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29 August 2013

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

Submission on Application A1080
Food derived from dicamba- and glufosinate-tolerant cotton MON 88701
for inclusion in Standard 1.5.2; submitted by Monsanto Australia Limited

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

There is no scientific basis to claim any food plant with genetically engineered DNA is "equivalent" to a conventional counter-part food plant.[i] Introducing genetically engineered / modified / transgenic food crops into the food chain – whether for human or animal consumers – raises significant concerns. In this instance, we refer to:

- Unscientific assumptions and questionable and/or 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 growing quantities of multiple and substantially different transgenes on a daily basis, potentially for a lifetime.

Large numbers of the scientific and medical fraternities are deeply concerned about feeding human and animal populations foods containing novel DNA sequences not found in nature. On an evolutionary time scale, the introduction of transgenic material into the food chain has not allowed for genetic changes to evolve for the human or animal systems to cope with these previously unknown transgenes. Animal studies indicate there will be adverse effects and professional bodies point to the evidence accumulating that consuming genetically engineered foods has adverse effects on human health.

Transgenic food crops - safety assessments

Most studies claiming transgenic food crops to be safe run for relatively short periods and are largely conducted by the developer of the food, a body that will also benefit from sales of the product.

Recently, the European Food Safety Authority (EFSA) issued guidelines for two-year whole food rodent feeding studies to assess the risks of long-term toxicity and the establishment of protocols for case-by-case studies. It provides a commentary on OECD TG 453[ii] 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. These would be applicable to transgenic foods.[iii]

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 and yet they are very basic studies which are rodent and not human studies and although they may demonstrate the presence of toxicity they are not capable of proving safety for human consumption.

PSGR has found no evidence to suggest developers and promoters of transgenic food crops, and food ingredients or additives have, to date, conducted studies meeting even these very basic toxicity assessments of the new recommendations in the EFSA guidelines.

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 because it challenges their claims.[1]

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.

The request to introduce novel trans-genically derived foods, with their novel chemistry, is substantially equivalent to an application to introduce new chemicals in the form of new pharmaceuticals into approved human consumption. 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, unpredictable changes in

[1] **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

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 genetically engineered derived foods from their non-genetically engineered counterparts, and the attendant risk that this difference creates to human health, dictates that foods containing genetically engineered 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 genetically engineered sourced foods.

Transgenic food crops – ingestion and effects on human health

Cottonseed is widely used in foods processed for human consumption in the form of: oil, shortening and margarine; dressings and sauces; food additives such as thickeners, stabilisers, emulsifiers and fillers; cottonseed flour; potato chips; ice cream; breads, snack foods and other processed foods. It is also used extensively as animal feed.[iv]

In 2011, 90 percent of the US cotton crop was transgenic.[v] These statistics suggest 90 percent of food products containing cottonseed derivatives can potentially contain transgenic DNA. Equally, this percentage of food products when ingested by humans could contain transgenic fragments of DNA. (See later the effect of cottonseed in animal feed.) 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 were 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 were found 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 glufosinate ammonium and dicamba, consumers will, without knowing, be ingesting the resistant transgene/s, even if as minute fragments, from whatever part of the plant they consume. They will also be exposed to ingesting residues of liberal herbicide applications.[vi] With dicamba, this could include other chemicals added to the product.

The effects of ingesting foods containing herbicide-tolerant cotton may not be as immediate as the effects from direct spraying. However, with multiple daily helpings of transgenes, cumulative effects will stack up, particularly as other transgenic crops form part of the human diet. The aim of vested interests is to produce near 100% of crops consumed by humans. Therefore, consumers will ingest increasing quantities of multiple varieties of transgenes.

At present the effects on humans of consuming multiple helpings of transgenic foods daily over long time frames is simply unknown. This is due to the following three factors. There is not a single long term study to determine whether this is safe. No one would dare to suggest such a study as it would propose using humans in a guinea pig fashion and finally, scientists at present risk their careers by even suggesting this is research needs to be undertaken.

Official bodies accepting the word of developers, and vested interests continuing to deny the possibility of adverse effects, does not mean there are none.[vii] Animal studies reveal the potential for conditions presenting now and in the short- and long-term future.

One study suggested exposure to even low doses of glufosinate in the infantile period in rats causes changes in the kainic acid receptor in the brain.[viii] In another study, mouse embryos exposed to glufosinate in vitro developed apoptosis (fragmentation of the cells leading to cell death) in the neuroepithelium of the brain.[ix] An earlier study found all embryos in treated groups had specific defects including overall growth retardation, increased death of embryos, hypoplasia (incomplete g/ml, and cleft lips at 20μ development) of the forebrain at 10g/ml.[x]

Should we, therefore, consider cottonseed resistant to glufosinate safe for human food products or animal feed?

The American Academy of Environmental Medicine[xi] has 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[xii] 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.[xiii]

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).[xiv] Changes in the kidney, pancreas and spleen have been documented.[xv]

It has been shown that ingested transgenic DNA does reach gut bacteria. Studies found intestinal damage in animals fed transgenic foods, including proliferative cell growth[xvi] and disruption of the intestinal immune system.[xvii] In 2004, Netherwood et al[xviii] proved transgenes move from ingested food to bacteria in the human gut. In an earlier, four-year study, Professor Dr Han-Hinrich Kaatz, then Head of Apidology at the Institute for Bee Research, University of Jena, found the transgene conferring resistance to glufosinate had transferred in bees’ guts to microbes.[xix] Since the pat gene can transfer to gut bacteria in bees, and since genetic material from transgenic soy can transfer to human gut bacteria, it is likely that the pat gene can also transfer from any transgene to human intestinal flora. The effects of such transfer have not been studied.

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 the foregoing risks becoming reality in the interests of public health, and to meet FSANZ's mandated duty of care. The cost to the Health System of ignoring risks could be huge.

Transgenic foods – herbicide resistance and residues

Herbicide-resistant crops are genetically engineered to withstand copious spraying. In the process, standing crops become contaminated with excessive residual spray and grow in ground holding residual spray which can potentially be taken up by the plant. With the number of major herbicide-resistant weeds species growing, more frequent spraying has become the norm, spraying that can include more toxic chemicals such as 2,4-D.

Spraying close to harvest to suggest uniform maturity and facilitate easy lifting of the yield – desiccation - leaves significant residual chemical/s on the crops to be harvested.

With protein-rich feed, herbicide is also sprayed directly onto the grain several days before it is sold as concentrated feed (see also below).

Dicamba (3,6-dichloro-2-methoxybenzoic acid)[xx] is classified as either a benzoic acid or chlorophenoxy herbicide. Sold as a herbicide, dicamba frequently contains other active herbicides; e.g. 2,4-D[2] MCPP[3], and MCPA[4]. Signal words on products containing dicamba range from Caution to Danger. The signal word reflects the combined toxicity of the active ingredient and other ingredients in the product.

When applied to plants dicamba is rapidly taken up by the leaves and roots and translocated to other plant parts. Therefore any part of the plant consumed will contain transgenes.

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

Glufosinate

Glufosinate 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.[xxii] Such residue or a significant portion of that residue would be ingested.

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[2] For information on 2,4-D and glyphosate see http://www.psgr.org nz/index.php?option=com_content&view=article&id=112:2012-food-standards-anz-5-december&catid=25:food-standards-australia-new-zealand-fsanz-&Itemid=39

[3] MCPP (mecoprop, or methylchlorophenoxypropionic acid); a herbicide often combined with 2,4-D, dicamba, and MCPA. Mecoprop is a mixture of two stereoisomers, with the (R)-(+)-enantiomer ("Mecoprop-P", "Duplosan KV") possessing the herbicidal activity.

[4] MCPA or 2-methyl-4-chlorophenoxyacetic acid is a phenoxy herbicide.

Transgenes express in the xylem of plants: leaves, fruit, flowers, pollen, nectar, and guttation fluid of plants. Therefore, glufosinate transgenes will be ingested from any part of an engineered plant used as food and could transfer to gut bacteria (Netherwood et al, 2004).

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

PSGR urges FSANZ to curb the risks now.

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

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

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[i] WHO answers questions on genetically modified foods http://www.who.int/mediacentre/news/notes/np5/en/
[ii] http://www.efsa.europa.eu/en/efsajournal/pub/3347 htm
[iii] EFSA Journal 2013;11(7):3347 [18 pp.]. doi:10.2903/j.efsa.2013.3347, European Food Safety Authority Acknowledgment Contact, Type: Scientific Report of EFSA On request from: European Commission Question number: EFSA-Q-2013-00316 Approved: 26 July 2013 Published: 31 July 2013 Affiliation: European Food Safety Authority (EFSA) Parma Italy, http://www.efsa.europa.eu/en/efsajournal/pub/3347 htm.
[iv] http://www.gmo-compass.org/eng/grocery_shopping/crops/161.genetically_modified_cotton.html http://www kew.org/plant-cultures/plants/cotton_food html
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Ends