

2017 Review of the National Gene Technology Regulatory Scheme

5th September 2017

Many thanks for the opportunity to make a submission to this Review.

We understand that this review is looking at the broader or contextual issues so the National Gene Technology Review scheme can respond appropriately to emerging issues. The review will look at the Gene Technology Agreement and its interface with other regulatory schemes.

We wish to have the following issues reviewed:

1) Where is the research showing that the health and safety of people and the environment has been protected from GM? (Term of Reference 2)

- a. No epidemiological data on health effects of eating GM
- b. No testing or monitoring of glyphosate based herbicides (GBH) in our food, water or bodies
- c. Peer reviewed studies show GM crops and related pesticides are harmful
- d. People and animals' health mirror peer-reviewed studies' findings
- e. GM crops cause an increase in pesticides, super pests, super weeds and antibiotic resistance
- f. Monsanto Tribunal finds abuse of numerous human rights including the right to food, health and a healthy environment.
- g. Suppression of scientists and relentless trolling to misinform the public and decision makers by the GM industry
- h. Regulators dismiss peer reviewed science on spurious grounds and companies attack, intimidate and try and defund scientific body, IARC.
- i. GM industry manufactures an echo chamber of false reports, studies and third party endorsers.
- j. GM industry wins with fake news

2) Where is the evidence showing that Gene Technology is a safe and needed development? (Term of Reference 1)

- a. Precise and predictable genes and GM is a mirage, not science.
- b. Patents and neoliberalism mean companies avoid transparency and accountability
- c. Results of gene technology are the opposite of what was promised
- d. GM crops are dangerous to the climate, biodiversity and health and rely on misinformation, fraud and aggression
- e. Agroecology cools the climate, restores the soil, local economies and feeds people well, where is the Agroecology Act, enabling regulators and research support?

3) Transparency and accountability must be legislated into the Scheme. (Term of Reference 3)

- a. The definition of GM must be left as it is so it captures all the new GM techniques.
- b. Transfer of power from the commons to the private realm
- c. Legislation to protect the health and safety of people and the environment must be part of the Scheme.
- d. Legislation for compensating harm must be created and the ability to stop technology must exist
- e. Recognition that this is life altering, and possibly planet destroying, technology
- f. We need to put people's needs first.

4) Funding arrangements must ensure the protection of people's health and safety and that of the environment. (Term of Reference 4)

- a. People have a right to participate in their health and safety and that of their world
- b. What are the cost/benefits of GM to people and the environment?

The object of the Gene Technology Act 2000 is to protect health and safety of people and the environment.

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

1) Where is the research showing that the health and safety of people and the environment has been protected from GM? (Term of Reference 1)

The Term of Reference No 2 states the desire for "an agile and effective Scheme which ensures continued protection of health and safety of people and the environment."

The claim is "continued protection". For this to be proven there needs to be some evidence that people and the environment <u>are</u> being protected.

• No epidemiological data on health effects of eating GM

There has been no epidemiological research anywhere in the world to show the effect of eating GM food on people. GM labelling is inadequate everywhere, meaning no studies can be done as people do not know when they are eating GM.

No testing or monitoring of glyphosate based herbicides (GBH) in our food, water or bodies

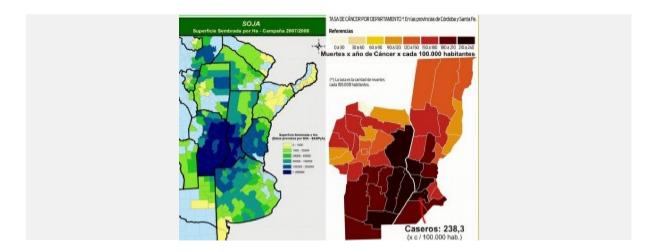
Overseas testing has shown GBH in food, water, alcohol, rain, urine and breastmilk in most of the samples taken. Australia has no assessment of the level of glyphosate in our food, water and bodies. This is unacceptable especially considering it is the most widely used pesticide and that GM crops have massively increased our exposure to it. The most prestigious research body into cancer, the WHO's International Agency for Research into Cancer (IARC) found glyphosate to be a probable carcinogen.ⁱⁱ

• Peer reviewed studies show GM crops and related pesticides are harmful

Numerous peer-reviewed studies show harm from animals fed GM crops and their associated pesticides. The damage includes: Non-alcoholic fatty liver diseaseⁱⁱⁱ, liver and kidney toxicity^{iv}, increased allergy potential^v, novel proteins and toxins, immune and endocrine dysfunction, damage to the gastro-intestinal system^{vi}, and birth defects^{vii}.

People and animals' health mirror peer-reviewed studies' findings

Doctors, vets, farmers and people are finding that removing GM food and pesticides from their diet improves health. In Argentina, the health crisis from GM crops and pesticides led to physicians organizing conferences reporting on the cancers, birth defects and respiratory illnesses that emerged only following the introduction of GM soy. "The research also shows that the incidence and prevalence of cancer in general triple the ones observed in cities, that oncological patients are younger than expected, that endocrine and respiratory problems double the expected prevalence, and that the impact on reproductive health is impossible to hide.



Distribution of crops resistant to glyphosate and distribution of cancer mortality in Cordoba and Santa Fe, according Minagria and provincial Ministry of Health

The rate of unexplainable spontaneous miscarriages of wanted pregnancies goes from 10% to 22% in women of reproductive age within a period of 5 years, and the rate of children born with malformations are two or three times higher than the expected rates or those observed in the rest of the country." viii

GM crops cause an increase in pesticides, super pests, super weeds and antibiotic resistance

Two thirds of the glyphosate used in the US since it was first released in 1974 has been used in the last 10 years. Glyphosate use worldwide has risen 15-fold since the introduction of GM crops. Evolutionary pressure on pests and weeds caused by the use of GM crops has resulted in super pests and weeds and the use of increasingly toxic pesticides and combinations of pesticides. Antibiotic resistance bacteria caused by GM have been found in every river tested in Chinaxi and in air from feedlots in the USxii. Australia has done no research into the environmental effects of GM in the soil, water, or in respect of plant and animal pathologies. It is likely that human and environmental health is severely affected by GM crops and pesticides.

 Monsanto Tribunal finds abuse of numerous human rights including the right to food, health and a healthy environment.

Five judges listened to 28 witnesses from all around the world report on human, plant and animal illnesses and the damage to the environment caused by GM crops and their associated pesticides. The full testimonies can be found on the Monsanto Tribunal site^{xiii}. They include reports of birth defects^{xiv} caused by exposure to Roundup, the most widely used pesticide on GM crops and a probable carcinogen, mass kidney disease in Sri Lanka^{xv}, cancer^{xvi}, and animal^{xviii} and plant^{xviiii} pathology.

• Suppression of scientists and relentless trolling to misinform the public and decision makers by the GM industry

The Monsanto Tribunal found that the human right to free expression and the freedom indispensable for scientific research was being abused xix. This is being corroborated by evidence produced in a court case in the US where Monsanto is being sued over cancer caused by glyphosate based herbicides. Documents show: collusion between regulators and Monsanto xx, Monsanto s distortion of science xxi, Monsanto ghostwrote xxii its supposedly independent safety review, it orchestrated a fraudulent campaign to get Professor Seralini's study retracted (now republished) and it employs an army of trolls and relentless PR to attempt to silence any critical voice xxiv.

 Regulators dismiss peer reviewed science on spurious grounds and companies attack, intimidate and try and defund scientific body, IARC.

Peer reviewed science showing harm is frequently dismissed by regulators here and overseas, not by reference to other peer reviewed studies but by reference to industry research,

sometimes secret, or to internal reviews and assertions of safety by the regulator. This is inadequate especially as the public has no rights to a merit based review of GM approvals, unlike the GM companies. Decision making bodies, like the Forum, rely on information from bodies like FSANZ who have never refused an application for a GM food and whose work has been criticized^{xxv}. It doesn't matter how well researched an objection is, or how full of scientific gaps the application is, GM foods are always approved.

The Australian Pesticide and Veterinary Medicines Authority (APVMA) has dismissed the IARC finding on glyphosate as a probable carcinogen^{xxvi}. They refer to assessments done by EU agencies which have been shown to allow industry to write and edit their documents^{xxvii} or who have conflicts of interest^{xxviii}. The chemical industry has been running a campaign to discredit the IARC and remove its funding^{xxix}. This is the predicable reaction of an industry but is predatory, sinister and cannot be tolerated. Governments and regulatory bodies are here to look after the public interest, not to be intimidated by outrageous behavior by an industry they are supposed to be regulating.

• GM industry manufactures an echo chamber of false reports, studies and third party endorsers.

Brookes and Barfoot of PG Economics produce numerous reports favourable to the GM industry^{xxx}. Their reports are quoted as if they are not commissioned by the industry. The same is true of Clive James of the ISAAA^{xxxi} which routinely glosses over the failures of the industry. Scientific studies are claimed to show safety or farmer benefits when they do no such thing. Alison Van Eenenaam, an ex-Monsanto employee, claims billions of animals have eaten GM feed, proving it safe. Over 90% of the animals were broiler chickens killed at 49 days. Other studies claimed to be long term were not. There were no controls, no one knew how much GM feed they were fed, no histopathology was done to see the health of the animals and no one knew whether changes in husbandry had any effect on the animals^{xxxii}. This study is entirely irrelevant to human health but is treated by the GM industry as proof of safety.

A meta-analysis (Klumper and Qaim 2014) reports that GM crops have benefitted farmers in India and reduced pesticides. These studies are highly selective in the crops and time frame they examine. They concentrate on the early years of growing GM before pest resistance and ignore the later years where GM crops lost their efficacy and new pests developed xxxiii.

Not one GM food we are eating that has had long term, multi-generational, developmental and toxicological studies done on it. Lists of studies claimed to show safety are a hodgepodge of irrelevancies that cannot prove GM is safe for people to eat^{xxxiv}. A 10-year EU study claimed to show safety only has 5 animal feeding studies in it. None of them are on a commercialized GM food^{xxxv}.

Groups of third party advocates and scientists, who appear to have no connection to the GM industry, promote GM and attack critics. They include Jon Entine of the Genetic Literacy Project^{xxxvi}, Bruce Chassey and David Tribe from Academics Review^{xxxvii} and Kevin Folta from GMO Answers and the University of Florida^{xxxviii}. Their links with the industry have been revealed leading to doubts about their credibility. Even universities like Cornell have been shown to have an unhealthy link to their corporate funders leading to the silencing of academics and promoting GM^{xxxix}.

The GM industry presents any criticism of GM as due to biased scientists, against whom they mount vicious and unjust campaigns. This suppresses important evidence of harm. Seralini is one of the scientists. His study showing liver and kidney damage as well as unexplained tumours, has been republished yet our regulator FSANZ still treats this as a retracted study on its webpage. This is despite a clear, unfair, mercenary campaign to discredit Seralini revealed in recent court documents. This happened as his research showed that the GM industry is making rats, and therefore probably people, ill. Their actions are a desperate attempt to avoid responsibility.

• GM industry wins with fake news

It is spectacular that the industry is treated seriously despite agronomic failure reported worldwide from the US to India, peer reviewed studies showing harm and reports from farmers, doctors and the public about improved health when GM and pesticides are removed from the diet. The GM industry is a master at creating fake news to suppress real harm and distress. The details and references as to how this is done can be read in these reports Spinning Food^{xl}. The harassment of scientists^{xli}, pressure on regulators^{xlii} and manipulation of the media^{xliii} is explained in Monsanto Tribunal presentations.

MADGE requests investigation into the health and environmental effects of GM crops and their associated pesticides to ensure the Scheme is carrying out the object of the Gene Technology Act.

2) Where is the evidence showing that Gene Technology is a safe and needed development? (ToR1)

Term of Reference 1 aims to make recommendations for existing and future advancements in technology. This assumes that the current actions and future developments are beneficial. Once again there needs to be discussion of this.

• Precise and predictable genes and GM is a mirage, not science.

Companies have patented the essentials of life, namely food and organisms, using now discredited assumptions about genes and nucleic acids (DNA and RNA). DNA was discovered in the 1950s and was heralded as the master molecule. Many people still assume that their DNA is fixed and unchangeable. Recent science has shown that genetic information found in DNA and RNA operates at the level of the cell. The cell, not DNA, is the basic unit of life. Cells repeatedly carry out many functions, genetically engineering RNA or DNA will have a cascade of secondary effects within these cells. None of these are tested for or evaluated.

Humble microbes create earth's climate and make all life on earth possible. We cannot exist without the microbes on and within us. Genes are not discrete items like Lego blocks but work in families. What they make, and who they make it with, depends on the situation. Everything is interconnected and iterative therefore the idea that you can alter a gene or strand of RNA and predict what it will do, and claim it will only do one thing, is magical thinking.

Patents and neoliberalism mean companies avoid transparency and accountability

The development of gene technology is happening in an environment of neo-liberalism. This is an extreme form of capitalism created by deregulation, privatization and globalization. In this worldview profit is the aim and patented technologies that make private profits are seen as the natural focus of science and society. Multinational corporations have evaded responsibility for their technologies including: avoiding full labelling, avoiding adequate and long term testing of their products, using their influence to spread misinformation and their financial power and avoiding being responsible for the economic, social and health effects of their technology.

Results of gene technology are the opposite of what was promised

What is gene technology supposed to be for? If it is for increasing yield, it has failed as it produces the same or less than non-GM^{xliv}. The weed killer dicamba, sprayed on the new GM crops, is drifting and killing or deforming neighbouring crops in the US^{xlv}, farmers affected in this way are not covered by insurance. If it is for enriching farmers, it has failed as it is more expensive. If it is to reduce pesticide use, it has failed as it has increased use. If it is to control the food system, it has had partial success as, if all the planned mergers go ahead, only four chemical companies will control almost all commercially traded seed. If it is to sell more herbicide it is a success. If it was to give consumers choice it has failed as it is not labelled and it contaminates non-GM and wild plants.

• GM crops are dangerous to the climate, biodiversity and health and rely on misinformation, fraud and aggression

GM technology is highly dependent on the fossil fuel industry, it is part of the monoculture, global food industry that is bankrupting farmers, producing junk food and ruining the climate. Numerous reports show that we urgently need to move away from this system of farming if we are to survive this century as a species xlvi. A recent UN report found that pesticides used on GM crops and in industrial farming are killing 200,000 people a year directly and harming countless more. They are not needed to grow food and they are only continuing to be used due to the aggressive tactics of the industry xlviii.

Glyphosate, the weed killer used on most GM crops, was approved in 1974 using studies done by the Industrial Bio-Test Laboratory. It was nicknamed 'The Swamp' as the animals were so badly treated they died and decomposed in their cages. Scientists swapped dead animals and made up data. It was eventually closed due to fraud but none of the chemicals approved, including glyphosate, were required to be retested vlviii.

Endocrine disruptors, many of which are pesticides, are reducing IQ, increasing infertility and autism and causing a huge cost burden on the government and private grief to countless families^{xlix}. This can only continue if policy makers, the government, farmers and the general public continue to uncritically accept the platitudes of scientists with a vested interest and corporations. To maintain this stance will have catastrophic effects.

• Agroecology cools the climate, restores the soil, local economies and feeds people well, where is the Agroecology Act, enabling regulators and research support?

Agroecology can double yield in the places that need it most while reducing rural poverty and cooling the climate¹. Local food systems reduce food insecurity and build community and economies. The world produces more than enough food to feed everyone yet Australia has up to two million food insecure people. Global agribusiness made huge profits during the food crises¹ⁱ. Global agribusiness is in the business of extracting profits. This is not the same as ensuring a safe, fair, clean, affordable, nutritious food supply for Australia, or anywhere.

If the scheme is to protect the health and safety of people and the environment then it needs to look at the nutritional needs of people. Entrenching and expanding food insecurity, malnutrition, poverty for the benefit of corporations must be avoided.

MADGE requests investigation into agroecology as an alternative to GM to ensure the Scheme is carrying out the object of the Gene Technology Act.

- 3) Transparency and accountability must be legislated into the Scheme. (ToR3)
 - The definition of GM must be left as it is so it captures all the new GM techniques.

The Gene Technology Act has a deliberately broad definition of GM so that all new techniques are covered, and so regulated. All associated regulatory bodies must use the GTA definition of GM.

• Transfer of power from the commons to the private realm

The creation of the National Gene Technology Regulatory Scheme allows the GM industry to operate in Australia. It decides on the responsibilities of and rewards to the corporations, scientists, research bodies regulators and governments involved with GM. It has also put liabilities onto the general public, farmers, food companies and all future generations without their full understanding, agreement or assent. It has allowed the genetics of plants, animals and microbes to be permanently and irreversibly altered. It has resulted in a vast transfer of power from the common realm to that of corporations, governments and scientists.

• Legislation to protect the health and safety of people and the environment must be part of the Scheme.

Legislation for the 'needs of the Scheme' must be in accordance with the object of the Act, namely the protection of human and environmental health and safety. The new GM techniques like CRISPR can be used repeatedly with potentially alarming results, for example a bacterium could be repeatedly altered until it becomes an anthrax bacterium. The US intelligence community annual worldwide threat assessment report found CRISPR to be a potential weapon of mass destruction lii.

• Legislation for compensating harm must be created and the ability to stop technology must exist

The NGTRS creates benefits for the GM industry and scientists by allowing them to use gene technology. There are no proven benefits for anyone else therefore the public must have a mechanism for being compensated for harm done. It must be noted that adequate

compensation for destroying the biosphere, as outlined below, is hard to envisage therefore the ability to stop the use of technology must be a possibility.

Recognition that this is life altering, and possibly planet destroying, technology

GM is not just another widget that can be removed from sale if found to be faulty or superseded. It is altering the basis of life. It is living, contaminating, self-replicating, permanently changing life forms that has not evolved with the biosphere and yet have been set loose as contaminating agents forever. GM constructs are interacting with, and contaminating, the bacteria, fungi, plants and animals that support us. There must be billions of horizontal GM gene transfers going on every day in fields, animal and human guts all over the planet. No studies can predict where this will lead. This is extreme recklessness.

• We need to put people's needs first.

The justification for GM often evaporates when the problem to be solved is reframed. For example, people do not need GM high vitamin A rice (which is still in development and is not proven to work) but poverty reduction and a varied diet. This is a political and economic issue, not a lack of GM breeding. GM is a reductionist mindset that encourages dangerous dreams of omnipotence while blinding everyone to the human failings that lead to desperate conditions for many people around the world and in Australia.

MADGE requests that the legislative requirements ensure that the health and safety of people and the environment are ensured. We request that adequate compensation is provided for and that a veto on technologies is available and a viable alternative.

- 4) Funding arrangements must ensure the protection of people's health and safety and that of the environment. (ToR4)
 - People have a right to participate in their health and safety and that of their world

It is anti-democratic, paternalistic and opaque to make decisions that will affect people's health and safety and that of the biosphere without their participation. The discussion and implementation of genetic technology has occurred with a distain for critics, whether scientists or not. Funding arrangements must mean more that funding committees and regulators whose interaction with the public is minimal. When the public and scientists do submit their comments, they are routinely ignored or dismissed.

• What are the cost/benefits of GM to people and the environment?

The discussion of why the public should continue to fund GM research and the regulatory bodies that oversee it needs to be explored. To date there has been a huge, unmonitored genetic and chemical experiment let loose. No one knows the results so far or what may happen in future from those GM constructs already released. GM is not a technology that is discrete and simply assessed. It is a world view. It is reductionist and sits in a reductionist neoliberal economic climate where people's rights and well-being are secondary to profit. It is dangerous and the costs may be catastrophic. The benefits are hard to see and it is clear that holistic agriculture and research, as shown by agroecology, has a multiplicity of benefits with none of the downsides of GM.

MADGE requests that the funding arrangements ensure that people have full access to information and discussion on the health and safety of people and the environment as regards to gene technology. We request that adequate consideration is given to alternatives.

v https://www.nature.com/articles/srep37855

ix https://enveurope.springeropen.com/articles/10.1186/s12302-016-0070-0

2012 Dec 18;46(24):13448-54. doi: 10.1021/es302760s.

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xii Antibiotics, Bacteria, and Antibiotic Resistance Genes: Aerial Transport from Cattle Feed Yards via Particulate Matter

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i https://www.legislation.gov.au/Details/C2016C00792

ii https://www.iarc.fr/en/media-centre/iarcnews/2016/glyphosate_IARC2016.php

https://www.nature.com/articles/srep39328?WT.feed_name=subjects_molecular-biology

iv https://enveurope.springeropen.com/articles/10.1186/s12302-014-0014-5

vi http://earthopensource.org/gmomythsandtruths/sample-page/3-health-hazards-gm-foods/3-1-myth-gm-foods-safe-eat/
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xi Chen, J. Jin M. Oiu ZG, Guo C, Chen ZL, Shen ZO, ..., Li JW. (2012) A survey of drug resistance bla genes originating from synthetic plasmid vectors in six Chinese rivers. Environmental Science and Technology

xiii http://www.monsanto-tribunal.org/Multimedia 1

xiv https://vimeo.com/188164021

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xvi https://vimeo.com/189144039

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xxii https://www.bloomberg.com/news/articles/2017-08-09/monsanto-was-its-own-<u>ghostwriter-for-some-safety-reviews</u>
xxiii <u>http://gmwatch.org/en/news/latest-news/17764-uncovered-monsanto-campaign-to-get-</u>

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xxiv https://www.rt.com/usa/386858-monsanto-hired-trolls-court/

xxv http://www.madge.org.au/sites/default/files/articlefiles/FED-UP-WITH-FSANZ-OCT2012.pdf

xxvi https://apvma.gov.au/node/13891

xxvii https://corporateeurope.org/efsa/2017/07/industry-edited-efsa-glyphosate-evaluationahead-publication

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xxix http://www.huffingtonpost.com/carey-gillam/iarc-scientists-defend-gl b 12720306.html http://powerbase.info/index.php/PG Economics

xxxi http://powerbase.info/index.php/International Service for the Acquisition of Agri-Biotech Applications

xxxiii http://www.gmwatch.org/en/news/archive/2014/15669

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