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New Zealand Charitable Trust

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Submission on Application A1139 - Food derived from GE potato lines F10, J3, W8, X17, Y9 and E56

PSRG urges Food Standards Australia New Zealand to **reject** the above application (**Option 2**). Products containing potato from the above-mentioned GE lines are very likely to be supplied to markets in New Zealand and New Zealanders have the right to expect regulatory authorities to adopt a cautious approach to food safety and health considerations. On the grounds of human health and safety, PSRG believes that acceptance of this application is not warranted.

Considerations:

Toxicity and allergenicity of GE foods

Research consistent with the WHO published protocols (1) has not yet been carried out on the effect of any novel proteins on humans, the intended consumers of these potatoes. Novel proteins are very likely to arise as a result of the DNA insertion event/s occurring during the GE process, regardless of the origin of the DNA being inserted, i.e., whether it is *trans*- or *intra*genic. To assume that the increase in such novel protein/s, and that the DNA insertion process will not result in considerable changes to levels of primary or secondary metabolites in the cell, shows little regard for thorough scientific process or food safety.

Feeding studies on laboratory animals and farm livestock have found that some GE crops, including those already commercialized, have toxic or allergenic effects. Effects, which may arise from the GE crop itself, and/or from residues of the pesticides used on them, include:

- Liver and kidney toxicity (2,3,4,5)
- Enlarged liver (6)
- Disturbed liver, pancreas and testes function (7,8,9)
- Accelerated liver ageing (10)
- Disturbances in the functioning of the digestive system and cellular changes in liver and pancreas (11)
- Less efficient feed utilization and digestive disturbance (12)
- Altered gut bacteria (13,14)
- Intestinal abnormalities (15)
- Excessive growth in the lining of the gut, similar to a pre-cancerous condition (16,17)
- Altered blood biochemistry, multiple organ damage, and potential effects on male fertility (18,19)
- Immune disturbances (20, 21, 22), immune responses (21,13) and allergic reactions (23)
- Enzyme function disturbances in kidney and heart (24)
- Stomach lesions and unexplained deaths (25, 26, 27, 28)
- Higher density of uterine lining (29)
- Severe stomach inflammation and heavier uterus (30)
- Differences in organ weights (14), which is a common sign of toxicity or disease.

In the most detailed feeding study ever carried out on a GE food, severe damage to the liver, kidney, and pituitary gland was found in rats fed a commercialized GE maize and tiny amounts of the Roundup herbicide it is grown with over a long-term period. Additional observations were increased rates of large tumours and mortality in the rats fed GE maize and/or Roundup (29). GE maize that had not been treated with Roundup had similar toxic effects to the GE maize sprayed with Roundup and to Roundup on its own, indicating that the GE crop itself was toxic.

This study came under heavy attack by pro-GE critics and was retracted by the journal that published it, over a year after it had passed peer review and appeared in print. However, the retraction was condemned as invalid by hundreds of scientists worldwide (30, 31).

The argument that trillions of GE meals have been eaten with no ill effects is disingenuous. No epidemiological studies have been carried out to track consumption of GE foods and to assess whether there are ill effects that correlate with consumption. What is more, such studies are not even possible on the continent where most GE meals are consumed – North America – as GE foods are not labelled there. Unless consumption causes an acute and obvious reaction that can be immediately traced back to a GE food, the link cannot be made. An increase in incidence of a common, slow-developing disease like cancer, allergies, or kidney or liver damage would be difficult or impossible to link to GE foods.

Food allergies that arise from new proteins or metabolites thereof are a very important food safety issue and should be tested for as such on an on-going basis. Not only can people and animals become allergic to foreign proteins, but they can also develop new cross allergies to other unrelated foods because they have become sensitised. This has occurred with mice fed on GE peas (Fabaceae family), genetically engineered with a protein derived from the closely related bean, also in the Fabaceae family (17).

An example of an extensively used GE food ingredient that has a record of health problems associated with it is GE soy. Research on GE soy shows that allergies to such soy have become a serious health issue. Soy allergies increased by 50% in the UK not long after GE soy was introduced (32). A portion of the transgene from ingested GE soybeans, along with the promoter that switches it on, transfers into human gut bacteria after ingestion (33). Therefore, long after people stop eating GE soy, they may be constantly exposed to its potentially allergenic protein, which is being created within their gut. (This protein may be made more allergenic due to mis-folding, attached molecular chains, or rearrangement of unstable transgenes, but there is currently insufficient data to support or rule out these possibilities.)

Allergies to GE foods have already been widely recorded in the US, where thousands of consumers complained to food manufacturers about possible reactions to StarLink corn (34, 35).

Lack of published data on the safety of GE potato varieties

There is no peer-reviewed, published scientific literature on GE potato feeding studies that has unequivocally established the safety of these GE potato lines. There are, however, published studies detailing the toxicity of other GE potato lines, which contained DNA constructs that were thought to be harmless. A 1998 feeding study of Monsanto's genetically engineered NewLeaf potato, bred in 1995 from the Russet Burbank variety to be resistant to the Colorado Beetle, showed the potatoes did considerable damage to the organs of the rats in the study. In comparison rats in "control groups" fed on normal potatoes or on a non-potato diet were healthier, and had much less organ and tissue damage. (36)

Ewen and Pusztai (1999) studied the effects of GE potatoes engineered to produce naturally occurring insecticides (lectins) on rats. Their feeding studies showed that these potatoes damaged the animals' gut, other organs, and immune system (12).

Whilst the GE potatoes in this application A1139 are claimed to contain only DNA from the *Solanum* genus, one must also consider the other genetic elements present in the inserted DNA construct, such as the CaMV35S promoter, a viral promoter completely unrelated to the *Solanum* genus. In addition, the risk of downstream effects from insertional mutagenesis is inevitable to some degree.

Professor David Williams, a New Zealander carrying out medical genetic engineering research at the San Diego School of Medicine, California, is quoted as saying:

"I'm afraid that most of us who work with transgenics are pretty uncritical. Most of us assay for the transgenic product and ignore the secondary effects. Even those people doing functional genomics on transgenics mostly ignore changes that 'don't make sense', i.e., cannot be seen as immediately attributable to the transgene. Hence, it's hard to get an idea of the extent and prevalence of downstream effects from insertional mutagenesis and simple imbalances caused by transgene expression. The biggest risk is that we don't know. The problem with transgenics that are released into the environment and used in the food supply, however, is that the potential consequences of deleterious unknowns are clearly greater."

Assessment of the A1139 Application

Compositional data is referred to in **section 1.2** of this application. This can only identify known compounds and therefore would not detect/quantify unknown compounds that could easily be toxins and/or carcinogens. Novel proteins/metabolites may only be known about after their negative effects on humans/animals eating the GE foods are noted. This requires animal feeding experiments, as safety cannot be assumed on the basis of compositional data.

No investigation into the safety of these GE potatoes has been carried out. As stated in **section 2.1** "This assessment does not address… any risks to animals that may consume feed derived from GE plants" and "no potential public health and safety concerns have been identified". The lack of regard for food safety is further reiterated with "…food derived from potato lines W8, X17, Y9, F10 and J3 is considered to be as safe for human consumption as food derived from conventional potato cultivars". A statement that a GE food is safe (by FSANZ) is not evidence of that food's safety.

In **section 2.2.1** it says that the "raw or uncooked tubers as well as processed products derived from lines W8, X17, Y9, F10 and J3… would be expected to contain novel DNA and/or novel protein. If so they are likely to require labelling as genetically modified". There are two issues to consider here:

Firstly, no detail is given on the methodology of how any novel DNA or protein will be detected.

Secondly, any raw or uncooked tubers, or even small pieces of raw tubers, can regenerate easily into potato plants. Any raw GE potato material could be responsible for the establishment of wild populations of these potatoes. These could spread easily by asexual (vegetative) reproduction or by sexual reproduction via the flower/seed route. The fact that we need to import potatoes is absurd, given that our climate and soils are ideally suited to their cultivation.

McDonalds in the US decided not to use Simplot's GE potatoes for its French fries (37, 38)

High-performing non-GE potato alternatives currently available

In **section 2.4.3** it states that the applicant has indicated that reduced blackspot bruising of these GE potato lines can reduce wastage during storage and processing, and that the potatoes are resistant to the fungal disease known as foliar late blight. There are already several non-GM varieties of blight-resistant potatoes (including 'Waneta' and 'Lamoka'), which have been released by plant breeders from the University of Cornell (US). These varieties are ideal for chips, because they store very well and produce a good colour when cut (39). The Cornell breeding programme develops chipping and tabletop varieties, focussing on colour, size, shape, texture, and disease- and pest-resistance.

Cumulative consumption of GE potato in processed foods

Potato products are widely used in the production of processed foods, often for those who are intolerant or sensitive to gluten. The GE potato products (e.g. potato flour/starch) could therefore be widely consumed on a daily basis in multiple food products.

Summary

There have been no independent, long-term, peer-reviewed studies proving that the ingestion of any GE foods is safe for humans or animals. Nor has the US population – being the principle country releasing untested, unlabelled GE foods over a period of years - been monitored for any resulting effects of ingesting multiple transgenic foods on a continuous, daily, long-term basis. There has been no independent scientific study to investigate the link (or not) between the two- to ten-fold increase in food-borne illnesses in the US (1994 to 1999) and the commercial release of transgenic crops there from the mid 1990s onwards. In Scandinavia, where genetically engineered foods have not been widely allowed in the food chain, the same statistics have remained virtually static. The US has not evaluated rates for cancers or other statistically monitored health problems since the introduction of GE foods.

Assumptions made by FSANZ that the GE potato lines F10, J3, W8, X17, Y9 and E56 are safe to eat are not backed up by any comprehensive food safety research data.

The fact that McDonalds (USA) decided not to use Simplot's GE potatoes for its French fries shows a lack of confidence in the regulatory process.

PSGR regards GE foods as inherently unsafe, with current safety assessments not complete or rigorous enough to protect from, or even identify, most of the risks.

PSGR supports a zero-tolerance level for genetically engineering organisms in foodstuffs. This is technically achievable.

PSGR supports an Identity Preservation traceability system being in place on all foodstuffs to ensure that labelling accurately reflects the presence or absence of food or food ingredients produced using GE technology. Mandatory IP traceability would facilitate quality control, the verification of labelling claims, and the possible necessity of withdrawing products, should unforeseen adverse effects to human health or the environment occur. It will also facilitate the monitoring of potential effects that GE organisms could have on human and animal health and the New Zealand environment.

PSGR supports mandatory, fully detailed, accurate, Country of Origin labelling for all packaged and unpackaged meat, fish, dairy produce, fruit and vegetables, be they in a whole form or as part of an ingredient or additive, or used in the production thereof.

PSGR supports full public disclosure of all information gathered by, or required to be gathered by, government on residues in foods whether they be from pesticides, herbicides or insecticides, heavy metals, industrial chemicals or their by-products, veterinary medicines and any other contaminants.

Such information is crucial in allowing New Zealanders to make informed purchasing decisions, and to meet the basic human rights of New Zealanders to know where food purchases originate.

PSGR are unable to present this submission in person.

This submission has been prepared with the assistance of Dr Elvira Dommisse, BSc (Hons.), PhD, a former Genetic Engineering Scientist for DSIR/Crop & Food Research, Lincoln.

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References

1. FAO/WHO "Evaluation o f allergenicity of genetically modified foods." (FAO/WHO, Jan 22–25, 2001).

2. Seralini GE, Mesnage R, Clair E, Gress S, de Vendômois JS, Cellier D. Genetically modified crops safety assessments: Present limits and possible improvements. Environ Sci Eur. 2011; 23. Doi:10.1186/2190-4715-23-10.

3. De Vendamois 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; 5:706–26.

4. Seralini GE, Cellier D, Spiroux de Vendomois J. New analysis of a rat feeding study with genetically modified maize reveals signs of hepatorenal toxicity. Arch Environ Contam Toxicol. 2007; 52:596–602.

5. Kilic A, Akay MT. A three generation study with genetically modified Bt corn in rats: Biochemical and histopathological investigation. Food Chem. Toxicol. 2008; 46:1164–70. doi:10.1016/j.fct.2007.11.016.

6. US Food and Drug Administration (FDA). Biotechnology consultation note to the file BNF No 00077. Office of Food Additive Safety, Center for Food Safety and Applied Nutrition; 2002. Available at: http://bit.ly/ZUmiAF.

7. US Food and Drug Administration (FDA). Biotechnology consultation note to the file BNF No 00077. Office of Food Additive Safety, Center for Food Safety and Applied Nutrition; 2002. Available at: http://bit.ly/ZUmiAF.

8. Gu J, Krogdahl A, Sissener NH, et al. Effects of oral Bt-maize (MON810) exposure on growth and health parameters in normal and sensitised Atlantic salmon, Salmo salar L. Br J Nutr. 2013;109:1408-23. doi:10.1017/S000711451200325X.

9. Poulsen M, Kroghsbo S, Schroder M, et al. A 90-day safety study in Wistar rats fed genetically modified rice expressing snowdrop lectin Galanthus nivalis (GNA). Food Chem Toxicol. 2007;45:350-63. doi:10.1016/j.fct.2006.09.002.

10. Schroder M, Poulsen M, Wilcks A, et al. A 90-day safety study of genetically modified rice expressing Cry1Ab protein (Bacillus thuringiensis toxin) in Wistar rats. Food Chem Toxicol. 2007;45:339-49. doi:10.1016/j.fct.2006.09.001.

11. Trabalza -Marinucci M, Brandi G, Rondini C, et al. A three-year longitudinal study on the effects of a diet containing genetically modified Bt176 maize on the health status and performance of sheep. Livest Sci. 2008;113:178–190. doi:10.1016/j.livsci.2007.03.009.

12. Ewen SW, Pusztai A. Effect of diets containing genetically modified potatoes expressing Galanthus nivalis lectin on rat small intestine. Lancet. 1999;354:1353-4. doi:10.1016/S0140-6736(98)05860-7.

13. Pusztai A, Bardocz S. GMO in animal nutrition: Potential benefits and risks. In: Mosenthin R, Zentek J, Zebrowska T, eds. Biology of Nutrition in Growing Animals.Vol 4. Elsevier Limited; 2006:513–540. Available at: http://www.sciencedirect.com/ science/article/pii/S1877182309701043.

14. Kroghsbo S, Madsen C, Poulsen M, et al. Immunotoxicological studies of genetically modified rice expressing PHA-E lectin or Bt toxin in Wistar rats. Toxicology. 2008;245:24-34. doi:10.1016/j.tox.2007.12.005.

15. Fares NH, El-Sayed AK. Fine structural changes in the ileum of mice fed on delta-endotoxin-treated potatoes and transgenic potatoes. Nat Toxins. 1998;6(6):219-33.

16. Krzyzowska M, Wincenciak M, Winnicka A, et al. The effect of multigenerational diet containing genetically modified triticale on immune system in mice. Pol J Vet Sci. 2010;13:423-30.

17. Prescott VE, Campbell PM, Moore A, et al. Transgenic expression of bean alpha-amylase inhibitor in peas results in altered structure and immunogenicity. J Agric Food Chem. 2005;53:9023–30. doi:10.1021/jf050594v.

18. Gab – Alla AA, El-Shamei ZS, Shatta AA, Moussa EA, Rayan AM. Morphological and biochemical changes in male rats fed on genetically modified corn (Ajeeb YG). J Am Sci. 2012;8(9):1117–1123.

19. El-Shamei ZS, Gab-Alla AA, Shatta AA, Moussa EA, Rayan AM. Histopathological changes in some organs of male rats fed on genetically modified corn (Ajeeb YG). J Am Sci. 2012;8(10):684–696.

20. Finamore A, Roselli M, Britti S, et al. Intestinal and peripheral immune response to MON810 maize ingestion in weaning and old mice. J Agric Food Chem. 2008;56:11533–39. doi:10.1021/jf802059w.

21. Tudisco R, Lombardi P, Bovera F, et al. Genetically modified soya bean in rabbit feeding: Detection of DNA fragments and evaluation of metabolic effects by enzymatic analysis. Anim Sci. 2006;82:193–199. doi:10.1079/ASC200530.

22. Hines FA. Hines FA. Memorandum to Linda Kahl on the Flavr Savr tomato (Pathology Review PR–152; FDA Number FMF–000526): Pathology Branch's evaluation of rats with stomach lesions from three four-week oral (gavage) toxicity studies (IRDC Study Nos. 677–002, 677–004, and 677–005) and an Expert Panel's report. US Department of Health & Human Services; 1993. Available at: http://www.biointegrity.org/FDAdocs/17/view1.html.

23. Pusztai A, Bardocz S. GMO in animal nutrition: Potential benefits and risks. In: Mosenthin R, Zentek J, Zebrowska T, eds. Biology of Nutrition in Growing Animals.Vol 4. Elsevier Limited; 2006:513–540. Available at: http://www.sciencedirect.com/ science/article/pii/S1877182309701043.

24. Pustzai A. Witness Brief – Flavr Savr tomato study in Final Report (IIT Research Institute, Chicago, IL 60616 USA) cited by Dr Arpad Pusztai before the New Zealand Royal Commission on Genetic Modification. 2000. Available at: http://www. gmcommission.govt.nz/.

25. Pustzai A. Can science give us the tools for recognizing possible health risks of GM food? Nutr Health. 2002;16:73-84.

26. Pustzai A, Bardocz S, Ewen SWB. Genetically modified foods: Potential human health effects. In: D'Mello JPF, ed. Food Safety: Contaminants and Toxins. Wallingford, Oxon: CABI Publishing; 2003:347–372

27. Brasil FB , Soares LL, Faria TS, Boaventura GT, Sampaio FJ, Ramos CF. The impact of dietary organic and transgenic soy on the reproductive system of female adult rat. Anat Rec Hoboken. 2009;292:587–94. doi:10.1002/ar.20878.

28. Carman JA, Vlieger HR, Ver Steeg LJ, et al. A long-term toxicology study on pigs fed a combined genetically modified (GM) soy and GM maize diet. J Org Syst. 2013;8:38–54.

29. Seralini GE, Clair E, Mesnage R, et al. [RETRACTED:] Long term toxicity of a Roundup herbicide and a Roundup-tolerant genetically modified maize. Food Chem Toxicol. 2012;50:4221-4231.

30. EndScience EndScienceCensorship.org. Statement: Journal retraction of Séralini GMO study is invalid and an attack on scientific integrity. 2014. Available at: http://www.endsciencecensorship.org/en/page/Statement#.UwUSP14vFY4. Accessed February 19, 2014.

31. Institute of Science in Society. Open letter on retraction and pledge to boycott Elsevier. 2013. Available at: http://www.i-sis. org.uk/Open_letter_to_FCT_and_Elsevier.php#form. Accessed February 19, 2014.

32. Townsend , M.Why soya is a hidden destroyer. Daily Express, Mar 12, 1999.

33. Netherwood et al. Assessing the survival of transgenic plant DNA in the human gastrointestinal tract. Nature Biotech. 22 (2004): 2.

34. Freese, B. The StarLink affair: Submission by Friends of the Earth to the FIFRA scientific advisory panel considering assessment of additional scientific information concerning StarLink corn (Jul 17–19, 2001).

35. Assessment of additional scientific information concerning StarLink corn (FIFRA scientific advisory panel report, No. 2001–09, Jul 2001).

36. Medical -biological investigations of transgenic potatoes resistant to Colorado beetle (under agreement with Monsanto Co.). Russian Academy of Medical Sciences, Institute of Nutrition Moscow, 1998. Signed off by V A Tutelian, Deputy Director. Physiological, biochemical and morphological investigations in rats. Full report 275pp, including raw data.

37. www.fooddive.com/news/genetically-engineered-potato-varieties-approved-by-us/437206
38. www.motherjones.com/tom-philpott/2014/11/simplot-innate-new-gmo-potato-mcdonalds
39. www.isaa.org/kc/cropbiotechupdate/article/default.asp?ID=7422

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