PSGR

Physicians and Scientists for Global Responsibility

Charitable Trust

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Food Standards Australia New Zealand
WELLINGTON 6143 and CANBERRA BC ACT 2610

Submission on Application A1081Food derived from Herbicide-tolerant Soybean line SYHT0H2 genetically engineered to be tolerant to the herbicides glufosinate-ammonium and mesotrione. Applicants: Bayer CropScience and Syngenta Seeds

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

The World Health Organisation in its '20 Questions on Genetically Modified Foods' states:

> "Genetically modified organisms (GMOs) can be defined as organisms in which the genetic material (DNA) has been altered in a way that does not occur naturally."[i]

Any food altered at such a basic structural level is not "equivalent" to a conventional food. If we feed populations novel foods not found in nature, the probability is there will be adverse reactions. On an evolutionary time scale, the rapid introduction of transgenic material into the human diet has not allowed for genetic changes to evolve for the human system to cope with these previously unknown transgenes.

Introducing genetically engineered/modified (transgenic) food crops into the food chain – whether of human or animal consumers – raises significant concerns. In this instance, we refer to:

- Inadequate safety testing
- The volume of transgenic DNA fragments likely to be ingested by the average person in an average day
- The cumulative effect of ingesting quantities of multiple and substantially different transgenes on a daily basis potentially for a lifetime

There is substantial evidence that consuming genetically engineered foods has adverse effects on human health and warnings have been issued by appropriate bodies.

Safety assessments of all transgenic food crops

Most studies claiming transgenic food crops to be safe run for 40 days or less and are largely conducted by the developer of that food who will also benefit from sales of the product.

Recently, the European Food Safety Authority (EFSA) issued guidelines for two-year whole food feeding studies to assess the risks of long-term toxicity. These should be applied to transgenic foods.[ii]

The EFSA report aids the establishment of protocols for chronic toxicity and/or carcinogenicity studies in rodents with whole food/feed. It provides a commentary on OECD TG 453 with considerations on its applicability to support the safety assessment of long-term consumption of a given food with respect to its chronic toxicity or carcinogenicity potential.

EFSA recommended that conducting chronic toxicity and/or carcinogenicity studies with whole food/feed should be taken on a case-by case basis and be based on the evaluation of all available information on the whole food/feed resulting from compositional analyses and any other available nutritional and toxicological studies. Its conduct and reporting should be in line with good laboratory practice standards.

Of significance is EFSA cautioning strongly against relying on historical control data. Industry has frequently used dated data from a wide variety of sources. EFSA says,

"The use of historical control data should be considered with caution. The historical controls might not be useful because the incidences of neoplastic (or non-neoplastic) lesions would possibly be from control animals kept on different diets than the diet applied in whole food/feed study, and because the diet itself (high/low fat, type of fat, % of carbohydrate, type of carbohydrate, etc.) can influence the formation of neoplastic or non-neoplastic lesions. Where the diet formulation used in the experiment for the control groups cannot be demonstrated to be equivalent to that used for the generation of historical control data, the inclusion may be considered of an additional control group (as similar as possible to the historical controls), in addition to the concurrent control group(s)."

EFSA also requires an a priori power analysis to ensure an appropriate sample size.

The EFSA guidelines are a significant improvement on the weak, or lack or absence of, guidelines previously followed by the developers and promoters of transgenic food crops.

PSGR has found no evidence to suggest developers and promoters of transgenic food crops have conducted studies meeting any of the recommendations in the new EFSA guidelines as a matter of good scientific practice in their studies conducted the past. Studies not applying these guidelines could fail to find adverse effects. An assumption of safety following an inadequate study does not preclude potential adverse effects being present.

The EFSA guidelines also largely validate the work of such non-aligned scientists as Dr Gilles-Eric Séralini of the University of Caen, Institute of Biology, whose work the industry has persistently vilified.

> **See** 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

Transgenic foods – ingestion and effects on human health

Transgenic soy represents 77% of global soy production. This percentage suggests that three quarters of the products that use soy in some form and ingested by humans could contain transgenic fragments of DNA. Estimates suggest that up to 80% of US processed foods may contain an ingredient from a transgenic crop such as soy flour or soy lecithin (Hallman et al., 2003). PSGR acknowledges this consumption statistic would be less in New Zealand. Nevertheless, such products are increasingly entering the Australasian market, either as ingredients for the food processing industry, or in imported foods, or in pharmaceutical or dietary supplement products. Transgenes can potentially also enter New Zealand as an integral component of animal feed, contaminate feeding stock and thus enter the human food chain.

In one study calculation - where it was assumed 50% of the diet came from transgenic foods and transgenes represent an estimated 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 have been 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 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 2004, Netherwood et al[iii] proved transgenes move from ingested soy to bacteria in the human gut.

To research bees pollinating a glufosinate-resistant canola/rapeseed field trial, Professor Dr Han-Hinrich Kaatz then Head of Apidology at the Institute for Bee Research, University of Jena, now at Martin-Luther-University Halle, Germany, built a netted enclosure in the field. This allowed bees to fly freely from their hive within it. Dr Kaatz used pollen traps at the hives to extract pollen samples from the bees' hind legs as they entered. He fed the collected pollen 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 transferred in the bees' gut to the microbes.

In human food crops developed to resist glufosinate ammonium and mesotrione, consumers will unknowingly be ingesting the resistant transgene/s, even if as minute fragments, from whatever part of the plant they consume, and be exposed to ingesting residues of greater than average herbicide applications.[iv]

Whilst the effects of ingesting herbicide-tolerant soy may not be as immediate as the effects from direct spraying, with multiple daily helpings of ingested herbicide-resistant soy, cumulative effects will stack up, particularly bearing in mind that other transgenic crops already form part of the human diet. If vested interests achieve what they have set out to do, given time consumers will be ingesting food that is near 100% transgenic. 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 transgenic ingredients.

The European Commission has determined that 1% is an acceptable limit of cross-contamination in non-transgenic products. Consumer interest groups argue only zero percent is acceptable. Current technology is not able to detect minute trace quantities of transgene contamination.

Ensuring zero percent contamination using existing methodologies cannot be guaranteed. One percent may be below the ability of some current testing methods to detect. Even so, traces so small they are virtually undetectable could potentially have cumulative effects. This is especially true for everyday highly processed food products, such as breakfast cereals and breads, where the ingredients used to make these products have come from multiple sources. All transgenic foods, food ingredients and additives should be labelled whatever the percentage applying.

Transgenic foods and human consumption

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 not risk using human guinea pigs in trials, or risk their careers by suggesting this is crucial research. Instead, the industry and government agencies have approved transgenes without any monitoring in the population and without initiating independent studies. When a rare individual speaks out he/she is vilified.

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.[v] Animal studies reveal the potential for conditions presenting now and in the short- and long-term future, and we can learn from past experience. An example is a consumer unknowingly ingesting Botulin toxin; just LD-50 of 0.4 billionth of a gram per kilogram of body weight. Only when paralysis sets in will it be obvious. Arsenic exploits cell pathways, 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.[vi] Transgenes may have considerable negative effects long-term.

Recently, the American Academy of Environmental Medicine[vii] 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[viii] 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.[ix]

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).[x] Changes in the kidney, pancreas and spleen have been documented.[xi]

A 2008 study linked genetically engineered with infertility, showing a significant decrease in offspring over time and significantly lower litter weight in mice fed transgenic corn.[xii] This study also found that over 400 genes were expressed differently in the mice fed with the 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 transgenic foods, including proliferative cell growth[xiii] and disruption of the intestinal immune system.[xiv]

There is an absence of substantive data on the potential interactions of chemicals that a transgenic product has been designed to resist. There is also 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. It is crucial to prevent that risk becoming reality in the interests of public health, and to meet FSANZ's mandated duty of care. The cost to the Health System could be huge.

Transgenic foods – herbicide resistance and residues

Herbicides primarily affect plant metabolism, effectively killing virtually all green plants within a few days of spraying. Herbicide-resistant crops are genetically engineered to withstand this spraying. In the process, standing crops are created that are contaminated with excessive residual spray and growing in ground holding residual spray. Today, as the number of major weeds species that are resistant grow, more frequent spraying has become the norm, spraying that includes more toxic chemicals such as 2,4-dichlorophenoxyacetic acid (2,4-D), an ingredient in Agent Orange.

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.

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Transgenes express in the xylem of plants: leaves, fruit, flowers, pollen, nectar, and guttation fluid of plants. In other words, in all parts used as food in some form and ingested by consumers.

Glufosinate-ammonium

Glufosinate-ammonium has been found to cause a number of neurological symptoms in laboratory animals, can affect central nervous system development in young rats and cause abnormalities in the development of embryos in mammals both in vitro and in vivo; principally deformities in the brain. One study found all the embryos had specific defects including overall growth retardation, increased death of embryos, hypoplasia and cleft lips.[xv]

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.[xvi]

Such residue or a significant portion of that residue would be ingested.

Mesotrione

Mesotrione is a triketone herbicide which inhibits the enzyme 4-hydroxyphenolpyruvate dioxygenase (HPPD) which in turn leads to a reduction of carotenoids (Mitchell et al. 2001).

Carotenoids in the human diet provide health benefits by decreasing the risk of disease, particularly certain cancers and eye disease. One beneficial effect of carotenoids is acting as antioxidants.[xvii]

The immune system is a major component in the pathogenesis of chronic diseases such as cancer and cardio-vascular disease. Epidemiological studies consistently find an inverse relationship exists between intake of vegetables and fruit and the risk for these diseases (Steinmetz & Potter, 1991; Block et al. 1992; Keyet al. 1996; Ness & Powles, 1997).

Additionally, an inverse association between dietary intake of b-carotene and the risk of cancer has been observed in several epidemiological studies (Mayne, 1996). Dietary carotenoids act as antioxidants and quench singlet oxygen, which results in lower generation of free radicals (Bendich, 1996). Free radicals impair the integrity and functionality of membrane lipids and affect signal transduction and gene expression in immune cells (Meydani et al. 1995b).

Carotenoids are provided by vegetables and fruit and clearly play an essential part in human health. As stated above, Mesotrione inhibits the enzyme 4-hydroxyphenolpyruvate dioxygenase (HPPD) which leads to a reduction of carotenoids. Thus, at a time when nutritional health experts are advising consumers to eat more vegetables reflecting the presence of carotenoids, FSANZ is promoting a food with a reduced capacity to produce carotenoids.[xviii] [xix]

Transgenic food crops – why there should be caution applied

As quoted at the start of this submission, the World Health Organization states transgenic plants are organisms in which DNA has been altered in such a way that 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."[xx]

Regulators continue to increase acceptable residue levels to meet industry demands, largely as a result of the development of transgenic crops and the need to spray liberally and frequently. 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. Such moves are unacceptable and irresponsible, risking human and environmental health.

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. This is without labelling, with no mandated registering of potential adverse effects, and with 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.[xxi]

Allergenicity - an acknowledged human health risk associated with ingesting transgenes[xxii]

When introducing a novel gene into a plant there is the acknowledged 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 indication of risk of causing unexpected allergic reactions.[xxiii]

- Transgenic Starlink™ Corn, introduced in 1998 and approved for animal feed only, contaminated the human food chain. A US EPA advisory panel found it was possible Cry9C was an allergen (CDC 2001, Lemaux 2008, Hefle and Taylor 2001) and the FDA was unable to rule out allergenicity.
  From 2000 to 2007, the USDA tested corn until no measurable amounts of StarLink transgenes were determined (EPA 2007). Potentially, minute traces remain.[xxiv]

We know an allergic reaction occurs when ingestion exposes a consumer to a new protein. In the case of transgenic food crops, this is a novel protein that does not occur in nature.[xxv] Reactions by an allergic person can range from a tingling sensation around the mouth and lips to death.

Eight types of food account for over 90% of allergic reactions in affected individuals. That list of eight includes soy.

Allergic disease is the fifth leading chronic disease in the US among all ages, and the third most common chronic disease among children under 18 years old.[xxvi] Studies have failed to explain the recent substantial increases in allergic reactions in the US. From 1997 to 2007, the prevalence of reported food allergy increased 18% among children under age 18 years. Children with food allergy are two to four times more likely to have other related conditions such as asthma and other allergies, compared with children without food allergies." [xxvii]

The Power of Prevention: Chronic disease . . . the public health challenge of the 21st Century[xxviii] from the US National Centre for Chronic Disease Prevention and Health Promotion, also reveals the following information. In 2006, US expenditure on health care was over twice the average of 29 other developed countries. More than 75% involved chronic conditions. Average life expectancy in the US is below nations that spend less on health care annually and seven out of 10 deaths in US citizens are from chronic diseases. In 2005, 133 million US citizens, virtually one of every two adults, had at least one chronic illness. Cancer claims over half a million US lives annually, the second leading cause of death. Nearly 24 million have diabetes and an estimated 57 million adults have pre-diabetes. If current trends continue 1 in 3 US citizens born in 2000 will develop diabetes during their lifetime.

The US stands alone in that its citizens have been ingesting substantial quantities of multiple transgenic foods, and food ingredients and additives on a daily basis since the mid 1990s: without knowing, unlabelled, and on best practice principles inadequately tested. This situation singles them out from other nations, even those where some genetically engineered foods are available. PSGR asks is anyone looking to see if there is a connection with such increases as that of allergic reactions mentioned above or the general poor standard of health.

No independent substantive studies have been made of the results of feeding transgenes into the human system, excepting the one study of the effects of one meal of transgenic soy.[xxix] 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.[xxx]

Extracted plant DNA in soil can be taken up in bacteria[xxxi] 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.

Horizontal gene transfer (HGT) is the transfer of DNA between sexually incompatible organisms and incidences of HGT between bacteria and fungi, between bacteria and the single-cell organisms protozoa, between bacteria and higher plants and animals, and between fungi, and between insects, have been identified.[xxxii] 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.[xxxiii] DNA transfer can involve DNA carried by a variety of vectors, such as viruses and bacteria, as are used with genetic engineering technology experiments.[xxxiv] The effects of such transfers are not adequately studied.

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.[xxxv]

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[xxxvi] and can potentially have an unforeseen, negative impact on human health. Studies on rats show there are appreciable differences in their intestines when fed transgenic potatoes, and other physical aberrations.[xxxvii]

Transgenic foods – tracing effects

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.[xxxviii] 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 6).

A significant study using human participants showed transgenes can move from transgenic soy into bacteria in the human gut.[xxxix] After transgenic soy was introduced in Britain, doctors reported allergic reactions to soy increased 50%.[xl] The Irish Doctors' Environmental Association told how increased soy allergies in the Irish Republic mirrored the experience in Britain.[xli]

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..."[xlii]

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."[xliii]

Long-term effects of ingesting transgenes

Transgenic food crops are utilised in many forms in human food and animal feed production. These potentially present residue and the ingestion of fragments of transgenic DNA. The cumulative effects of human ingestion of novel foods, even in minute amounts, on a daily basis for unlimited periods simply have not been studied. Increasingly, data show it is biologically possible for transgenic foods to cause adverse health effects in humans. The regulatory system should remove transgenic food crops and their derivatives and transgenic feed from the market.[xliv] The valid use of scientific evidence is to set precaution, not to perpetuate permissive standards for vested interests.

PSGR urges FSANZ to adopt as a minimum of caution the new EFSA guidelines as best practice for all applications for transgenic food crops, foods additives and ingredients, in meeting its duty of care for the consumer public.

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

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