GE Free New Zealand

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Dear Chair and Committee,

We thank you for your letter of clarification sent on the 25th June, and would like to re submit our appeal now that the A1073 food has been gazetted in New Zealand under section 11L of the Food Act 1981.

Our complaint focuses on the section 11E (1) (a), (2) (a-c) of the Food Act, did the Minister take into account the preconditions for issuing the food standard in relation to the obligations to protect human health.

Under section 2(a) & (e) of the Regulatory (Disallowance) Act 1989[1] GE Free NZ would like to draw to the attention of the House the approval of A1073 governing food produced with gene technology, Standard 1.5.2 under the Food Standards Australia New Zealand Regulations 1994, Major Procedure[2] (see detail in section on inter governmental agreements relating to our concerns, below) as made by the Ministers of the Crown under the Trans Tasman Food Standards Australia and New Zealand (FSANZ) Act.

The Minister has approved the application A1073 for a genetically modified soybean tolerant to 2,4-D, glyphosate and glufosinate ammonium into the food chain under her obligations in respect to of genetically modified food as part of the Food Act 1981, 11C (2) (d)[3] and it has also been gazetted in the General Section Food Standards Australia New Zealand Food Standards Australia New Zealand Act 1991 Australia New Zealand Food Standards Code – Amendment No. 140[4] under section 11L of the Food Act 1981, dated 15 May 2013 which came into effect on the 20 June 2013.

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[1] Regulatory (Disallowance) Act 1989
http://www.legislation.govt.nz/act/public/1989/0143/latest/DLM195540.html

[2] Food Standards Australia New Zealand Regulations 1994 (Major Procedure)
http://www.comlaw.gov.au/Details/F2010C00453

[3] Food Act 1981
http://www.legislation.govt.nz/act/public/1981/0045/latest/DLM50188.html

[4]http://www.dia.govt.nz/pubforms.nsf/NZGZT/NZGazette44Apr13.pdf/$file/NZGazette44Apr13.pdf

1. The Regulation does not give confidence for public safety.

2. The amendment does not fulfill the publics expectation of rigorous scientific assessment required of Food Standards Agency /Authority

3. These applications have not been subjected to acceptable levels of scientific scrutiny to guide proper assessment.

4. There is no evidence that they have undertaken any dietary exposure modeling or conducted scientific risk assessment son ingestion of the whole food.

5. The USDA has deferred the approval of the commercial planting of this soybean until 2014 as there is insufficient evidence of safety as to the environmental and health effects.

6. The food is not going to be labelled so they have not been able to provide information to consumers on the product to enable consumer choice.

7. The lack of studies that would meet the international best-practice guidelines of Codex Alimentarius and considered necessary to ensure a GMO food is safe, means consumers cannot have confidence in the assessment.

8. We believe that the health concerns we raised in our submissions have been dismissed not considered in a measured and scientific way.

9. We have been involved in the submission process and written an urgent request of our concerns to all the members of the Ministerial Council and the NZ Minister notified us that she would not be asking for a review our concerns.

10. We believe this lack of respect shown to concerned submitters makes us believe that we have not been treated in an open and accountable manner on the issues we raised.

Background:
We have been involved is the submission process of A1073 from the beginning.

To this end, GE Free NZ members have met with Mr. Dean Stockwell Manager of FSANZ NZ and Ms. Trish Ranstead from the Ministry of Primary Industries. Ms. Trish Ranstead advised us that our concerns should be referred to the Regulatory Disputes Select Committee.

It is the right and expectation of consumers to expect that the regulatory assessments of FSANZ have followed the legislated procedures and meet the legitimate public safety guarantees over food produced with gene technology, as stipulated by the FSANZ Act, the Australia, New Zealand Food Standards code and the Food Act in relation to public safety.

We would like the approval decision for A1073 made under the Food Act 1891 11L to be

considered for regulatory dismissal under Standing Order 310 and 315 (2) (a) – (h) as set out below.

There are severe omissions of information and data in the risk /safety assessments, these omissions impose on the rights and abilities of consumers and health professionals to make informed choices about health in relation to the GM foods. This soybean has been genetically engineered to withstand three herbicides — 2,4-D, glyphosate and glufosinate ammonium. All of these herbicides have been linked to damage of digestive, endocrine, reproductive and organ systems. This damage could potentially lead to liver and kidney failure, reproductive disorders, auto-immune disease and cancers.

1. The Authority approval of A1073 is not in accordance with the general objectives and intentions of the Food Act 11B and 11E(a) to protect public health. The approval has negated the rights and liberties of persons dependent on administrative decisions:-

   The public is led to believe that the public health risk and safety have been assessed through extensive and comprehensive expert assessment. However, the A1073 approval has relied on the information supplied by the applicant, and the raw data, for its initial assessment. The FSANZ science mission statement says that it relies on peer reviewed published data yet in its assessment of A1073 the data provided by the applicant had no published science on the effects of the whole food when consumed. Independent published feeding studies (Seralini et al, 2012)[5] have raised concerns over the harm to animals eating transgenic herbicide tolerant foods. Though FSANZ has openly criticised these findings it has not adequately addressed the evidence of harm or provided research to validate its opinion.

2. The approval appears to make unusual and unexpected use of powers conferred by the statute under which it is made.

   The FSANZ appears to rely on the absence of evidence in so much as they have approved a food that the European Food safety (EFSA) Authority has declined due to absence of vital information of its safety.
   The USDA has deferred approval for commercial planting of this 2,4-D soy and corn saying that it has

   > *"determined that its regulatory decisions may significantly affect the quality of the human environment ... [and] therefore believes it necessary under NEPA to prepare these two EIS's to further assist the Agency in evaluating any potential environmental impacts before we make a final determination regarding the products' regulatory status".*

[5] Seralini. G-E., Clair. E., Mesnage. R., Gress. S., Defarge. N., Malatesta. M,. Hennequin. D., and de Vendomois. JS. (2012) Long term toxicity of a Roundup herbicide and Roundup tolerant genetically modified maize. *Food and Chemical Toxicity*. Vol: 50, (11) 4221–4231http://dx.doi.org/10.1016/j.fct.2012.08.005

This is a telling flaw in the safety assessment as how can an absence of evidence prove safety? How did FSANZ have enough information for food safety when the USDA had not?

To date there is no understanding as to what effect the bacterial transgenes and the pesticides sprayed onto the soybean will have when consumers ingest it. Therefore it is misleading of FSANZ to say this food is safe and to have recommended this food for entry into the human food chain given the lack of any biological scientific data.

FSANZ conducts no independent scientific study of its own. The NZ MPI /ESR does not commission its own studies and simply reviews the assessments made by the FSANZ staff in Australia with no reference to any relevant science data that the applicant does not provide. This is in contrast to the safety approach taken by The European Food Safety Authority (EFSA), which has initiated the requirement to have a 90-day feeding study on GM applications.

The earlier applications for approval of gene technology foods set a precedent, in that feeding studies on small animals were conducted. However, the requirement for such studies in an assessment on a major application has been dropped. No feeding studies, let alone lifetime feeding studies, are now provided.

The absence of feeding studies poses a danger to public health. We would like to highlight an example of a transgenic soybean[i].

Nordlee et al[6] tested transgenic soybeans, modified with the Brazil nut 2S albumin, on nine subjects who undertook allergen testing by a skin prick test. The subjects reacted to the transgenic soybeans and the Brazil nuts but not conventional soybeans. The soybeans were not permitted entry into the food chain as the study showed that an allergen from a food known to be allergenic could be transferred into another food by genetic engineering. (Nordlee et al, 1996.) [7]

The most recent study on the effects of GM foods (Glyphosate, glufosinate and Bt) on animals (pigs) Carman *et al* (2013) found [7]

> *GM-fed pigs had uteri that were 25% heavier than non-GM fed pigs (p=0.025). GM-fed pigs had a higher rate of severe stomach inflammation with a rate of 32% of*

[6] Nordlee J.A., Taylor S.L., Townsend J.A., Thomas L.A., and Bush R.K. (1996) Identification of a Brazil-Nut Allergen in Transgenic Soybeans. *The New England Journal of Medicine.* Vol. 334:11: 688-692

[7] Carman J., Vlieger H., Veer Steeg L., Sneller V., Robinson G., Jones C, Haynes J. & Edwards J. (2013) A long-term toxicology study on pigs fed a combined genetically modified (GM) soy and GM maize diet Journal of Organic Systems Vol.8 No.1 http://www.organic-systems.org/journal/81/abstracts/8106.html

GM-fed pigs compared to 12% of non-GM-fed pigs (p=0.004). The severe stomach inflammation was worse in GM-fed males compared to non-GM fed males by a factor of 4.0 (p=0.041), and GM-fed females compared to non-GM fed females by a factor of 2.2 (p=0.034).

Until such a study is conducted there can be no meaningful biological data to assess in relation to public safety and any potential effect cannot be known. There fore there is no science to allow the Minister to take into account the preconditions for issuing the food standard, 11L.

3. Trespasses unduly on the rights and liberties on the choice and health of the public.

The latest Application (A1073) has three engineered genes conferring resistance to highly toxic herbicides. Even though there are 30,000 pages of information in the application there is a total absence of scientific studies on the effects of eating this food. This departure from prior practice, not requiring feeding studies, does not match the public expectation of expert safety review. The recommendation by ESR/MPI to add "endogenous allergen" experiments to the safety report[8] has not been complied with.

4. Other reasons for our request –

We acknowledge that New Zealand has given over it sovereign right to have its own experts assess foods produced using gene technology. We also acknowledge that the MPI has no higher standing in the process that a public submitter. However the minister has, she is equal member in the process of approval and should have raised these concerns for the New Zealand public.

The Unintended effects and substantial differences between the comparator and the GE soy have also not been followed using scientific methodology.

The FSANZ document of the "Safety of GM Foods"[9] states:

The 'intended effects' of genetic modification are those that happen as a direct result of the presence of new genetic material and proteins, as described above. However, genetic modification may also have 'unintended effects'. For example, it may change the levels of toxins, allergenic components, nutrients or anti-nutrients in a food. The safety assessment looks specifically at these characteristics, to ensure that there are no major differences between the GM food and its conventional equivalent. p.12

[8] Dr. Rob Lake. ESR review of FSANZ safety assessment report A1073 for genetically modified (GM) food. November 2012

[9] GM foods: Safety Assessment of Genetically Modified Foods (2005) Food Standards Australia New Zealand. ISBN 0 642 34599 6

and

The safety assessment process used for GM foods is more thorough than that used for any other food. It is designed to ensure that GM foods provide all the benefits of conventional foods with no additional risks. p.14.

This assurance given to the public cannot be given effect in the absence of vital biological effects of ingestion data. The absence of information means that "intended" or "unintended" effects on any sector of the population whether healthy or suffering from pre existing health issues, cannot be evaluated.

5. There is no avenue provided for public hearings to be held though the public has been led to believe they are required.

6. The decisions put WTO obligations ahead of public safety as their decision in A1073 says

> *"not preparing a draft variation to the Code was considered likely to be inconsistent with Australia's and New Zealand's WTO obligations,'"*

The trade obligations are secondary to the first and foremost obligation, safety to public health, as the Act provides. This makes it even more important that the regulatory process gives effect to the intention and indeed the wording of the Act itself around public and consumer safety. Standing Order 310 (2) (d) indicates that this must be of interest to the committee.

The consequences of these discrepancies are:

By making decisions about GM foods without having available or considering essential scientific data on the health impacts of those foods FSANZ has denied the publics right to fundamental information about the food they are eating, and the right to choose products they believe to be safe.

Specifically, new GM foods and their increasingly complex structure expose consumers to a range of insecticides and herbicide "resistance proteins" and herbicide residues, which have been proven to cause serious harm in in vivo studies. This harm could impact adversely on certain individuals and have long-term impacts on public health.

A lack of feeding studies and absence of any data to inform the risk analysis of GM foods cannot underpin an expert assessment for safety. Toxicity concerns and dangers to health from the medium-term ingestion of GM foods have been addressed by independently published studies as well as in previous submitter data. Livestock

farmers are reporting serious reproductive and digestive problems in animals that are eating these foods[10].

Consumers have a right to know that consumption of GM foods has been shown to cause health problems and expect that at level of data on ingestion have been assessed for public information and safety.

We would like to present our submission on applications A1073, A1042, and 1046[11] to you as they reflect the public concerns that have arisen around the regulations that provide the foundation for decision making to protect the public health of New Zealanders:

In summary the following actions would satisfy our concerns:

1. That The Regulations review Committee reviews the Food Act 11L amendment and FSANZ approval application A1073.
2. Comprehensive long-term feeding studies are conducted on relevant mammals as part of the assessment.
3. That MPI /ESR when in receipt of an application for food produced using gene technology does not only review the applicant data presented but uses a range of peer reviewed published science considered as part of the assessment of foods produced by gene technology.
4. That studies conducted by independent scientists are part of the initial documentation provided by the applicant of all foods produced using gene technology
5. That FSANZ reviews new scientific data as it comes available regarding the safety or otherwise of an already approved GM food product, using independent scientific advisors.
6. 1 year feeding studies on humans are part of the applicant's information at request for approval.
7. Lifetime or long term (longer then 6 months) feeding studies on small mammals are part of the applicant's information at request for approval.
8. Post monitoring with diagnostic tools are made available to Health Professionals.
9. Animal foods are labeled if they contain GE ingredients.
10. Oils sourced from GE crops are labeled.
11. That information as to the type of gene construct used is part of the label.

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[10] GM Soy linked to health damage in pigs -- a Danish Dossier
http://gmwatch.eu/latest-listing/1-news-items/13882

[11] Submission to A1073. http://www.gefree.org.nz/reports-and-submissions

FSANZ site for application.
http://www.foodstandards.gov.au/foodstandards/applications/applicationa1073food5541.cfm

12. We suggest the labeling code follows the construct name e.g. Bt11, RR, LL, Dow etc.

We would like to be heard and further present our reasons and have Professor G-E Seralini, Professor Don Huber and Dr. Frank Rawson as witnesses to the Committee.

Yours sincerely,

Jon Muller
Secretary GE Free NZ in Food and Environment.

GE Free NZ in Food and Environment is a voluntary non-governmental organisation (NGO) whose aims are to engage, through dissemination of information and submissions,
with the government, public and our members over issues of genetic engineering.

The intergovernmental agreements relating to our concerns are set out below -

The Food Act 1981

11C Minister may issue food standards

- (1) The Minister may from time to time issue standards in respect of food manufactured or prepared for sale or sold in New Zealand, or imported into New Zealand.

  (2) Without limiting the generality of subsection (1), standards may be issued under that subsection for the purposes of, or in relation to, all or any of the following:

  (a) food safety:

  (b) the composition of food, including (without limitation)—

  - (i) the maximum amounts of contaminants or residues that may be present in food:
  - (ii) the maximum or minimum amounts of additives or other substances that must or may be present in food:
  - (iii) the microbiological status of food:

  (d) the genetic modification of food:

  (i) the sale of food:

(j) information about food, including (without limitation) the labelling, promotion, and advertising of food:

(k) food safety programmes:

(m) such other matters relating to food as may affect public health.

11E Preconditions for issuing food standard

- (1) In issuing any food standard, the Minister shall take into account the following:

  (a) the need to protect public health:

  (2) The Minister shall not issue any food standard unless the Minister is satisfied that appropriate consultation has been carried out with respect to the food standard, including (without limitation)—

  (a) adequate and appropriate notice of the intention to issue the food standard; and

  (b) a reasonable opportunity for interested persons to make submissions; and

  (c) adequate and appropriate consideration of any such submissions.

11L Amendment and revocation of food standards

- (1) The Minister may at any time amend or revoke any food standard.

  (2) Subject to subsection (3), the provisions of sections 11E to 11K shall apply in respect of any amendment or revocation of any food standard.

  (3) Nothing in section 11E(2) applies in respect of any amendment to any food standard to correct any obvious mistake (including, without limitation, grammatical and typographical errors or omissions).

The "Agreement between the Governments of Australia and New Zealand[12] concerning a joint food standards system outlined in state:

(1) Food standards shall be developed under the Australia New Zealand Food Standards System in accordance with the following principles:

[12] Agreement Between The Government Of Australia And The Government Of New Zealand Establishing A System For The Development Of Joint Food Standards

(a) the protection of public health and safety;

*(b) the provision of adequate information relating to food to enable consumers to make informed choices; (*Annex A)[13]

- **Principles used by FSANZ in assessing the safety of GM foods[14]**
- Safety assessments for GM foods should:
- be based on the best current scientific knowledge
- be carried out on a case-by-case basis (because the safety concerns depend on the type of food and the nature of the genetic modification)
- fully consider the safety of each new component in a GM food (that is, any new DNA and protein) separately
- consider both the intended effects of the genetic modification (for example, the presence of a new protein) and the unintended effects (for example, changes to the levels of toxins or allergens) p11

The **Joint Ministerial Council Policy Guidelines On Novel Foods[15]** state:

- **High Order Principles**
- *To ensure that priority is given to the protection and improvement of public health and safety in relation to food matters.*
- *To ensure that consumers have access to sufficient information to enable informed and healthy food choices.*
- *Be consistent with and complement Australian and New Zealand national policies and legislation including those relating to nutrition and health promotion.*
- *To draw on the best elements of international regulatory systems*

[13] Annex A Principles For The Establishment Of Australia New Zealand Food Standards p.10

[14] GM foods: Safety Assessment of Genetically Modified Foods (2005) Food Standards Australia New Zealand. ISBN 0 642 34599 6

[15] Ministerial Council Policy Guidelines On Novel Foods *www.health.gov.au/internet/main/publishing.../**novel_guidelines**.pdf*

(i.e. protocols, standards, guidelines, assessment processes) and be responsive to future trends and developments (i.e. CODEX, WHO/FAO).

- *To provide a regulatory environment that is timely, cost effective, transparent and consistent with minimum effective regulation, and which encourages fair trade, industry growth, innovation and international trade.*

Specific Principles

- *To ensure that public and industry confidence in the food system is maintained.*

- *To provide an assessment process that aims to protect commercially sensitive information and recognise industry's intellectual property to the maximum extent possible.*
- *To ensure consumers are not misled by novel foods or food ingredients, which appear similar to existing foods but may differ in terms of nutrition or function.*

We find FSANZ regulations and implementation are not in accordance with the intentions of the FSANZ Act. This means that they come within your jurisdiction under Standing Order 310 (2) (a).

The FSANZ Act[16] requires under Section 3 the Object of the Act:

3. Object of Act

The object of this Act is to ensure a high standard of public health protection throughout Australia and New Zealand by means of the establishment and operation of a joint body to be known as Food Standards Australia New Zealand to achieve the following goals:

(a) a high degree of consumer confidence in the quality and safety of food produced, processed, sold or exported from Australia and New Zealand;

(b) an effective, transparent and accountable regulatory framework within which the food industry can work efficiently;

(c) the provision of adequate information relating to food to enable consumers to make informed choices;

[16] The Food Standards Australia New Zealand Act (1991) http://www.comlaw.gov.au/Details/C2012C00311/Html/Text#_Toc320010420

(d) the establishment of common rules for both countries and the promotion of consistency between domestic and international food regulatory measures without reducing the safeguards applying to public health and consumer protection.

The regulations allow[17]

3 Major procedure

3.1 This procedure applies to:

(a) an application for the development of a new food regulatory measure; and

(b) an application for the variation of a food regulatory measure that:

(i) involves scientific or technical complexity that makes it necessary to adopt this procedure for the application consideration process for the application; or

(ii) involves a significant change to the scope of the food regulatory measure that makes it necessary to adopt this procedure for the application consideration process for the application.

Examples

1 An application for the development of a new food regulatory measure, or a major variation to a food regulatory measure, involving:

(a) developing a new standard; or

(d) adding a new substance affecting a wide range of foods; or

(e) a pre-market approval, with no similar previous approvals.

2 This kind of application is likely to:

(a) involve a very extensive and complex assessment of the risk to public health and safety; or

(b) have a very broad and significant social or economic impact; or

(c) require a very extensive and complex toxicological, nutritional, food technology, dietary modelling or microbiological assessment; or

[17] Food Standards Australia New Zealand Regulations 1994 (Major Procedure) http://www.comlaw.gov.au/Details/F2010C00453

(d) require a very extensive and complex assessment of risk management measures; or

(e) involve the development of a very extensive and complex community communications strategy to address public concern; or

(f) require targeted consultation with key stakeholders or special interest groups; or

(g) require the development and distribution of community education material; or

(h) require extensive consultation with government agencies, industry, health professionals and consumer groups; or

(i) require the establishment of high-level advisory groups to discuss and interpret scientific evidence and social perceptions; or

(j) require community meetings including public hearings.

References

1. Food Act 1981
   http://www.legislation.govt.nz/act/public/1981/0045/latest/DLM48687.html

2. Agreement Between The Government Of Australia And The Government Of New Zealand Establishing A System For The Development Of Joint Food Standards

3. Annex A Principles For The Establishment Of Australia New Zealand Food Standards p.10

4. Ministerial Council Policy Guidelines On Novel Foods
   *www.health.gov.au/internet/main/publishing.../**novel_guidelines**.pdf*

5. The Food Standards Australia New Zealand Act (1991)
   http://www.comlaw.gov.au/Details/C2012C00311/Html/Text#_Toc320010420

6. Food Standards Australia New Zealand Regulations 1994 (Major Procedure)
   http://www.comlaw.gov.au/Details/F2010C00453

7. New Zealand Gazette notice (p.1372)
   http://www.dia.govt.nz/pubforms.nsf/NZGZT/NZGazette45May15.pdf/$file/NZGazette45May15.pdf

8. USDA Announces Intent to Prepare Environmental Impact Statements for Genetically Engineered Plants Under Review for Deregulation http://www.aphis.usda.gov/newsroom/2013/05/brs_24d_and_dicamba.shtml

9. Inadequate data prevent EFSA from concluding on safety of GM maize 98140 http://www.efsa.europa.eu/en/press/news/130416.htm?utm_source=newsletter&utm_medium=email&utm_content=hl&utm_campaign=20130417

10. Seralini. G-E., Clair. E., Mesnage. R., Gress. S., Defarge. N., Malatesta. M,. Hennequin. D. and de Vendomois. JS. (2012) Long term toxicity of a Roundup herbicide and a Roundup-tolerant genetically modified maize. Food and Chemical Toxicity. Vol: 50, (11) 4221–4231http://dx.doi.org/10.1016/j.fct.2012.08.005

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