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New Zealand Charitable Trust

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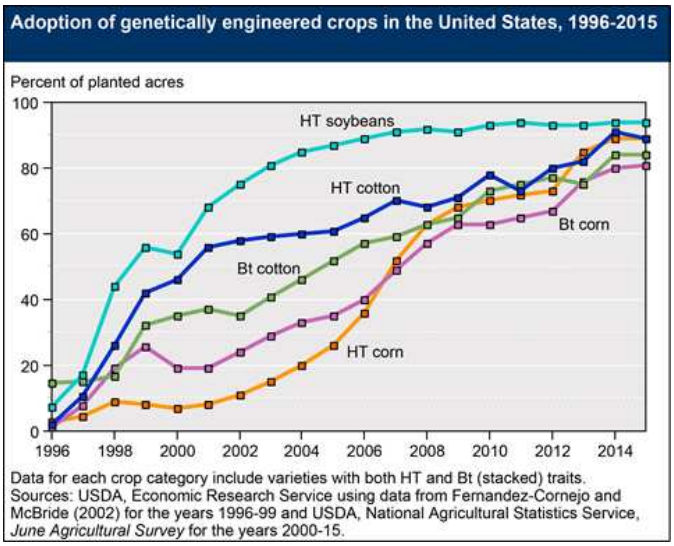
Application A1118 – food derived from corn line MON87419 made by Monsanto Australia Pty Ltd, genetically engineered to be tolerant to the herbicides dicamba and glufosinate ammonium.

The Trustees and Members of PSGR urge Food Standards Australia New Zealand (FSANZ) to meet their duty of care and reject this application.

Many scientific and medical fraternities worldwide 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 have found adverse effects and professional bodies point to the evidence accumulating that consuming transgenic foods and food additives has adverse effects on human health. Since these crops were first grown commercially the quantity of the four main transgenic food crops used by the food processing industry has grown enormously and continues to grow.



http://www.ers.usda.gov/data-products/adoption-of-genetically-engineered-crops-in-the-us/recent-trends-in-ge-adoption.aspx

The Canola Council of Canada puts transgenic canola grown in country at 95% and the sugar beet industry puts transgenic sugar beet also at around 95%. Almost 100% of all the white sugar beets grown in Canada are Monsanto's herbicide-tolerant Roundup Ready sugar beets.[1]

Add to this the range of transgenic food crops being approved and plantings expanded. In fact, the aim of developers is to take over as much of the seed market as possible, and thus the products consumed. In the meantime, human consumers are guinea pigs without credible adequate safety testing, informative labelling, and monitoring of potential effects, including those in countries importing transgenic food crops.

This has continued for two decades. At the time of the initial US FDA approvals of transgenic foods, the consensus of its scientific experts was that genetically engineered food crops were inherently risky, and might create hard-to-detect allergies, poisons, gene transfer to gut bacteria, new diseases, and nutritional problems. These experts urged rigorous long-term tests. They were ignored then and are seen to be ignored today. (See also our Submission on Application A1116 page 2 from line 33 page 2.)

Equally irresponsible is the continuing practice of deficient credible safety testing and the total lack of a monitoring system to look at the effects of human and animal ingestion of transgenes on a long term basis, or what the resulting effects are of the intermingling of transgenic food products.

Transgenes express in the xylem of plants: leaves, fruit, flowers, pollen, nectar, and guttation fluid. Whatever part of a transgenic plant is used as a food or food ingredient, consumers will ingest transgenes, even if as minute fragments, from whatever part/s of the plant they consume. Two decades on from releases, medical professionals are finding adverse health effects in consumers indicative of association with transgenic foods. Reports from the US say even the health of pets improves when taken off transgenic foodstuffs. Meantime, no government or regulatory authority is monitoring or even looking for effects.

This application is similar to other applications to introduce food derived from transgenic sources into the New Zealand food supply, a food supply shared by our most vulnerable: pregnant women and their unborn children, infants and children, those with challenged immune systems, and the elderly. This also includes those with lower spendable incomes leaving them virtually unable to choose what food they eat. These groups would represent a significant percentage of the population.

With regard to the long-term effects of transgenic foods on human health and the environment a British Medical Association report concluded that, "many unanswered questions remain" and that "safety concerns cannot, as yet, be dismissed completely on the basis of information currently available".[2]

What never appears to be considered in the approval process is the fact that, while one food may have minimal adverse effects in an authority's opinion, consumers are ingesting multiple transgenic foods and food ingredients every day.

We raise these general concerns in relation to animal and human health:

- **Combination effects**: Studies have shown that the toxicity of pesticides can be increased when taking into account the effects of the active and other ingredients comprising a pesticide. Formulations have been shown to be more toxic to humans than the active ingredient alone.[3]

[1] http://gmoinquiry.ca/wp-content/uploads/2015/03/where-in-the-world-gm-crops-foods.pdf
2 http://bma.org.uk/
[3] http://www.pananz.net/wp-content/uploads/2013/04/Glufosinate-monograph-12-Dec-2008.pdf.

Researchers tested the toxicity of nine pesticides involving the active ingredient and the added ingredients. Their results "challenge the relevance of the Acceptable Daily Intake for pesticides because this norm is calculated from the toxicity of the active principle alone. . . . Chronic tests on pesticides may not reflect relevant environmental exposures if only one ingredient of these mixtures is tested alone."[4]

The US National Pesticide Information Centre[5] highlights that some of the other ingredients in a pesticide can be toxic and in some cases those other ingredients can pose greater risks than the active ingredient itself.

- **Chemicals**: There is an absence of substantive data arrived at by independent studies 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 to humans through unique combinations of other chemicals in food that are accepted as probable or feasible. These can create unmanaged, unmonitored risks.

  In highlighting the effects of pesticide spray, the US National Pesticide Information Centre says that, "infants and children are more sensitive to the toxic effects of pesticides than adults because an infant's brain, nervous system, and organs are still developing after birth. When exposed, a baby's immature liver and kidneys cannot remove pesticides from the body as well as an adult's liver and kidneys." Ingestion of said pesticide would pose similar results. Does FSANZ take into account those so threatened?

- **Bioaccumulation**: Bioaccumulation is a normal process. All animals, including humans, bioaccumulate ingested material and can bioaccumulate substances in the body to levels that can cause harm. Of particular concern here, is the ability of the human system to bioaccumulate agri-chemicals and the potential for adverse health effects from those chemicals; and not just the chemicals in question, but also the combination of multiple agri-chemicals and other chemicals. (See also our submission A1106.)

- **Unmonitored long-term effects**: Studies on animals fed transgenic feed have revealed the potential for conditions presenting now and in the short- and long-term future.

  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.[6]

  The American Academy of Environmental Medicine[7] says animal studies 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).[8] Kidney, pancreas and spleen changes have been documented.[9]

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4 http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3955666/ December 2013
5 http://npic.orst.edu/ingred/inert.html
6 Finamore 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 et al. Immunotoxicological studies of genetically modified rice expression PHA-E lectin or Bt toxin in Wistar rats. Toxicology. 2008; 245:24-34.
7 http://www.aaemonline.org/gmopost.html
8 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

Nowhere in the world is there a regulatory authority or a government health organisation known to be monitoring long-term the effects of ingesting genetically engineered foods and food ingredients.

- **Questionable safety testing and 'substantial equivalence'**: Most studies claiming transgenic food crops to be safe run for relatively short periods and are largely conducted by the developer of the food, a body that will obviously benefit from sales of the product.

  Pharmaceuticals are not granted approval unless extensive animal and human trials have demonstrated relative safety and have gone as far as reasonably possible in defining risks and benefits. Even after extensive animal and human trials it is recognized that a high percentage of side effects are not discovered until after the drug is released onto the market for general use, the post-marketing surveillance period, which in effect extends indefinitely. The risk of the new pharmaceutical chemical given orally is acknowledged as a 'prescription poison'.

  Pharmaceuticals are clearly distinct and identifiable single agents, whereas food derived from genetic engineering contains transgenes, unpredictable changes in plant chemistry, and often have higher levels of accompanying pesticide residues. These are multiple, complex and poorly defined alterations compared with those from a food sourced from non-genetically engineered sources.

  The industry custom of treating genetically engineered derived foods and non-genetically engineered derived foods as substantially equivalent has no scientific basis and should not be used or accepted by anyone, especially food regulators who have a clearly defined duty of care to uphold public safety under administrative law.

  The inherent difference of foods derived using genetic engineering technology from their non-genetically engineered counterparts, and the attendant risk that this difference creates to human and animal health, dictates that foods containing genetically engineered organisms should be regulated as if they were 'substantially equivalent' to pharmaceuticals and not substantially equivalent to non-genetically engineered foods.

  Responsible regulation of foods containing transgenes should therefore mean that they are only able to be approved for use with similar controls to those applied to pharmaceuticals. This would include the significant animal testing required for pharmaceuticals and the human testing and post-marketing surveillance on and recording of human health effects. As there is no expected benefit to consumers of a transgenic food over a conventional non-transgenic food, medical ethics would require that a medical practitioner would advise patients to avoid genetically engineered sourced foods.

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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

[9] 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.

Dicamba

Dicamba (3,6-dichloro-2-methoxybenzoic acid) is classified as either a benzoic acid or chlorophenoxy herbicide. Sold as a herbicide, dicamba almost without exception contains other active ingredients and herbicides[10]; e.g. 2,4-D, MCPP, and MCPA. Signal words on products containing dicamba range from Caution to Danger; the signal word reflecting the combined toxicity of the active ingredient and other ingredients in the product.

Dicamba has been known to induce a significant increase in the frequency of sister chromatid exchanges (SCEs) in human lymphocytes at 200 ug/ml. At 500 µg/ml, dicamba was proven cytotoxic, a substance or process which results in cell damage or cell death. It may also be a human teratogen and interfere with normal embryonic development.[11]

Glufosinate ammonium

We refer FSANZ to our submission on Application A1116 and the material supplied on the effects of glufosinate ammonium starting on line 21, page 4.

Exposure to even low doses of glufosinate ammonium in infant rats can cause changes in the kainic acid receptor in the brain.[12] Mouse embryos exposed to glufosinate ammonium in vitro developed apoptosis (fragmentation of the cells leading to cell death) in the neuroepithelium of the brain.[13] All embryos in treated groups had specific defects including overall growth retardation, increased death of embryos, hypoplasia (incomplete g/ml, and cleft lips at 20µ development) of the forebrain at 10g/ml.[14]

MAFF UK states that when used as a desiccant, glufosinate residues are detectable in dried peas, field beans, wheat, barley, oilseed rape, and linseed. Wheat grain containing residues ground into flour retained 10-100% of the residue; bran residue levels 10-600% of those in grain.[15] Such residue or a significant portion of that residue would be ingested by consumers.

Adding to the pesticide intake of consumers

Since the aim of vested interests is to produce a substantial volume of transgenic food crops consumed by humans, consumers will ingest increasing quantities of multiple varieties of transgenes and the associated chemicals such as dicamba and glufosinate ammonium.

We repeat, the effects of ingesting multiple helpings of transgenic foods daily over long timeframes is simply unknown. This is principally because there are no long-term studies to determine whether they are safe and such a study would have to use humans in a guinea pig fashion. Scientists could currently risk their careers by suggesting this research needs to be undertaken. Added to this no regulatory authority anywhere worldwide is known to be monitoring and recording effects. The few scientists who have researched the effects are without exception vilified.

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[10] http://npic.orst.edu/factsheets/dicamba_gen.html#products
[11] http://npic.orst.edu/factsheets/dicamba_tech.pdf. http://npic.orst.edu/mcapro/index.html
[12] Fujii, T., T. Ohata, M. Horinaka, Alternations in the response to kainic acid in rats exposed to glufosinate-ammonium, a herbicide, during infantile period. Proc. Of the Japan Acad. Series B-Physical and Biological Sciences, 1996, Vol. 72, No. 1, pp. 7-10.
[13] Watanabe, T. , Apoptosis induced by glufosinate ammonium in the neuroepithelium of developing mouse embryos in culture. Neuroscientific Letters, 1997, Vol. 222, No. 1, pp.17-20. 17.
[14] Watanabe, T. and T. Iwase, Development and dymorphogenic effects of glufosinate ammonium on mouse embryos in culture. Teratogenesis carcinogenesis and mutagenesis, 1996, Vol. 16, No. 6, pp. 287-299.
[15] http://www.pan-uk.org/pestnews/Actives/glufosin.htm. Pers. Comm., MAFF, Pesticides Usage Survey Group. MAFF, York.

Official bodies accepting the word of developers, and vested interests continuing 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.

Further, without comprehensive mandatory labelling consumers will not know they are ingesting transgene/s, even if as minute fragments. They will also be exposed to residues of greater than average herbicide applications, and be exposed to the spray regime associated with plant desiccation prior to harvest where used. All this is without monitoring of health effects or independent studies.

PSGR urges FSANZ to reject this application, curb the risks now, and apply the precautionary principle in the future.

- Uphold public safety by banning transgenic foods from the New Zealand food supply, as there is no credible scientific proof that they are equivalent to non-transgenic foods or that they are safe.

- If transgenic foods continue to be allowed into the New Zealand food supply FSANZ should insist on comprehensive mandatory labelling to identify them and to warn of potential health risks.

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On behalf of

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Ends