personal and public benefit. (Ref: *Australia State of the Environment Report 2011, "Current and emerging risks to biodiversity"*).

19) AUSTRALIA LACKS ADEQUATE PROTECTION MEASURES.

(a) A major and rapidly increasing threat is cyber-hacking. Prime Minister Malcolm Fraser on ABC FM radio news, 24 Jan 2017 warned: *"Cyber-hacking is the new frontier of warfare."* Even the US Pentagon and our ASIO have been hacked. Gene technology data is not immune. CRISPR, Synthetic Biology and other new gene techniques have the potential to build new organisms from scratch and 'gene edit' others, greatly increasing challenges and risks to biosafety.

(b) Without absolute protection against hacking, no new computer-derived technologies should be introduced. Obtaining absolute protection is highly unlikely.

(c) What steps would be taken to ensure protection of national security? Invasion by stealth cannot be ruled out. Regulatory capture / loss of regulatory sovereignty are a real and present danger. New or exacerbated health and environmental issues arising from experimentation with new technologies risk security.

(d) Risks to safety of some new technologies are extreme – the Precautionary Principle should be applied.! Failing that, strong regulation, strict compliance measures and utmost caution on all new techniques and their products would be absolutely imperative, as these organisms have no history of safe use and many are likely to cause may cause intractable biosafety problems. The logistics and huge cost on ensuring safety would far outweigh any benefits of implementing such new techniques.

(e) A Biosafety Protocol is imperative in Australia, but we have none. UN's Biosafety Protocol is supported by 170 member countries, emphasizing Australia's backwardness. Protection of human health and environmental health depend on a Biosafety Protocol..

(f) A Biosafety Protocol in Australia would allow our country to bar imports of genetically altered seeds, microbes, animals and crops they regard as a threat to their environment.

(g) Biosecurity would need to be greatly increased but instead is being seriously weakened, and the scope does not include GMOs. Just as agricultural biotechnology has so far produced a multitude of problems, many believe the same will occur with animal biotechnology, including gene contamination and super pathogens.

(h) An Appropriate Level of Protection Policy (ALOP) is urgently needed in conjunction with the work of OGTR. We do not have one.

(i) Needed is a tracking system through the food supply. We do not have one

(j) Human, animal and environmental health and safety cannot be assured.

GMOs and SMOs require very high level biosecurity surveillance, diagnostics and management in the absence of:

-a Precautionary Principle appropriately applied to GMOs.

-a legal framework to deal with GMOs.

-a dedicated, long term, national surveillance system for the potential health effects of GMOs

- GMO targeted state pre-border, border and post-border monitoring system.

(k) Surveillance and intelligence strategies that target GMO and SMO biosecurity threats, and provide means of early detection and eradication or containment – currently not covered by Biosecurity !

(l) Until these matters are properly addressed, all decisions on approval new technologies/ techniques cannot be made.

(m) Government would need to enforce contingency plans, in the event GMOs and SMOs caused an emergency. Accidents are inevitable. Are there credible plans in place? No-one yet knows what to anticipate. How would such an emergency be dealt with if it went beyond Australian borders? What liability would Australia face?

20) SERIOUS BIOSECURITY CONCERNS:

(a) In the CSIRO Biosecurity Future Report, listed is a 'megashock - the government 'walking away' from environmental biosecurity.

<http://www.csiro.au/en/Research/Farming-food/Innovation-and-technology-for-the-future/Biosecurity-Future-Report>

(b) New biotechnologies and their products therefore cannot be used in Western Australia, as this 'walking away' from Biosecurity has already begun here. We note with considerable community concern, the WA Biosecurity Council 10 July 2015 report indicating the WA Government is attempting to hand over Biosecurity to industry and the community, apparently taking no responsibility itself. Stakeholder engagement is in question as genuine "community" participation has not occurred, local government involvement is apparently very restricted and not named.

The Auditor General (OAGWA) has cited the role of DAFWA under the current BAM Act. **DAFWA has responded saying it is limited to education, it does not have the staff or resources for control operations, so DAFWA appears unable to fulfill its primary role under the BAM Act.** This appears leaves Western Australia largely defenceless in a biosecurity emergency.

DAFWA's reply to the OAGWA suggests that the department now only provides information, and is no longer engaged in surveillance and pest and disease control operations. This a serious, unacceptable state of affairs. In WA responsibility appears to be handed over to the public. The public does not have the expert knowledge or resources to deal with pest and disease control. Very few among the public would be aware of all this. Eg DAFWA no longer has a bee researcher despite the rising problem of commercial bee decline.

(c)The govt talks of "agility, innovation and leadership in science" but how? Independent scientific expertise is necessary in the interests of public health and wellbeing but is not forthcoming, indeed it is even being suppressed. .

(d)The potential current and emerging Biosecurity risks of introducing genetic engineered technology into Australia are listed as possibly 'major' to 'catastrophic'. [Ref: Australia State of the Environment report 2011, Commonwealth Govt].

(e) it is vital that "industry" does not end up controlling biosecurity. Which industry? Predatory multinationals intent on colonialism? Industry cannot be trusted, it acts in self-

interest, not in the public interest.

(f) Cumulative risks from GMOs from all new technologies are being rapidly raised at the same time as our state and national biosecurity has been weakened. This is dangerous and foolhardy – eg in WA,, human health, animal welfare, food safety, contamination and chemical residues were removed this year from the definition and scope of WA 's Biosecurity, even though under WA State legislation (BAM Act 2007).all these can, and properly should be included. At the same time GMOs are excluded without explanation. Why the concurrence? Would SMOs and all products of new radical /extreme GM techniques also be excluded?

In this way both the new changes to national biosecurity (Biosecurity Act 2015, effective since 16 June 2016), and the new WA biosecurity strategy 2016 – 2025 **have improperly preempted this OGTR review.** These are just cause for outrage, cynicism and deep distrust.

M and P Wilson

Plases advise if you require more details, references etc.