GE Free New Zealand

In Food and Environment Inc.

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Dear Chair and Committee,

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.

We would like to draw to the attention of the House the FSANZ regulations around decisions governing food produced with gene technology, Standard 1.5.2. As set out in the Food Standards Australia New Zealand Regulations 1994, Major Procedure (see detail in section on inter governmental agreements relating to our concerns, below).

Our complaint focuses on the right of consumers to expect that the regulatory assessments of FSANZ have followed the legislated procedures and meet the legitimate public expectations over GM food safety approvals, as stipulated by the FSANZ Act and regulations. 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.

The Application A1073 for a genetically modified soybean tolerant to 2,4-D, glyphosate and glufosinate ammonium is undergoing the approval process governing food produced with gene technology. The assessment does not follow the principles stated for the approval process as set out in the intergovernmental agreements and regulations outlined in the grounds below.

We would like the FSANZ approval decision to be considered for regulatory dismissal under Standing Order 310 and 315 (2) (a) – (h) relating to A1073 application.

1. The Authority approval of A1073 is not in accordance with the general objectives and intentions of the FSANZ Act, which negates 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, FSANZ relies on the information supplied by the applicant, and the raw data if any, for its initial assessment. The FSANZ science mission statement says that it relies

on peer reviewed published data yet in its latest two assessments there have been only data provided by the applicant with no published science on the effects of the whole food when consumed. Independent published feeding studies (Seralini et al, 2012)[1] 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.

   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[2] 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]

   Until such a study is conducted on the whole soybean in application A1073 there can be no meaningful biological data to assess and any potential effect cannot be known.

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[1] 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

[2] 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

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.

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[3] has not been complied with.

4. Other reasons for our request –

   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"[4] 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

   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.

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

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

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 FSANZ decisions are not subject to review through the legal system and the approval of GM foods does not allow any legal avenue for challenge by a public – interest submitter. 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 allowing consumers to eat a range of insecticides and herbicide resistance proteins may cause serious harm to 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[5].

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.

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

We would like to present our submission on applications A1073, A1042, and 1046[6] 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:

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

The "Agreement between the Governments of Australia and New Zealand[7] 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:

(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)[8]

- **Principles used by FSANZ in assessing the safety of GM foods[9]**
- 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

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

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

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

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

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

the levels of toxins or allergens) p11

The **Joint Ministerial Council Policy Guidelines On Novel Foods**[10] 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 (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[11] requires under Section 3 the Object of the Act:

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

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

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;

(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[12]

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:

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

(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

(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.

The ways in which the current regulatory process differs from the requirements of the Agreement and the Act are:

In summary the following actions would satisfy our concerns:

1. That application A1073 have a "stop Clock" placed on it and the applicant called on to provide long term feeding studies on small mammals.
2. 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.
3. That studies conducted by independent scientists are part of the initial documentation provided by the applicant of all foods produced using gene technology
4. 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.
5. 1 year feeding studies on humans are part of the applicant's information at request for approval.
6. Lifetime or long term (longer then 6 months) feeding studies on small mammals are part of the applicant's information at request for approval.
7. Post monitoring with diagnostic tools are made available to Health Professionals.
8. Animal foods are labeled if they contain GE ingredients.
9. Oils sourced from GE crops are labeled.
10. That information as to the type of gene construct used is part of the label.
11. 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 up to 3 expert witnesses to the Committee.

Yours sincerely,

Jon Muller
Secretary GE Free NZ in Food and Environment

References

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

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

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

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

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

6. 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

7. 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

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