



moonbeam@earthling.net
14/06/2011 04:50 PM

To GTMC.Secretariat@health.gov.au
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Subject Submission on Review of Gene Technology Act [SEC=No Protective]

DOCUMENT NOT YET CLASSIFIED

Submission on Review of Gene Technology Act

Over the last five years much new information has come forward relevant to the assessment of GM crops, yet it the gene regulators evaluation system has apparently ignored it. It is time to change that.

Overlooking of new published evidence on the toxicity and teratogenic qualities of GM crops places the entire Australian population at risk and contradicts the stated aims of the policy which is to protect the health of the Australian people and environment.

If the purpose of the act is indeed to ensure the health of the Australian people and safety of the environment then the gene technology act needs to be rewritten to reflect the discoveries made over the last five years (1,2,3,4), on the toxic effects of GM crops and to specifically address those toxicities.

The previous version of the gene technology act is written under the assumption that no differences would be discovered between genetically modified (GM) foods and non-GM foods. Now that a wide range of differences have been proven in the laboratory(1,2,3,4), the act needs to be rewritten to take into account those differences, the same way the bushfire act is amended after a major bushfire.

Briefly just some of the proven differences between GM crops and non-GM crops that have been discovered since the last writing of the gene technology act include; damage to kidney and liver cells by GM crops (2,3), mutagenicity and teratogenic effects from consumption of GM crops which are sprayed with glyphosate (Roundup) herbicide (4), survival of the GM bacillus thuringiensis (BT) insecticide into the bloodstream of humans and embryos (1).

The act needs to be rewritten so that it will be more objective in its assessment of GM crops and less supportive in its assessment of GM crops. The therapeutic goods act is not written to be supportive of individual products, but clearly the gene technology act is highly supportive of GM crops, which of course was appropriate before discoveries of toxic effects from GM crops were proven (see references 1,2,3,4 below). The assessment begins as if GM crops are substantial equivalent to non-GM crops, which is an invalid assumption and an assumption that has been proven untrue by references one through four below.

The height of the hurdle required to prevent the release or initiate a recall of GM crop is not specified. There are no examples given of the kind of findings which would prevent the release of a GM crop. Several specific examples of the kinds of discoveries that would prevent the release of the GM crop should be given by the regulator. This would make the regulation process more transparent

and easier to manage. For example if mammals are shown to have kidney damage by consumption of GM crops (Ref 2) then such GM crops should not be released or long-term multi-year trials of mammals consumption of GM crops should be initiated to ensure no harm comes from such kidney damage. For example, if insecticidal proteins inserted into GM crops are discovered in pregnant women, the GM crops should be recalled and not released and multi-year studies of the long-term effects of such insecticidal proteins begun, as was recommended by Séralini et al (Ref 3).

The precautionary principle is not being observed. By assuming GM crops are totally safe and substantially equivalent to non-GM crops, the reverse of the precautionary principle occurs. Yet the act focuses on the safety of people and the environment, thus the policy does not implement the intent of the act in relation to safety of the population.

Now that substantial differences have been scientifically demonstrated between GM crops and non- GM crops (reference 1,2,3,4) proper implementation of the policy, would be to assume possible adverse effects from GM crops and require the GM crop to be proven to be safe, in a similar way that therapeutic goods have to be proven to be safe. The act is not implemented by assuming GM crops are safe when the studies below suggest danger from GM crops.

As Séralini et al 2011 write on this topic, "it is unacceptable to submit (Australians) and several billions of consumers worldwide to the new pesticide GM-derived foods or feed, this being done without more controls (if any) than the only 3-month-long toxicological tests and using only one mammalian species, especially since there is growing evidence of concern. This is why we propose to improve the protocol of the 90-day studies to 2-year studies with mature rats, using the Toxotest approach, which should be rendered obligatory, and including sexual hormones assessment too. The reproductive, developmental, and transgenerational studies should also be performed. The new SSC statistical method of analysis is proposed in addition. This should not be optional if the plant is designed to contain a pesticide, as it is the case for more than 99% of cultivated commercialized GMOs.

A study for three months of the health effects of asbestos at Whitenoon in West Australia would have determined that asbestos was totally safe, since asbestosis takes 20 or 30 years to develop. In this case all Australians are exposed to the GM product, now proven to be not substantially equivalent to the non-GM product (1,2,3,4) so much more rigorous testing is required than if only one township is exposed to the product. A policy based on the assumption that GM products are not substantially different to non-to GM products will be quite different to the present policy, which assumes substantial equivalence. This is just one change that needs to be implemented in addition to Séralini above-mentioned suggestions.

Glyphosate (Roundup) may be registered for killing weeds in crop situations, but has it been tested and shown to be safe when sprayed directly on edible crops that are resistant to Roundup? Clearly Carrasco study (Ref 4) shows that edible crops are not safe when sprayed with Roundup. The precautionary

principle must be exceedingly cautious because the whole population is exposed and not just a small part of the population exposed.

In relation to environmental protection from GM crops which the act specifies. One of the key environmental species is the Bee. In assessing the safety of GM crops in relation to bees only direct mortality of GM crops on Bees was assessed. Indirect mortality or sublethal effects of GM crops on Bees were never assessed. It has now been shown that GM crops have substantial sublethal effects on bees, which eventually can result in delayed indirectly lethal effects on the Bees.

Reference 5 shows below that insects such as the Bee, can survive the BT insecticide which is incorporated into many GM crops, by having a strong immune response, which protects them from the Bt insecticide.

Furthermore, reference 6 shows that insects such as the Bee experience impaired associative learning if they have an immune response. (Reference 5 showed that bees and all insects get an immune response from Bt insecticide.)

In Reference 7 below, Ramirez-Romero et al. show that learning in Bees is indeed impaired after exposure to Bt Cry toxins: quote "honey bees exposed to 5000 ppb of Cry1Ab had disturbed learning performances".

Thus it is proven (Ref 5) that the Bt toxin is produce an immune response in all insects including bees. It is proven that when experiencing an immune response bees exhibit impaired learning abilities (Ref 6,7,9).

It is also demonstrated that bees do indeed exhibit impaired learning ability from BT toxins (Ref 5,6,7).

Of course such impaired learning ability does not kill a bee. The Bees life cycle is totally dependent upon a perfect learning ability for complex navigational tasks. If a bee exhibits impaired learning ability it would also not be able to memorise the location and scents of flowers, which it does by memorising instructions given to him by other bees in the beehive. Nor would bee be able to memorise the location of the beehive, thus the Bee would become lost in the field and the beehive would become empty. Bees use protein in constructing memories and also use protein in constructing their immune response. Thus such a learning would be most impaired in winter when pollen protein supplies are limited. Such is indeed the case. (Refs 7,8)

Thus we request that sublethal effects of GM BT pollen should be assessed on key environmental species such as the bee. Since the BT pollen is already demonstrated to adversely affect bees. (Refs 7,8,9)

The GM crops should be proven not to affect cognitive functions of Bees, because are key environmental pollinator.

Science is always finding more results not less results and as more results on the toxicity of GM crops are discovered, the regulatory system needs to provide for factors that may be discovered in the future.

The gene regulator limits his assessment of information on GM crops to peer reviewed papers. A wider range of material should be considered by the gene regulator. For example soy allergy jumped from 10% in 1998 to 50% in 1998

in Britain when GM soy from USA was imported (Ref10).

Contamination of organic agriculture and financial impact upon said organic agriculture through contamination through airborne pollen not considered by the gene regulator. Thus financial burden is placed on the organic industry by the GM crops is unfair and harms the organic industry unduly.

The period of testing of GM crops is totally inadequate according to recent peer reviewed public published study (Ref 3). Due to 100 percent of population being exposed to GM crops period of study should be longer and more intense than study for which only a small percent of population is affected. Therapeutic goods which 1% of population use, must be tested for many years, not so for GM crops for which 100 percent of population is exposed. The precautionary principle fail to be implemented. But financial principle is fully implemented. Financial motivation is overriding precautionary principle.

Recent drop in USA fertility rate. The Australian government opposed the Vienna study showing infertility in rats on an academic basis, yet infertility in the USA population is at a record level. The government displays a bias in favour of GM crops and thus biased in favour of placing population at risk when the act says safety of people and the environment is the priority.

The Government does not implement the act through its support of GM crops. The Government does not have a neutral position but has positive position towards GM crops, in contradiction of the safety aspects of the act.

The implementation of the act is to allow GM crops to be grown, not to test whether they are safe, they are assumed to be safe and the references below suggest they are not safe and change is needed.

Peter Olson
Lot 4 Mill Rd
Goonengerry
2480

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Volume 31, Issue 4, May 2011, Pages 528-533

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Aziz Arisa, Samuel Leblancc

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New analysis of a rat feeding study with a genetically modified maize reveals signs of hepatorenal toxicity.

Séralini GE, Cellier D, de Vendomois JS.

Arch Environ Contam Toxicol. 2007 May;52(4):596-602. Epub 2007 Mar 13.

<http://www.ncbi.nlm.nih.gov/pubmed?term=17356802>

quote:

Chemistry measurements reveal signs of hepatorenal toxicity, marked also by

differential sensitivities in males and females. Triglycerides increased by 24-40% in females; urine phosphorus and sodium excretions diminished in males by 31-35%

3.

Genetically modified crops safety assessments: present limits and possible improvements

Gilles-Éric Séralini, Robin Mesnage, Emilie Clair, Steeve Gress, Joël S de Vendômois and Dominique Cellier

Environmental Sciences Europe, 2011, 23:10

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Glyphosate-Based Herbicides Produce Teratogenic Effects on Vertebrates by Impairing Retinoic Acid Signaling

Alejandra Paganelli, Victoria Gnazzo, Helena Acosta, Silvia L. Lopez, and Andrés E. Carrasco*

Chem. Res. Toxicol., 2010, 23 (10), pp 1586–1595

Publication Date (Web): August 9, 2010

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