PSGR

Physicians and Scientists for Global Responsibility

New Zealand Charitable Trust

Formerly Physicians and Scientists for Responsible Genetics New Zealand

[redacted]

[redacted]

www.psgr.org.nz

5 February 2015

Food Standards Australia New Zealand
PO Box 7186
CANBERRA BC ACT 2610
AUSTRALIA

Food Standards Australia New Zealand
PO Box 10559
The Terrace WELLINGTON 6143
NEW ZEALAND

Application A1097 - food derived from transgenic Zea mays event MON 87411 engineered against corn rootworm (Diabrotica spp.) and for resistance to the herbicide glyphosate; Monsanto Australia Ltd.

The Trustees and Members of PSGR urge Food Standards Australia New Zealand (FSANZ) to reject this application based on the facts presented here.

The World Health Organization recommends adequate post market monitoring be carried out to ensure the safety of transgenic foods.[1] No such monitoring is carried out anywhere in the world. Thus it cannot be said that transgenic foods are or are not safe for human and/or animal consumption. Applying the Precautionary Principle and rejecting and rescinding approvals of such applications is well overdue.

International institutions are often cited as claiming transgenic organisms are safe for human and animal consumption yet a US-based group has compiled a list of over 120 expert organisations that have variously stated transgenic organisms have not been proven safe.[2] [3]

There is no scientific basis to claim any food plant altered at such a basic structural level is "equivalent" to a conventional counter-part food plant.[4] Introducing genetically engineered / modified / transgenic food crops into the food chain – whether for human or animal consumers – raises significant concerns. We query:

- Questionable and/or inadequate safety testing;
- The quantity of transgenic DNA fragments ingested by the average person in an average day; and especially
- The cumulative effect of ingesting growing quantities of multiple and substantially different transgenes on a daily basis, potentially for a lifetime.

[1] http://www.who.int/foodsafety/areas_work/food-technology/faq-genetically-modified-food/en/
[2] 9 December 2014 http://beyond-gm.org/who-says-gmos-are-safe-and-who-says-theyre-not/
[3] 27 January 2015 Dr Thierry Vrain http://wakeup-world.com/2015/01/27/former-pro-gmo-scientist-speaks-dangers-genetically-modified-food/
[4] WHO answers questions on genetically modified foods http://www.who.int/mediacentre/news/notes/np5/en/

Large numbers of the scientific and medical fraternities are deeply concerned about feeding human and animal populations foods containing novel DNA sequences not found in nature. On an evolutionary time scale, the introduction of transgenic material into the food chain has not allowed for genetic changes to evolve for the human or animal systems to cope with these previously unknown transgenes. Animal studies indicate there will be adverse effects and professional bodies point to the evidence accumulating that consuming genetically engineered foods has adverse effects on human health.[5] Of particular concern, is the growing number of such DNA fragments entering and accumulating in the human body on a daily continuing basis.

Transgenic food crops – ingestion and effects on human health

A statement first published in late 2013 came in response to claims from industry and some scientists that there is a "scientific consensus" that transgenic foods and crops are safe for human and animal health and the environment. Over 300 scientists and legal experts signed it to the effect that there is "No consensus" on the safety of transgenic crops and foods.[6] The statement has been published in a peer-reviewed open access journal, *Environmental Sciences Europe* and now stands as a citable publication. The statement remains open for further signatories at http://www.ensser.org/.

An original signatory of the statement, Dr Belinda Martineau, formerly of the Michelmore Laboratory at the UC Davis Genome Centre, University of California, helped commercialize the world's first genetically engineered whole food, the FlavrSavr® tomato. She has said, "I wholeheartedly support this thorough, thoughtful and professional statement describing the lack of scientific consensus on the safety of genetically engineered crops and organisms."[7]

Dr Nicolas Defarge, Université de Caen Basse-Norma, Institut de Biologie Fondamentale et Appliquée (IBFA), a co-author of the statement and a member of the ENSSER board, has said: "Progress in science occurs through controversial debate involving scientific arguments. Our statement, peer-reviewed and published in the open access literature, is now one of them. The debate about the health effects of the long-term consumption of GMOs and of the residues of pesticides they contain is ongoing. It can only be solved by further studies using accurate protocols enabling the investigation of long-term effects. These must be published in open access journals with the raw data being made available and not kept secret. We should bear in mind that the studies performed by industry to support the release of GMOs on the market are usually not peer-reviewed at the time the GMO is commercialized."

Another co-author to the statement, Jack Heinemann, Professor of Genetics and Molecular Biology at the Centre for Integrated Research in Biosafety, University of Canterbury, New Zealand, has said: "Public confidence in GMOs will not increase as long as some scientists try to keep the public and other scientists from asking legitimate questions about their safety, efficacy and value. Even if all questions about existing GM plants were answered tomorrow, that would not mean that future products should be exempt from questioning and thorough testing. Instead of shouting, 'Don't look here, we have a consensus already', we should address the cause of public mistrust. This is best done by embracing open discussions of GMOs informed from a variety of points of view, acknowledging and including the true diversity of scientific opinions."

---

[5] de Vendômois JS, Roullier F, Cellier D, Séralini GE. A Comparison of the Effects of Three GM Corn Varieties on Mammalian Health. Int J Biol Sci 2009; 5(7):706-726. doi:10.7150/ijbs.5.706. Available from http://www.ijbs.com/v05p0706.htm

[6] 'No scientific consensus on GMO safety', Hilbeck et al, Environmental Sciences Europe 2015, 27:4 doi:10.1186/s12302-014-0034-1, 24 January 2015, http://www.enveurope.com/content/27/1/4/abstract

[7] http://www.ensser.org/media/

In one study calculation - where it was assumed 50% of the diet came from transgenic foods and transgenes represent an estimated conservative 0.0005% of the total DNA in food - the consumption figure is put at 0.5–5 µg/day. While DNA is claimed to be mostly degraded during the industrial process and in the digestive tract, small fragments were detected in body tissues such as leukocytes, liver, spleen and gut bacteria (Schubbert et al., 1997). Fragments of orally administered phage M13 and plant DNA were found to be taken up by phagocytes as part of their normal function as immune system cells (Schubbert et al., 1998). Fragments could pass into other organs, including the foetus (Beever et al., 2000; Goldstein et al., 2005; Jonas et al., 2001).

In food crops developed to resist glyphosate and insecticides, consumers will, without knowing, be cumulatively ingesting the resistant transgene/s, even if as minute fragments, from whatever part of the plant they consume. They will also be exposed to ingesting greater than normal residues of chemicals from herbicide applications.[8] Herbicide applications can contain harmful chemicals in addition to the active ingredient itself and a number of studies have shown the formulation Roundup to be more toxic than the active ingredient glyphosate by itself.[9]

The ingestion effects may not be as immediate as the effects from direct spraying. However, with multiple daily helpings of transgenes, cumulative effects will stack up, particularly as other transgenic crops form part of the human diet. The effects that can arise with humans consuming multiple helpings of transgenic foods daily over long periods are uncertain simply because no one is looking, or dare risk using human guinea pigs in trials, or risk their careers by suggesting that this is crucial research. Instead, regulatory agencies have given transgenes a tick of approval without initiating independent long-term studies and without any monitoring in the population, seemingly bowing to a concentration of market power.

Because official bodies accept the word of developers, and vested interests continue to deny the possibility of adverse effects, does not mean there are none. Animal studies reveal the potential for conditions presenting now and in the short- and long-term future, and we can learn from past experience. Equally and historically, transgenes have proven fatal in the field. For example:

- In India, post mortem results showed severe irritation and black patches in both intestines and liver and enlarged bile ducts of sheep grazed on Bt cotton plants. Preliminary evidence strongly suggested a toxin caused the mortality and that that toxin was most probably Bt-toxin. A follow-up feeding study by the Deccan Development Society, India, found all sheep fed Bt cotton plants died within 30 days while those grazing natural cotton plants remained healthy. In Andhra Pradesh, when buffalo grazed Bt cotton plants for the first time, all were sick on the second day and all died within three days.[10]

- In Denmark, pig farmers have proven connections between transgenic soy and health problems in sows; one contending a link between Roundup (glyphosate) herbicide residues and stillbirths and malformations in pig litters. Since switching to non-GE soy feed, health problems and medical costs have declined dramatically, well covering the extra costs in buying non-GE soy feed and increasing profits.[11]

---

[8] http://www.ifrc.org/PageFiles/89755/Photos/307000-WDR-2011-FINAL-email-1.pdf.
www.gmo-compass.org/eng/agri_biotechnology/gmo_planting/257.global_gm_planting_2009.html

[9] For example, Mesnage R, Defarhe N, de Vendomois JS, Séralini G-S. 2014. Major pesticides are more toxic to human cells than their declared active principles. BioMed Research Int. dx.doi.org/10.1155/2014/179691.

[10] http://www.responsibletechnology.org/doctors-warn

[11] 13 April 2012, 'GM Soy linked to health damage in pigs, a Danish Dossier': www.gmfreecymru.org/pivotal_papers/danish_dossier.html

The American Academy of Environmental Medicine[12] has stated: "GM foods pose a serious health risk in the areas of toxicology, allergy and immune function, reproductive health, and metabolic, physiologic and genetic health, and are without benefit. There is more than a casual association between GM foods and adverse health effects. There is causation as defined by Hill's Criteria[13] in the areas of strength of association, consistency, specificity, biological gradient and biological plausibility. The strength of association and consistency between GM foods and disease is confirmed in several animal studies."

There is support for the specificity of the association of transgenic foods and specific disease processes. Multiple animal studies show significant immune dysregulation, including upregulation of cytokines associated with asthma, allergy, and inflammation.[14] The Academy says animal studies also show altered structure and function of the liver, including altered lipid and carbohydrate metabolism as well as cellular changes that could lead to accelerated aging and possibly lead to the accumulation of reactive oxygen species (ROS).[15] Kidney, pancreas and spleen changes have been documented.[16]

It has been shown that gut bacteria uptake transgenic DNA. Studies found intestinal damage in animals fed transgenic foods, including proliferative cell growth[17] and disruption of the intestinal immune system.[16] In 2004, Netherwood et al[18] proved transgenes move from ingested food to bacteria in the human gut. In an earlier, four-year study, Professor Dr Han-Hinrich Kaatz, then Head of Apidology at the Institute for Bee Research, University of Jena, found the transgene conferring resistance to glufosinate had transferred in bees' guts to microbes.[19] Since the pat gene can transfer to gut bacteria in bees, and since genetic material from transgenic soy can transfer to human gut bacteria, it is likely that the pat gene can also transfer from any transgene to human intestinal flora. Neither this event nor its effects have been further studied.

There is an absence of substantive data on the potential interactions of chemicals that a transgenic product has been designed to resist and an absence of data to assess potential health risks through unique combinations of chemicals in food that are accepted as probable or feasible. This is an unmanaged risk.

Herbicide- and insecticide-resistant crops are engineered to withstand copious spraying. Standing crops are contaminated with excessive residual spray and grow in ground holding residual spray which plants can uptake. Spraying close to harvest to suggest uniform maturity and facilitate easy lifting of the yield (desiccation) leaves further significant residual chemical/s on the crops to be harvested. Further, with protein-rich feed, herbicide is sprayed directly onto the grain several days before it is sold as concentrated feed.

---

[12] http://www.aaemonline.org/gmopost.html

[13] Hill, AB. The environment and disease: association or causation? Proceeding of the Royal Society of Medicine 1965; 58:295-300.

[14] Finamore A, Roselli M, Britti S, et al. Intestinal and peripheral immune response to MON 810 maize ingestion in weaning and old mice. J Agric. Food Chem. 2008; 56(23):11533-11539. Kroghsbo S, Madsen C, Poulsen M, et al. Immunotoxicological studies of genetically modified rice expression PHA-E lectin or Bt toxin in Wistar rats. Toxicology. 2008; 245:24-34.

[15] Malatesta M, Boraldi F, Annovi G, et al. A long-term study on female mice fed on a genetically modified soybean:effects on liver ageing. Histochem Cell Biol. 2008; 130:967-977. Velimirov A, Binter C, Zentek J. Biological effects of transgenic maize NK603xMON810 fed in long term reproduction studies in mice. Report-Federal Ministry of Health, Family and Youth. 2008. Kilic A, Aday M. A three generational study with genetically modified Bt corn in rats: biochemical and histopathological investigation. Food Chem. Toxicol. 2008; 46(3):1164-11707

[16] Finamore A, Roselli M, Britti S, et al. Intestinal and peripheral immune response to MON 810 maize ingestion in weaning and old mice. J Agric. Food Chem. 2008; 56(23):11533-11539. Velimirov A, Binter C, Zentek J. Biological effects of transgenic maize NK603xMON810 fed in long term reproduction studies in mice. Report-Federal Ministry of Health, Family and Youth. 2008. J Agric. Food Chem. 2008; 56(23):11533-11539.
Kilic A, Aday M. A three generational study with genetically modified Bt corn in rats: biochemical and histopathological investigation. Food Chem. Toxicol. 2008; 46(3):1164-1170.

[17] Ewen S, Pustzai A. Effects of diets containing genetically modified potatoes expressing Galanthus nivalis lectin on rat small intestine.Lancet. 354:1353-1354.

[18] 'Assessing the survival of transgenic plant DNA in the human gastrointestinal tract', Netherwood et al., Nat Biotechnol. 2004 Feb;22(2):204-9. Epub 2004 Jan 18. http://www.ncbi.nlm.nih.gov/pubmed/14730317.

[19] Antony Barnett, New Research Shows Genetically Modified Genes Are Jumping Species Barrier, London Observer, May 28, 2000.

Transgenes express in the xylem of plants - leaves, fruit, flowers, pollen, nectar, and guttation fluid of plants – and will be ingested from any part of an engineered plant used as food. Further, there is no long-term monitoring of health effects of such ingesting of transgenes. Official US figures already show chronic diseases have increased in step with increased use of glyphosate-resistant crops.[20] The negative impacts of glyphosate ingestion on humans manifest slowly over time damaging cellular systems, playing a part in most common diseases and conditions allied with a Western diet, including gastrointestinal disorders, obesity, diabetes, heart disease, depression, autism, infertility, cancer and Alzheimer's disease.[21]

When a rare individual speaks out about the risks of transgenic food he/she is generally vilified. This appears to be an indicator that a process of 'manufacturing consent' is operating in the transgenic market with the 'influence' of private interest seeking to trump public interest.

FSANZ has a clear responsibility to represent the interests of the New Zealand public in their decisions in regards to introducing novel substances into the New Zealand public food supply. Public law assigns a duty of care upon regulators to apply due diligence and to be reasonable in their consideration of the relevant evidence pertaining to applications.

Scientifically a lack of evidence of harm does not indicate evidence of safety. A precautionary and safe approach to transgenic foods would see any applications declined where there was no appropriate and convincing independently attained scientific evidence of safety.

Given that there are safe non-transgenic alternatives available to meet the food needs of the public, the approvals of transgenic foods into the public food supply to date appear to be scientifically and legally unreasonable.

The public have a legal right to FSANZ and its members operating independently and reasonably and representing the true safety interests of the New Zealand public and to be legally accountable in a court of law if they are challenged by the public on their decisions.

PSGR urges FSANZ to:

Advocate independent long-term health monitoring and independent long-term safety studies;

Insist on comprehensive mandatory labelling of foods containing transgenic material;

Rescind already approved applications and reject this and further applications for transgenic foods and food additives.

[20] http://gmfreescotland.blogspot.co.uk/2013/10/us-public-health-trends-after-gm.html
[21] 'Glyphosate's Suppression of Cytochrome P450 Enzymes and Amino Acid Biosynthesis by the Gut Microbiome: Pathways to Modern Diseases', Samsel et al, Entropy 2013, 15(4), 1416-1463; doi:10.3390/e15041416 http://www.mdpi.com/1099-4300/15/4/1416

Jean Anderson on behalf of
The Trustees and Members of Physicians and Scientists for Global Responsibility
New Zealand Charitable Trust

Paul G Butler, BSc, MSc, MB, ChB, Dip.Obst. (Auckland), FRNZCGP, General Practitioner, AUCKLAND

Jon Carapiet, BA(Hons), MPhil., Senior Market Researcher, AUCKLAND

Bernard J Conlon, MB, BCh, BAO, DCH, DRCOG, DGM, MRCGP (UK), FRNZCGP
General Practitioner, ROTORUA

Elvira Dommisse BSc (Hons), PhD, Mus.B, LTCL, AIRMTNZ, Scientist, Crop & Food Research Institute (1985-1993), working on GE onion programme, CHRISTCHURCH

Michael E Godfrey, MBBS, FACAM, FACNEM, Director, Bay of Plenty Environmental Health Clinic, TAURANGA

Elizabeth Harris, MBChB, Dip Obs, CNZSM., CPCH, CNZFP; DMM, FRNZCGP, General Practitioner, KUROW

Frank Rowson, B.Vet.Med., retired veterinarian, MATAMATA

Meriel Watts PhD, Coordinator Pesticide Action Network Aotearoa NZ, AUCKLAND

Peter R Wills, BSc, PhD, Associate Professor, University of Auckland, AUCKLAND

Damian Wojcik, BSc, MBChB, Dip.Rel.Studies, Dip.Obst., DCH, FRNZCGP, FIBCMT (USA), FACNEM, M Forensic Medicine (Monash), General Practitioner, Northland Environmental Health Clinic, WHANGAREI

Jean Anderson, [redacted].

Ends