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New Zealand Charitable Trust

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Application A1116 made by Syngenta Crop Protection LLC, on behalf of Syngenta AG and its affiliates, covering developed MZIR098 corn (maize; Zea mays L.), genetically engineered to resist the herbicide glufosinate ammonium and using Bacillus thuringiensis (Bt) to protect against corn rootworm.

As previously stated in submissions to FSANZ, PSGR is increasingly unconvinced by the claims made by biotechnology and food industries – claims boosted by multi-million dollar public relations campaigns - that deny the facts around transgenic products in a similar way to past campaigns funded by the tobacco industry.

PSGR questions:

- The failure of agencies like the United States Department of Agriculture (USDA), its Food and Drug Administration (FDA) and Environmental Protection Agency (EPA) to place a higher priority on public health than they place on corporate profit and influence; and

- New Zealand's regulatory authorities in accepting the inadequate standards of the USDA, FDA and EPA without robust independent research studies of transgenic food crops and organisms.

Using a human population as guinea pigs without their being extensively informed about the risks is unconscionable. After two decades of exposure, it is time regulatory agencies take a precautionary stance and reject such applications until proven safe by independent scientists running rigorous long-term tests.

The lack of integrity in decision making

With pharmaceuticals a risk benefit judgment needs to be made by a medical professional before any initiation of their use. Pharmaceuticals are clearly distinct and identifiable single agents whereas food derived using genetic engineering technologies contains transgenes, possibly from multiple sources, with unpredictable changes in plant chemistry and often higher levels of accompanying chemical residues. These are multiple, complex and poorly defined alterations compared with those from conventional food sources.

'Informed consent' is a basic premise of a patient-physician and subject-researcher relationship. It involves making the participant aware of and verifying understanding of the risks, benefits, facts, and the future implications of the procedure or test to which they are going to be subjected.[1] The definition of informed consent used by the US Food and Drug Administration (FDA) is complicated, a virtual "get out of jail free" card. After public outcry, US regulators adopted voluntary labelling of products with transgenic ingredients. In contrast, guidelines approved by the Codex Alimentarius Commission, allows countries to label transgenic foods and foods containing transgenic ingredients without breaching international free trade laws. With the secrecy around the Trans-Pacific Partnership (TPP) negotiations, will that Agreement override the right?

What is fact is that consumers – particularly citizens in the US where some 40 percent of transgenic crops are grown – have been guinea pigs for two decades, allowed no informed choice but to ingest multiple unlabelled transgenic foods or food ingredients on a daily basis. With about 94% of US soybean farmers and 72% of corn farmers using Roundup Ready crops - common ingredients in a substantial range of food products - a large majority of foods available to them will come from agrichemical-resistant transgenic crops to some extent. Animals fed such food crops will bio-accumulate those chemicals and/or their metabolites[2], adding to the human end user's intake.[3]

The safety of herbicide-resistant food crops and other novel DNA have not been substantiated by rigorous, independent scientific research. Studies used to legitimize approvals are generally short-term industry studies, often neither published nor peer-reviewed, and taken over a too-short timeframe, or crops are approved using the GRAS premise; generally regarded as safe. (See also page 3 paragraphs 3 to 5.) Guidelines issued by the European Food Safety Authority call for two-year whole food feeding studies to assess the risks of long-term toxicity.[4] If applied, this is at least an improvement on current practices.

It is safe to say transgenic food crops have mainly been evaluated by US regulatory bodies (FDA, USDA, EPA) and also that almost all of the safety testing has been carried out by the company developing the novel DNA, not by independent scientists. Those developers have an interest in recouping development costs and making money from sales.

In Alliance for Bio-Integrity et al v Shalala (1998) over 44,000 pages of files produced by the US Food and Drug Administration (FDA) at the behest of the Court revealed it had declared genetically engineered foods to be safe despite disagreement from its own experts, and that it falsely claimed a broad scientific consensus supported its stance. Internal reports and memoranda disclosed agency scientists repeatedly cautioned that foods produced through recombinant DNA technology - that is, genetically engineered organisms - entail different risks than do their conventionally produced counterparts and that this was consistently disregarded when FDA policy was written in treating transgenic food crops the same as conventional ones.

In taking this stance, the agency violated the US Food, Drug and Cosmetic Act in allowing genetically engineered foods to be marketed without testing on the premise that they are 'generally recognized as safe' by qualified experts.

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1 'The World's Largest Human Experiment, Monsanto Glyphosate-based Roundup Herbicide', by Madison Ruppert, Part One, GMOs, Roundup and The Monsanto Monstrosity, 10 July 2011 http://www.bibliotecapleyades.net/ciencia/ciencia_monsanto62.htm

2 In soil glufosinate ammonium is degraded by microbial action to 3-methylphosphinico-propionic acid (MPP) and 2-methylphosphinico-acetic acid (MPA), and eventually to carbon dioxide under dark aerobic conditions (HSD 2003; EFSA 2005). Another metabolite, disodium L-2-acetamido-4-methylphosphinato-butyrate or N-acetyl-glufosinate (NAG), is found only in transgenic plants treated with glufosinate-ammonium and not in normal plants, as transgenic plants metabolise glufosinate-ammonium differently. MPP is found in both types of crop (KEMI 2002a). An additional unidentified metabolite has been found in a crop planted following the use of glufosinate (EFSA 2005).

3 http://extoxnet.orst.edu/tibs/bioaccum.htm, http://www.saferchemicals.org/resources/chemicals/pbts.html

4 EFSA Journal 2013;11(7):3347 [18 pp.]. doi:10.2903/j.efsa.2013.3347, European Food Safety Authority, Scientific Report of EFSA On request from: European Commission Question number: EFSA-Q-2013-00316 Pub 31 July 2013, Affiliation: European Food Safety Authority (EFSA) Parma Italy, http://www.efsa.europa.eu/en/efsajournal/pub/3347.htm.

The consensus of scientists working for the FDA at that time was that transgenic foods were inherently risky, and might create hard-to-detect allergies, poisons, gene transfer to gut bacteria, new diseases, and nutritional problems. They urged rigorous long-term tests. From this irresponsible start, applications have continued to be approved without independent safety testing, and regulatory authorities worldwide have taken such approvals as allowing them to follow suit.

The EPA has also been complicit in cover-ups regarding the dangers of herbicides. *Poison Spring: The Secret History of Pollution and the EPA*, written by Evaggelos Vallianatos, documents extensive cover-ups. Vallianatos worked for the US EPA as an analyst from 1979-2004. The book provides an indictment of the inner workings or the approval process for pesticides, herbicides and other chemicals used on farms, and in homes and on lawns.

When asked *how can toxic chemicals enter the market without proper testing yet still meet EPA standards,* he said, "Most chemicals enter the market without testing. Industry reports to EPA with rudimentary information about the chemicals they put up for sale, permitting the companies to advertise their products of 'meeting EPA standards.'"

Vallianatos says the relatively few chemicals tested before EPA approval like pesticides are questionable because the EPA allows the companies themselves or private labs to test for human safety and ecological effects, and the record of private testing cannot give us confidence for the integrity of such a process.

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 results in consumers indicative of association with transgenic foods and no government is monitoring effects.

Bacillus thuringiensis (Bt)

A new study has shown Bt toxin can survive and replicate in the human gut. Horizontal gene transfer (HGT) and DNA absorption of transgenic crops bearing the engineered Bt trait can and does occur. Spisák et al (2013) revealed that DNA molecules from various substances can survive processing and be absorbed into the bloodstream.[5] This includes Bt traits, designed to be self-replicating for the purpose of bursting the intestines of pests and killing them. The paper explains:

"Blood is not free of DNA. There are animal studies, mainly focusing on the GMO issue, supporting the idea that small fragments of nucleic acids may pass to the bloodstream and even get into various tissues. For example, foreign DNA fragments were detected by PCR based techniques in the digestive tract and leukocytes of rainbow trout fed by genetically modified soybean, and other studies report similar results in goats, pigs, and mice."

Kleter et al (2005)[6] lay the groundwork for how HGT affects humans, describing how transgenic crops directly alter intestinal flora through microbial "transgenes." The researchers pointed out how pre-approval safety assessments should but did not include an evaluation of the potential for HGT. It appears this has not changed.

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5 'Complete Genes May Pass from Food to Human Blood', Spisák et al, pub 30 July 2013 DOI: 10.1371/journal.pone.0069805 http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0069805.

6 'Health Considerations Regarding Horizontal Transfer of Microbial Transgenes Present in Genetically Modified Crops', Kleter et al, J Biomed Biotechnol. 2005; 2005(4): 326–352. doi: 10.1155/JBB.2005.326 PMCID: PMC1364539 http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1364539/

The biotech industry claims transgenes are destroyed by the digestive system. However, the Institute for Responsible Technology (IRT) also notes that transgenes are fully capable of surviving and persisting in the human gut.[7] IRT state that animal studies on non-engineered DNA also verify that it can pass through the placenta into the foetus, from the digestive channels into the blood and organs, and even penetrate the blood brain barrier. IRT explains:

"Once transferred into gut bacteria, transgenes may confer survival advantages, allowing them to endure and spread. The only human feed trial ever published confirmed that genetic material from Roundup Ready soy transferred into the gut bacteria in three of seven human volunteers. The transferred portion of the transgene was stable inside the bacteria and appeared to produce herbicide tolerant protein" and this after just one meal.[8]

Studies have shown that ingestion of built-in engineered Bt toxin pesticide by mammals can provoke a negative immune response, inflammation, allergies, and other harm. Present in the intestinal tract, this self-replicating poison can induce long-term health damage for which there may not be a remedy.

Glufosinate ammonium

The development of over 100 varieties of transgenic plants engineered to be resistant to glufosinate ammonium herbicide has significantly increased its use.

One study[9] states: "Incidents of poisoning in humans caused by the ingestion of the glufosinate ammonium containing herbicides are gradually increasing in Japan. This poisoning is characterized by various neurological symptoms such as disturbances of consciousness, convulsions and apnoea which appear after an asymptomatic interval of several hours."[10]

Chemicals can be toxic and prone to bioaccumulation, and can expose the general population to pesticide residues, including physical and biological degradation products present in the air, water, and food.[11] Of relevance is the fact that even low concentrations of many chemicals may not elicit acute detectable effects in organisms, but they may induce other damage, like genetic disorders and physiological alterations, which reduce an organism's life span in time.[12]

Glufosinate has been found to cause a number of neurological symptoms in laboratory animals. One study found low doses of glufosinate affected central nervous system development in young rats. Exposure to even low doses of glufosinate in the infantile period causes changes in the kainic acid receptor in the brain.[13]

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7 http://www.responsibletechnology.org/gmo-dangers/65-health-risks/5notes.
8 'Assessing the survival of transgenic plant DNA in the human gastrointestinal tract', Netherwood et al, 2004, http://www.cibpt.org/gabcomunicacao/EFSA24Jul07/artigonaturebiotec-jan2004-asssurvivaltransgenicplantdnahumangastrointestinaltract.pdf
9 'A toxicokinetic analysis in a patient with acute glufosinate poisoning', Hirose et al, PMID 10372751 Hum Exp Toxicol. 1999 May;18(5):305-8. http://www.ncbi.nlm.nih.gov/pubmed/103727511
10 Glufosinate-ammonium: common trade names Basta, Liberty. BASTA is a herbicide containing glufosinate-ammonium 18.5% and a surface-active agent. There were 6 fatalities in 34 cases of glufosinate-ammonium poisoning reported by the Japan Poison Information Centre. http://toxnet.nlm.nih.gov/cgi-bin/sis/search/a?dbs+hsdb:@term+@DOCNO+6666 Glufosinate ammonium CASRN: 77182-82-2
11 Fenik J, Tankiewicz M, Biziuk M. Properties and determination of pesticides in fruits and vegetables. Trends in Analytical Chemistry 2011; 30 [6]: 814-826. Mostafalou S, Abdollahi M. Pesticides and human chronic diseases: Evidences, mechanisms, and perspectives. Toxicology and Applied Pharmacology 2013; 268:157-177. http://cdn.intechopen.com/pdfs-wm/48406.pdf
12 Poletta GL, Larriera A, Kleinsorge E, Mudry MD. Genotoxicity of the herbicide formulation Roundup® (glyphosate) in broad-snouted caiman (Caiman latirostris) evidenced by the Comet assay and the Micronucleus test. Mutation Research 2009; 672: 95-102
13 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.

Studies on sub-lethal doses of glufosinate ammonium caused abnormalities in the development of embryos in mammals both in vitro and in vivo, and deformities in the brain.[14]

Glufosinate ammonium carries unacceptable risks to humans, especially to the neurological development of the foetus, to agricultural biodiversity, and to the environment. Formulations are more toxic to humans and the aquatic environment than the active ingredient alone,[15] Additionally glufosinate-ammonium is structurally similar to a neurotransmitter, glutamate, and interferes with proper functioning.

In a study published in December 2013, 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."[16]

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 concern, is the ability of the human system to bioaccumulate agri-chemicals and the potential for adverse health effects, not just the chemicals in question, but also the combination of multiple agri-chemicals. (See also our submission A1106.)

There is an absence of independent 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 to humans through unique combinations of chemicals in food that are accepted as probable or feasible. This is an unmanaged risk.

KEMI (2002a, 2002b), the Swedish National Chemicals Inspectorate, proposed the danger of serious damage to health by prolonged exposure to glufosinate ammonium if swallowed. The brain is particularly susceptible: the herbicide has serious effects on early embryonic development, including damage to the brain and neural tube. It can impair fertility, cause the loss of, or harm to, foetuses and damage to those actually born, including cleft lips. Trans-generational effects on brain function are reported.

KEMI states that acute toxicity effects are firstly gastrointestinal such as nausea, vomiting, abdominal pain and diarrhoea, followed by the onset of neurological symptoms such as convulsions and coma, then respiratory failure; death results from circulatory failure. There is no antidote. Chronic effects are primarily neurological and reproductive.

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

Transgenes have proven fatal in the field. In a feeding study by the Deccan Development Society, India, sheep fed Bt cotton plants all died within 30 days; those that grazed natural cotton plants remained healthy. Of 13 buffalo grazed on Bt cotton plants all became sick the next day and all died within three days.[17]

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14 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. 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.pananz.net/wp-content/uploads/2013/04/Glufosinate-monograph-12-Dec-2008.pdf
16 http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3955666/
17 http://www.responsibletechnology.org/doctors-warn

German farmer, Gottfried Glöckner, averaged 62 dairy cows maintained in optimal milk production. In 1997, one animal was awarded for high milk production of 114 tons and producing 14 calves over its life-time by the German Holstein Friesian Herd Book Organization. Glöckner received the German Food Society award in Frankfurt for 10 years of high yield and good quality milk production 1991-2000.

In 1997, Syngenta's Bt-maize 176 was approved as food and feed in the EU. Bt176 was engineered to express the Cry 1Ab protein to target Lepidopteran pests, stacked with glufosinate tolerance and resistance to ampicillin and other b-lactam antibiotics.[18] Glöckner grew the transgenic crop, but did not use glufosinate herbicide on it. He began planting with 5% of transgenic seed mixed with conventional seed in 1997, and progressively increased to 100% in 2000.

As the proportion of Bt maize grown increased, so was the amount in the feed fed to his cows; from zero percent to the maximum amount of 40%. Between May and August 2001, when the Bt maize in the feed had reached its maximum level, five abnormal deaths occurred in the herd of 66 cows; unprecedented in the history of the farm. Official tests by the German Ministry of Health and universities confirmed the deaths were not caused by microbial infections.

Glöckner's healthy cows decreased to 40% in 2002 when the maximum amount of Bt maize was fed to them, and many died preceded by long periods of partial paralysis with signs of kidney failure and mucosal and epithelial problems. Legal battles with the developer and denigration of Glöckner followed. The EU officially withdrew Bt176 maize in 2007.[19]

Glöckner kept meticulous records, including pathological reports by veterinarians of the unusual problems with the herd. He is now working with French molecular toxicologist at the University of Caen. Giles-Eric Seralini. to establish a full account of the first and longest on-farm experience of livestock fed a transgenic-rich diet.

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.[20] [21] [22]

If Bt / glufosinate crops can cause health issues including death with animals, what will they do to the human body?

A British Medical Association report concluded with regard to the long-term effects of transgenic foods on human health and the environment, that, "many unanswered questions remain" and that "safety concerns cannot, as yet, be dismissed completely on the basis of information currently available".[23]

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18 First Commercial Bt-Maize was Toxic, Scientist and Farmer Confirm http://www.i-sis.org.uk/First_Commercial_Bt-Maize_was_Toxic.php
19 See also Cows Ate GM Maize & Died. http://www.i-sis.org.uk/First_Commercial_Bt-Maize_was_Toxic.php.
20 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 a;. 'Immunotoxicological studies of genetically modified rice expression PHA-E lectin or Bt toxin in Wistar rats', Toxicology. 2008; 245:24-34.
21 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 et al, 'Biological effects of transgenic maize NK603xMON810 fed in long term reproduction studies in mice', Report-Federal Ministry of Health, Family and Youth. 2008.
22 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.
23 http://bma.org.uk/

We repeat, two decades of releases are revealing adverse health effects in consumers. Society may yet call to account companies producing transgenic food crops for the on-going damage caused to human and animal health, and also on authorities granting approvals without rigorous independent testing and on-going monitoring of effects.

PSGR urge FSANZ to apply the precautionary principle and reject this application.

Jean Anderson
On behalf of Physicians and Scientists for Global Responsibility New Zealand Charitable Trust

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Ends