PSGR

Physicians and Scientists for Global Responsibility

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

Application A1087 - Food derived from Soybean Line DAS-81419-2 genetically engineered to express the insecticidal proteins Cry1Ac and Cry1F from the soil bacterium Bt (Bacillus thuringiensis)

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

Foods genetically engineered with novel DNA are not "equivalent" to a conventional food. Introducing transgenic food crops into the food chain – whether of human or animal consumers – raises significant concerns.

1. Inadequate current protocols for safety testing

Current protocols for testing transgenic foods/feed are not adequate or acceptable, and do not show a duty of care, whether for the human or animal food chain. The European Food Safety Authority (EFSA) recently issued guidelines[i] for two-year whole food feeding studies to assess the risks of long-term toxicity. In the interests of human and animal health, these improvements on the current methods must be applied to transgenic foods until such time as protocols that are acceptable and fitting are made mandatory and/or until such time as the outcome of the ingestion of novel DNA sequences is made clear beyond question.

There is continued concern at the lack of rigour in reaching, and/or supporting documentation on, claims, and applicants not addressing environmental risks or safety in a comprehensive way. To meet FSANZ's duty of care, testing must be carried out by independent scientists. Foods must be tested 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, as well as long-term animal studies. Conduct and reporting should be in line with best current international laboratory practice standards, with constant assessment for improvement.

PSGR has found no evidence to suggest developers and promoters of transgenic food/feed crops, or regulatory or health authorities, have conducted or insisted upon studies conducted in the past meeting the above criteria as a matter of sound scientific practice. An assumption of safety following an inadequate study does not preclude potential adverse effects being present. There are sufficient scientific grounds for considering that food derived from transgenic DNA presents a significant risk to the public health and there are no countervailing benefits to the public from their introduction.

These EFSA guidelines also largely validate the findings of scientists whose work the industry has persistently vilified. For example: 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 on http://www.ijbs.com/v05p0706.htm.

We note the statement of 21 October 2013 issued by the European Network of Scientists for Social and Environmental Responsibility (ENSSER)[1]. It illustrates the strong body of professional opinion on the poor, or lack of, safety assessments of transgenic organisms in food and feed, that claims by vested interests of a "scientific consensus" on their safety is misleading and that the debate is not "over" as claimed. It also says most studies concluding that transgenic foods were as safe and nutritious as those obtained by conventional breeding were "performed by biotechnology companies or associates, which are also responsible [for] commercializing" transgenic plants. It highlights the fact that the lack of scientific consensus on the safety of transgenic foods and crops is underlined by the recent research calls of the European Union and the French government to investigate the long-term health impacts of their consumption in the light of uncertainties raised by animal feeding studies.

2. Potential allergenicity, toxicity and nutrient availability of transgenic food plants

Safety assessments of introduced novel DNA must consider potential increases in the allergenicity, toxicity, and nutrient availability of foods derived from transgenic plants. Most safety assessments are carried out by the developers of the transgenic plants and too little sponsorship is provided for independent scientists to test their safety, thus leading to a scarcity of substantive data from non-vested interests.[ii]

The adoption of genetic engineering technology to introduce foreign gene/s creates a functionally distinct transgenic plant, different to any naturally occurring species. Genetic engineering technology allows the introduction of individual genes from any living organism into the genome of the recipient engineered plant, whereas traditional breeding requires sexually compatible gene sources and acceptors.[iii]

The primary focus for safety of transgenic crops is on evaluating the potential toxicity of the protein or metabolites of transgenic enzymes and the allergenicity of the introduced protein/s, largely based on historical knowledge of toxins and allergens. The risks associated with allergens are for those who are sensitized to a protein causing the production of protein-specific IgE antibodies that can elicit an allergic reaction. The risk of allergy from traditional foods is manageable if allergic individuals know the identity of the food causing an allergy. The allergenicity assessment of transgenic crops must focus on the same risks of food allergy as posed by traditional foods, and as a preliminary safety measure provide for comprehensive mandatory labelling for such individuals.

[1] www.ensser.org

Studies show an estimated 100 to 200 fatal reactions occur in the US when allergic consumers are exposed unexpectedly to a food that causes their allergy and that there are over 100,000 visits to a hospital emergency department, in addition to mild reactions for which medical care was not sought.[iv]

The 'substantial equivalence' concept of transgenic plants relative to varieties of non-transgenic plants suggests any statistically significant difference is unacceptable, but in respect of allergenicity we need to know there is no increased expression of endogenous allergens for commonly allergenic crops such as soybean.[v]

Data suggest that environmental factors influence yield in modest to marked differences in the expression of proteins, including allergens, and that allergens and cross-reactive proteins cannot be identified by structure or sequence similarity alone. Despite observations that many important food allergens are stable to digestion by pepsin, some are still able to elicit an allergic response after cooking.[vi]

Despite little data being available that document normal variation of the expression levels of various allergenic proteins for varieties of most crops, most regulators expect a relative comparison of IgE binding to a new transgenic soybean and genetically similar non-transgenic varieties of soybean because soybean is considered a commonly allergenic crop.

3. Transgenic DNA fragments ingested by an average person in an average day

There are no known studies to show the cumulative effect of human ingestion of quantities of multiple and different transgenes on a daily basis, potentially for a lifetime. Neither has it been made known if a regulatory or health authority is monitoring the effects of human ingestion of novel DNA or has initiated an independent study on any transgenic food.

One study calculated - where 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 0.5–5 μg/day. DNA is claimed to be mostly degraded during the industrial process and in the digestive tract. However, small fragments have been detected in body tissues such as leukocytes, liver, spleen and gut bacteria.[vii] Fragments of orally administered phage M13 and plant DNA have been taken up by phagocytes as part of their normal function as immune system cells.[vii] Fragments could pass into other organs, including the foetus (Beever et al., 2000; Goldstein et al., 2005; Jonas et al., 2001). In the only known study of human ingestion of novel DNA in a food, Netherwood et al[viii] (2004) proved transgenes moved from ingested transgenic soy to bacteria in the human gut after a single meal.

With human food crops developed to resist herbicides and insecticides, consumers will be ingesting resistant transgene/s, even if as minute fragments, from whatever part of the plant they consume, and with sprayed chemicals will be exposed to ingesting residues of greater than average applications.[ix] The cumulative effects of multiple daily helpings will stack up, particularly because other transgenic crops already form part of the human diet.

It is vital cumulative effects be taken into account. If vested interests achieve their goal, given time consumers will be ingesting food that is near 100% transgenic. It is necessary to curb the risks now. It is also vital for the public to be made aware of the risks and be provided with full, detailed labelling to give consumers a choice to avoid food with transgenic ingredients.

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, their unborn children and infants, those with challenged immune systems, and the elderly.

For example, reports show a large percentage of New Zealand children are immune-challenged. We have the second highest rate of asthma[x] in the world and many children suffering multiple sensitivities manifesting as allergies and skin conditions. Under nutrition is an acknowledged condition of many of the elderly; novel DNA increasing risks to their health.

The enteric nervous system is located in the gastrointestinal system. Recent research has shown a very close link between the health of the gut and the immune condition of the body. Previously mentioned studies have shown transgenic DNA can transfer to gut microbes.

The request to introduce novel trans-genetically derived foods, with their novel chemistry, could be seen to equate to an application to introduce new chemicals in the form of new pharmaceuticals approved human consumption. However, 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.

After a new pharmaceutical is introduced it is usually available only with the individualised prescription of a registered medical doctor, for a specific person, with a specific therapeutic indication. The risk of the new pharmaceutical chemical given orally is acknowledged as a ‘prescription poison’. This risk of the recognized and unrecognized and unintended effects of pharmaceuticals is assessed by the medical practitioner and the patient, against the potential benefits of the new chemical. When this risk is significant it requires a process of informed consent for the patient before dispensing.

Pharmaceuticals are used in a context that a risk benefit judgment needs to be made by a medical professional, before the initiation of their use. Pharmaceuticals are clearly distinct and identifiable single agents, whereas food derived from genetic engineering contains transgenes, possibly from multiple sources, unpredictable changes in plant chemistry and often 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 convention of treating genetically engineered derived foods and non-genetically engineered derived foods, as substantially equivalent, has no scientific basis and should not be used by anyone, especially food regulators such as Food Standards Australia and New Zealand who have a clearly defined responsibility to uphold public safety under administrative law.

The inherent difference of foods created by genetic engineered technology from their conventional counterparts, and the attendant risk that this difference creates to human health, dictates that foods containing transgenic organisms should be regulated as if they were substantially equivalent to pharmaceuticals rather than 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 human health effects. It would also require informed consent before these transgenic foods are offered for human use. As there is no expected benefit to a transgenic food over a non-transgenic food medical ethics would require that a medical practitioner would advise patients to avoid transgenic sourced foods. 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.[xi] Animal studies reveal the potential for conditions presenting now and in the short- and long-term future.

Transgenes may have considerable negative effects long-term. Effects are not being officially monitored and therefore remain uncertain. Genetically engineering a plant produces changes in the natural functioning of a plant's DNA causing native genes to mutate, be deleted, or be permanently turned off or on, and the inserted gene can become truncated, fragmented, mixed with other genes, inverted or multiplied. The novel protein it produces may have unintended characteristics that are potentially harmful. Professor David Schubert, Laboratory Head of the Cellular Neurobiology Laboratory at the Salk Institute for Biological Studies has said that industry claims are not only scientifically incorrect but exceptionally deceptive in making the GE process sound similar to conventional plant breeding.[xii]

In the US, over 80% of all processed foods contain trangenes in some form.[xii] Recently, the American Academy of Environmental Medicine[xiii] 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[xiv] 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.[xv] 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).[xvi] Changes in the kidney, pancreas and spleen have been documented.[xvii]

A 2008 study linked transgenic feed with a significant decrease in offspring over time and significantly lower litter weight in mice fed transgenic corn.[xviii] It also found that over 400 genes expressed differently in the mice fed with the transgenic corn, 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[xix] and disruption of the intestinal immune system.[xx]

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. Potentially, the cost to the Health System could be huge.

4. Potential associated risks to transgenes

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.[xxi] It is unacceptable and irresponsible to add to those risks by approving transgenic food and feed, especially as regulators continue to increase acceptable chemical residue levels to meet industry demands.

Claims that US citizens have eaten transgenic foods for years with no ill effects is seriously misleading. Certainly, their diet has contained transgenic foods for a decade and a half; this without labelling, thus offering no choice, and without substantive independent epidemiological studies on human subjects to see if there are any negative affects to health and without mandated registering of potential adverse effects. As the fore-mentioned report states, "no epidemiological studies in human populations have been carried out", therefore there is no foundation for a claim of without ill effect. "It is scientifically impossible to trace, let alone study, patterns of consumption and their impacts" based on the US experience and that claims that transgenic "are safe for human health based on the experience of North American populations have no scientific basis". The statement also states that claims that there is a consensus among scientific and governmental bodies that transgenic foods are safe or that they are no more risky than non-transgenic foods "are false".

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.[xxii] Transgenic food crops were introduced commercially in the mid 1990s. From 1997 to 2007, the prevalence of reported food allergy increased 18% among US children under age 18 years. This is almost one in five children, and 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." [xxiii]

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 and has not been ingested previously.[xxiv] Reactions by an allergic person can range from a tingling sensation around the mouth and lips to death.

Regulators can take note that it took decades to appreciate that ingestion of food high in trans-fats has been a factor in millions of deaths. Lessons can be learned from that experience by applying the precautionary principle to transgenic food crops.[xxv]

That US citizens have been ingesting substantial quantities of multiple transgenic foods, and food ingredients and additives, on a daily basis for a decade and a half that on best practice principles are inadequately tested singles them out from other nations, even those where some genetically engineered foods are available. PSGR asks when will an official, independent body be established to investigate if there is a connection with such increases as that of allergic reactions mentioned above or with the general poor standard of health widely reported in the US media.

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

It is known 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.[xxix]

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

As mentioned above, 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 it is easy to dismiss such claims. However, 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.[xxxii]

After transgenic soy was introduced in Britain, doctors reported allergic reactions to soy increased 50%.[xxxiii] The Irish Doctors' Environmental Association told how increased soy allergies in the Irish Republic mirrored the experience in Britain.[xxxiv]

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 (*Nature Biotechnology* 23, 170, 2005), she stated, "The need for careful monitoring is urgent, given the introduction of thousands of GM foods on a global scale."[xxxv] No such monitoring exists.

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."[xxxvi]

Transgenic food crops are utilised in many forms in human food and animal feed production. Potentially, these present chemical residues 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, are not monitored nor studied.

5. Long-term effects of ingesting transgenes

In 2013, new studies continue to question the impact and safety of engineered food. Government agencies have a duty of care to replicate them rather than rely on seriously inadequate studies undertaken and/or paid for by the developers. Inserting a gene in a genome using this technology can and does result in damaged proteins. Studies reported in scientific literature show that engineered corn and soya contain toxic or allergenic proteins.[xxxvii]

A long term feeding study of laboratory rats reported in *Food and Chemical Toxicology* (2012) shows they develop breast cancer, and kidney and liver damage. Increasingly, data show it is biologically possible for transgenic foods to cause adverse health effects in humans.

Regulators should remove transgenic food crops and their derivatives, and transgenic feed, from the market.[xxxviii] The valid use of scientific evidence is to set precaution, not to perpetuate permissive standards for vested interests. FSANZ should question the claims of those vested interests.

Science shows it is imperative to adopt a precautionary principle approach to transgenic foods. PSGR urges FSANZ to reject this application.

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