PSGR

Physicians and Scientists for Global Responsibility

Charitable Trust

Formerly Physicians and Scientists for Responsible Genetics New Zealand

PO Box 8188
TAURANGA 3145

Telephone +64 7 576 5721
[redacted]

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Food Standards Australia New Zealand

Application A1073

Food derived from Herbicide-tolerant Soybean DAS-44406-6:

a transgenic soybean tolerant to 2,4-dichlorophenoxyacetic acid (2,4-D), glufosinate ammonium and glyphosate.

The Trustees and Members of PSGR urge Food Standards Australia New Zealand to reject this application on the grounds of the facts presented below.

Transgenic soy represents 77% of global soy production. Soy protein is utilised in a multitude of food products[i]:

- Traditional soyfoods e.g. tofu, soymilk, soynuts and edamame (green soybeans);
- Food products from veggie burgers to pastas and cereals;
- Dough-based recipes such as pizza;
- Flour isolates and concentrates;
- Baked goods such as breads, cookies, crackers and cakes, doughnuts and pancakes;
- Breakfast cereals – used extensively in hot cereal mixes and breakfast bars;
- Beverages, toppings and dressings, e.g. coffee whiteners, liquid whipped toppings and pre-whipped toppings, sour cream dressings, instant beverages used as meal replacements;
- Processed and whole meat products such as frankfurters, bologna and sausages;
- Dairy analog products include imitation milk and cheese, non-dairy frozen desserts, coffee whiteners and yogurt;
- Soy/milk blends;
- Confectionary;
- Soups, gravies and sauces;
- Canned foods;
- Canned and bottled drinks.

This list demonstrates how easily most consumers would ingest several helpings of soy on a daily basis. With global production at 77%, more than three quarters of these helpings could be of transgenic soy. Estimates suggest up to 80% of US processed food may contain an ingredient from a transgenic crop, such as soy flour or soy lecithin (Hallman et al., 2003).

Because of the regulatory system, consumption would likely be less in New Zealand. Nevertheless, such products do enter the market places in Australia and New Zealand, either as ingredients for the food processing industry, or in imported foods, or in pharmaceutical or dietary supplement products.

In one calculation, assuming 50% of the diet is from transgenic foods and transgenes represent an estimated 0.0005% of the total DNA in food, the consumption figure is 0.5–5 μg/day. While DNA is claimed to be mostly degraded during the industrial process and in the digestive tract, small fragments have been detected in some body tissues such as leukocytes, liver, spleen and gut bacteria (Schubbert et al., 1997). Fragments of orally administered phage M13 and plant DNA have been shown 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 human food crops developed to resist 2,4-D, glufosinate ammonium and glyphosate, consumers will unknowingly be ingesting the resistant transgene/s from whatever part of the plant they consume and will also be exposed to ingesting residues of herbicide applications.[ii] Whilst the effects of ingesting herbicide-tolerant Soybean DAS-44406-6 may not be as immediate as the effects from spraying, with multiple daily helpings of ingested transgenic soy, cumulative effects are likely to stack up, particularly bearing in mind that other transgenic crops already form part of the human diet. If vested interests have their way, the public will be ingesting food that is near 100% transgenic in time. It is necessary to curb the risks now. It is also necessary for the public to be made aware of the risks, so that they can take any necessary action to avoid food with GE ingredients.

The EC has determined that 1% is an acceptable limit of cross-contamination in non-transgenic products. Consumer interest groups argue only 0% is acceptable. Companies such as Gerber baby foods[iii] and Frito-Lay[iv] avoid use of transgenic foods in any of their products to meet public demand. Current technology is unable to detect minute quantities of transgene contamination. Ensuring 0% contamination using existing methodologies cannot be guaranteed. A 1% threshold may even be below current levels of detectability. Even traces so small they are virtually undetectable could have accumulative effects. This is especially true of everyday highly processed food products such breakfast cereals where the ingredients used to make these products have been pooled from many different sources.

Transgenic foods - human health risks from chemical interactions

We note with concern the absence of data on the potential interactions of chemicals that the product has been designed to resist, and by implication may potentially be used together or applied within a close timeframe.

There is 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, and it is important to forestall that risk in the interests of public health and to meet FSANZ's mandated duty of care.

Transgenic food crops and herbicides

Herbicides primarily affect plant metabolism, effectively killing virtually all green plants within a few days of spraying. Resistant transgenic crops are engineered to withstand this spraying. In the process, crops that are contaminated from excessive spraying are created. More spraying has become necessary as resistant weeds increase in number.

The practice of "desiccation" – spraying close to harvest to facilitate easy lifting of the yield - leaves significant concentrations on the harvested crops. Before harvesting, farmers spray crops with broad-spectrum systemic herbicides to kill them off and give them the appearance of uniform maturity. With protein-rich feed the herbicide is sprayed directly onto the grain several days before it is sold as concentrated feed.

The resistant transgenes express in the xylem of plants: leaves, fruit, flowers, pollen, nectar, and guttation fluid of plants.

Glyphosate: The active ingredient in RoundUp is glyphosate. Glyphosate inhibits the enzyme EPSP synthase that is necessary for plants to grow.[v] When applied to crops, glyphosate becomes systemic throughout the plant and cannot be removed by washing.

Products containing glyphosate also contain other toxic compounds; e.g. surfactants known as polyoxyethyleneamines (POEA) which can be more toxic than the glyphosate itself. They are irritants of the respiratory tract, eyes and skin and are often contaminated with dioxane, a suspected carcinogen.

A 2009 study ran tests on human cells using formulations of RoundUp that were diluted up to 100,000 times or more. The cells died within 24 hours.[vi]

A report in the journal *Chemical Research in Toxicology* says the highest maximum residue level (MRL) for glyphosate in food and feed products in the EU is 20 mg/kg. Transgenic soybeans have been found to contain residue levels as high as 17 mg/kg. Malformations in frog and chicken embryos occurred at 2.03 mg/kg, ten times lower than the MRL. Human intake would involve multiple ingestations daily, which could take consumption levels over the MRL.[iii]

Glufosinate-ammonium inhibits the enzyme glutamine synthetase, necessary for the production of glutamine and for ammonia detoxification. It inhibits the same enzyme in animals.

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.[vii]

2,4-dichlorophenoxyacetic acid. The ester forms of 2,4-D penetrate foliage and are converted to acid within the plant. This accumulates in cells through passive diffusion, although active transport within the plant may occur. Accumulation is primarily at the meristem tissue of roots and shoots.

2,4-D is rapidly absorbed via oral routes.[viii] Studies on human volunteers who ingested pure 2,4-D, and on cases of accidental or voluntary acute poisoning with various 2,4-D herbicides, have shown that 2,4-D is very rapidly absorbed from the gut and carried in the blood to cells and tissues throughout the body.[ix] Human study participants excreted 5 mg/kg 2,4-D in 22.6 hours, 75% in urine within 96 hours. Concentrations in blood plasma paralleled concentration excreted in urine.[x]

2,4-D was detected in urine samples collected from all age groups in a large study of the US public. It claimed it is not clear how these residues may affect human health.

2,4-D is a synthetic auxin (plant hormone) and was a major ingredient in Agent Orange, in a 50:50 mixture with 2,4,5-T (trichlorophenoxyacetic acid) in iso-octyl ester form, manufactured for the US Department of Defense primarily by Monsanto Corporation and Dow Chemical. The result of spraying Agent Orange on civilians and military personnel in Vietnam reveals the overt effects of spraying 2,4-D and 2,4,5-T (contaminated with dioxin).

US Vietnam veterans were also affected,[xi] [xii] the effects being extensively documented. Presumptive conditions that resulted from the above spraying, and which are currently acknowledged, include: prostate cancer; respiratory cancers; multiple myeloma; type II diabetes; Hodgkin's disease; non-Hodgkin's lymphoma; soft tissue sarcoma; chloracne; porphyria cutanea tarda; peripheral neuropathy; chronic lymphocytic leukaemia; spina bifida in children of veterans exposed to Agent Orange; B cell leukaemia's, such as hairy cell leukaemia; Parkinson's disease; ischemic heart disease and birth defects (Baker, 2010).

Transgenic crops and human health

The World Health Organization states transgenic plants are organisms in which DNA has been altered in such a way that it does not occur naturally. By that description alone, such a plant cannot be "substantially equivalent" to a conventional plant and cannot by any scientific measure be regarded "as safe as the conventional food."[xiii]

Regulators continue to increase acceptable residue levels to meet industry demands. EU authorities have further raised the legal limit for glyphosate contamination in wheat and bread to 100 times the legal limit for vegetables and the limit for feed grains 200-fold.

Proponents of genetic engineering claim citizens of the US have eaten transgenic foods for years with no ill effects. This is a seriously misleading statement. Certainly, US citizens have been eating transgenic foods for years, but these foods are unlabelled, there is no mandated registering of potential adverse effects, and there are no substantive independent epidemiological studies on human subjects to see if there are any negative affects to health and wellbeing. Regulators can take note that it took decades to appreciate that trans-fats have caused millions of premature deaths. Lessons can be learned from that experience by applying the precautionary principle to transgenic food crops.[xiv]

The acknowledged human health risks associated with ingesting transgenes[xv] are:

Allergenicity: When introducing a novel gene into a plant there is the potential to create a new allergen or cause an allergic reaction in susceptible individuals. For example, engineering Brazil nuts into soybeans was abandoned because of the risk of causing unexpected allergic reactions.[xvi] Transgenic Starlink™ Corn, approved for animal feed, contaminated the human food chain. The resulting allergic reactions remain controversial. However, a US EPA advisory panel found it was possible Cry9C was an allergen (CDC 2001, Lemaux 2008, Hefle and Taylor 2001), the FDA was unable to rule out allergenicity, experts say it has a "medium likelihood" of being an allergen, and corn in the US was tested until no measurable amounts of StarLink transgenes are determined (EPA 2007). Potentially, minute traces remain.[xvii]

We know an allergic reaction occurs when ingestion exposes a consumer to a new protein; in the case of transgenic food crops, to a novel protein that may not occur in nature.[xviii] Substantive studies have failed to find a reason for the recent substantial increases in allergic reactions. These studies include: the International Study of Asthma and Allergies in Childhood (ISAAC)[xix], led by Professor Innes Asher of the University of Auckland, a collaborative effort involving over 100 countries; the GA²LEN study[xx]; and an objective study which showed through serological measurements at three time periods that earlier birth cohorts are less likely to have become atopic than more recent ones[xxi].

Medical professionals say the causes of the increased number of allergies in developed countries interplay between genetics and environmental changes. The timeframe is too short to explain a genetic change in the population. Allergies, including food allergies, have increased in New Zealand and other developed countries by epidemic proportions.

New Zealand: A conservative estimate of allergy sufferers in New Zealand is 9000 (2.156%). This low statistic may be because New Zealanders consume fewer transgenes than other countries and because allergies are acknowledged to be infrequently reported.[xxii]

Australia: One in 20 Australian children suffer from a potentially fatal food allergy. The biggest recent rise is in children under five.[xxiii]

United States: Allergic disease is the fifth leading chronic disease in the US among all ages, and the third common chronic disease among children under 18 years old. It is estimated that 20% of American children today have allergies.[xxiv]

United Kingdom: The UK population has the highest prevalence of allergies in Europe and ranks among the highest in the world.[xxv]

Worldwide: In 2004, the World Allergy Organization's Specialty and Training Council conducted a survey of member societies. Results indicated that in a population of 1.39 billion people 22% may suffer from some form of allergy.[xxvi]

The above countries have all added transgenes to the daily diet.

Regulators need to consider that a substantial number of the consuming public could express an allergy following ingestion of transgenes, which present proteins unknown in nature.

Unknown effects on human health:

Extracted plant DNA in soil can be taken up in bacteria[xxvii] and studies have shown transfer between transgenic plant DNA and bacteria can occur. The known mechanisms of transfer are transduction where DNA transfer is mediated by bacteriophages, conjugation where DNA transfer occurs between bacterial cells through conjugation apparatus, and transformation, the uptake of naked DNA. These three processes occur with gastro-intestinal tract bacteria. The most probable method for transfer in the human gut is natural transformation.

No independent substantive studies have been made of the results of feeding transgenes into the human system, excepting one study of the effects of one meal of transgenic soy.[xxviii]
However, the genes and promoters inserted into transgenic plants have characteristics and sequences similar to bacterial genomes and this may increase the likelihood of bacterial expression.

Whereas most DNA is degraded by digestive enzymes in the gut, studies have shown a small percentage survive passage through the gut and would be available to uptake by gut bacteria.[xxix]

Horizontal gene transfer (HGT) is the transfer of DNA between sexually incompatible organisms and incidences of HGT between bacteria and fungi, between bacteria and protozoa (single-cell organisms), between bacteria and higher plants and animals, and between fungi, and between insects, have been identified.[xxx] More than 99 percent of soil bacteria cannot be isolated using available culture techniques, which seriously limits detection of HGT. However, most DNA constructs inserted into transgenic crop plants include sections homologous to bacterial DNA. It is accepted DNA homology is an important factor in promoting HGT into bacteria.[xxxi] DNA transfer can involve DNA carried by a variety of vectors, such as viruses and bacteria, as are used with genetic engineering technology experiments.[xxxii] The effects of such transfers have not been adequately studied.

Human health and 2,4-D, glufosinate and glyphosate resistant soy

Natural habitats have potential for DNA transfer, e.g. in animal tissues and animal intestines, including those of humans.[xxxiii] [xxxiv] Bacterial uptake and expression of DNA can proceed within one minute of ingestion.[xxxv]

Studies commissioned by the UK Food Standards Agency found transgenic DNA transferred from transgenic soy into microbes in the human intestine after a single meal.[xxviii]

Glufosinate-resistant canola/rapeseed was grown in a field trial. Professor Dr Han-Hinrich Kaatz, then Head of Apidology at the Institut fur Bienenkunde (Institute for Bee Research) at the University of Jena, now at Martin-Luther-University Halle, Germany, built a netted enclosure in the field that allowed bees to fly freely within it. He installed pollen traps at the beehives to extract pollen samples from the bees' hind legs as they entered the hive. The collected pollen was fed to young honeybees in the laboratory, pollen being their natural diet. After feeding, Professor Kaatz extracted the intestines of young bees and spread the contents on growth medium. He found the gene that confers resistance to glufosinate, the pat-gene, was in the microorganisms, and in some bacteria and in a yeast species. After ingestion, the transgene had been transferred in the bees' gut to the microbes.

Scientists know that bacteria exchange genes and that acquired genes can create pathogenic bacteria. The sequencing of the genome of E. coli 0157 showed that 1387 genes had been acquired by HGT. This also showed strains of microbes exist which possess elevated potential to incorporate foreign DNA. For E. coli 0157, this potential led to its extreme toxicity.[xxxvi]

Transgenic technology is designed to replace natural reproductive processes. Selection occurs at the single cell level and the procedure is highly mutagenic, routinely breeching genera barriers. Pleiotropic (unforeseen and unpredictable) effects do occur.[xxxvii]

A German study found people with no direct contact with agriculture have significant concentrations of glyphosate in their urine. The journal, *Ithaka*, reported that every urine sample collected from city dwellers around Berlin tested positive for glyphosate. Values ranged from 0.5 to 2 nanograms per millilitre (ng/ml); i.e. five to 20 times the permissible upper limit for glyphosate in German drinking water set at 0.1 ng/ml. A conclusion was that glyphosate entered human populations through its presence in daily foods, including glyphosate-resistant soy. The glyphosate would be on resistant transgenic crops and expressed all parts of resistant transgenic plants.[xxxviii]

Pleiotropic effects can potentially have an unforeseen, negative impact on human health. We know transgenes ingested by human participants found their way into bacteria in the human gut.[xxvi] Studies on rats show there are appreciable differences in their intestines when fed transgenic potatoes, and other physical aberrations.[xxxix]

The effects of ingestion of herbicides containing 2,4-D and other compounds, some 2,4-D metabolites or manufacturing by-products were detected in tissues (Geldmacher-Von Mallinckrodt and Lautenbach, 1966; Prescott et al., 1979). Acute high doses administered to laboratory animals produced ataxia, myotonia, and evidence of histological injury to the kidneys, liver, thyroid, eyes, adrenals and gonads.[xl] The effects of ingesting these contaminants via transgenes have not been adequately studied. Epidemiological studies have reported associations of several types of cancer, such as soft tissue sarcoma and non-Hodgkin's lymphoma, with the exposure to chlorophenoxy herbicides as defoliants or contaminated herbicides.[xli]

Other risks: It is mandatory for drugs to be identified and monitored for adverse health effects. Without official tracking made of any adverse effects from transgenic foods, it is not easy to identify them when foods or food additives are so widely used. The almost complete lack of labelling of transgenic foods and food ingredients means it is virtually impossible to trace possible allergies or other reactions; and thus easy to dismiss such claims. However, these examples can be drawn on:

- In 2011, doctors at Sherbrooke University Hospital in Quebec, Canada, found Bt-toxin from transgenic corn accumulates in the human body. Researchers found significant levels of the insecticidal protein CryIAb in the blood of pregnant women; CryIAb being present in transgenic Bt crops. The toxin was identified in 93 percent of the pregnant women tested; 80 percent of umbilical blood in their babies; and 67 percent of non-pregnant women.[xlii]
- Cry9C, also an engineered *Bacillus thuringiensis* (Bt) protein, was engineered into StarLink™ Corn, approved for animal feed but contaminated the human food chain causing adverse reactions. (See also page 4).
- A significant study using human participants showed transgenes can move from transgenic soy into bacteria in the human gut.[xliii]
- After transgenic soy was introduced in Britain, doctors reported allergic reactions to soy increased 50%.[xliv] The Irish Doctors' Environmental Association told how increased soy allergies in the Irish Republic mirrored the experience in Britain.[xlv] The group wants the establishment of a register of diseases thought to be linked to transgenic foods.

Dr Suzanne Wuerthele, a toxicologist and risk assessor, has been a senior scientist at the US Environmental Protection Agency (EPA) for 20 years. Speaking in a personal capacity, she has stated, "The need for careful monitoring is urgent, given the introduction of thousands of GM foods on a global scale..."[xlvi]

A proponent of the potential benefits of transgenic crops, Ben Miflin, former director of the Institute of Arable Crops at Rothamsted, near London, concurred: "Under current monitoring conditions, any unanticipated health impact of such foods would need to be a 'monumental disaster' to be detectable."[xlvii]

Dona and Arvanitoyannis (2009) state: "Most studies with GM foods indicate that they may cause hepatic, pancreatic, renal and reproduction effects and may alter haematological (blood), biochemical, and immunologic parameters, the significance of which remains to be solved with chronic toxicity studies."[xlviii]

Safety assessments of 2,4-D and DAS-68416-4 soybean

On its website, the US Environmental Protection Agency states that in evaluating pesticides for re-registration it obtains and reviews *a complete set of studies from the producers of the pesticide*, describing the human health and environmental effects of each pesticide (our italics).[xlix]

The FDA's approval decision[l] reads: "*Dow has concluded* that its herbicide tolerant soybean variety, DAS-68416-4 soybean, and the food and feed derived from it are as safe as conventional soybean varieties, and with the exception of the herbicide tolerance traits, are not materially different in composition or other relevant parameters from other soybean varieties now grown, marketed and consumed in the United States. *At this time, based on Dow's data and information, the agency considers Dow's consultation on DAS-68416-4 soybean to be complete*" (our italics).

Neither site gives evidence of independent assessments.

Long-term effects of ingesting transgenes

Scientists and medical professionals do not know what effects there are with humans consuming multiple helpings of transgenic foods daily over long periods of time. Animal studies reveal the potential for conditions presenting now and in the short- and long-term future. Because official bodies accept the word of developers and vested interests continue to deny the possibility of adverse effects, does not mean there are no problems.[li] A consumer may not know he/she has consumed Botulin toxin - just LD-50 of 0.4 billionth of a gram per kilogram of body weight - until paralysis sets in. Arsenic exploits pathways in cells, binds to proteins, and creates molecular havoc. Small amounts taken over a long period of time produce weakness, confusion and paralysis. Poisons are effective in minuscule amounts, not always undetectable.[lii]

Recently, the American Academy of Environmental Medicine[liii] 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[liv] 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.[lv]

The Academy[lv] also 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).[lvi] Changes in the kidney, pancreas and spleen have also been documented.[lvii]

"A recent 2008 study links GM corn with infertility, showing a significant decrease in offspring over time and significantly lower litter weight in mice fed GM corn.[lviii]
This study also found that over 400 genes were expressed differently in the mice fed with GM corn. These are genes known to control protein synthesis and modification, cell signalling, cholesterol synthesis, and insulin regulation. Studies also show intestinal damage in animals fed GM foods, including proliferative cell growth[lix] and disruption of the intestinal immune system.[lx]

Transgenic food crops are utilised in many forms in human food and animal feed production. All foods potentially present residue. The cumulative effects of humans ingesting transgenic food crops, even in minute amounts, on a daily basis for unlimited periods simply have not been studied. We repeat - it took decades to appreciate that trans-fats have caused millions of premature deaths. The regulatory system should learn from that experience and remove transgenic food crops and feed from the market.[lxi]

Increasingly, the data show it is biologically possible for transgenic foods to cause adverse health effects in humans.

The valid use of scientific evidence is to set precaution, and not to perpetuate permissive standards for vested interests to use life and Earth's life-support system as one vast laboratory.

PSGR maintains that it is imperative to adopt a precautionary principle approach to transgenic foods.

The Trustees and Members of Physicians and Scientists for Global Responsibility

Paul G Butler, BSc, 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 BVetMed
Veterinarian, MATAMATA

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

Damian Wojcik, BSc, MBChB, Dip.Theology, Dip.Obst., DCH, FRNZCGP, FIBCMT (USA)
Director and founder of the Northland Environmental Health Clinic, WHANGAREI

Jean Anderson
Businesswoman retired, TAURANGA.

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