MADGE
Australia Inc.

FED UP WITH FSANZ

allowing GM in our food

OCTOBER 2012

PUBLIC HEALTH AND SAFETY IS BEING PUT AT RISK BY GENETICALLY MODIFIED (GM) CROPS. WE ARE BEING DENIED THE ABILITY TO CHOOSE GM-FREE FOOD.

The only long term, two-year, peer-reviewed toxicity study on GM corn (NK603) and its associated herbicide, Roundup, showed rats developed kidney and liver disease, mammary tumours and died prematurely.

The paper "Long term toxicity of a Roundup herbicide and a Roundup-tolerant genetically modified corn" by Seralini et al (2012) was published in the peer-reviewed journal Food and Chemical Toxicology.[1]

Russia has suspended the import and use of GM corn NK603 on the basis of this study.[2]

Australians have been eating NK603 possibly since 2002 when Food Standards Australia New Zealand (FSANZ) recommended it be approved. **It is in our food supply unlabelled.**

On October 4th FSANZ's claimed Seralini's peer-reviewed paper has limitations, the toxicity of Roundup is implausible and that it is not the only long-term trial of NK603. They cited Velimirov, et al, (2008),[3] a study which was later withdrawn.[4]

FSANZ had removed their reference to this study on their webpage by 8th October without explantation.[5] The Velimirov study was a reproductive study which showed reduced fertility in mice eating GM corn NK603xMON810. It did not track tumour development.

In regard to GM food, FSANZ is failing in its legislated objective of:

1) **Protection of public health and safety**
2) **Provision of adequate information to consumers**
3) **Prevention of misleading or deceptive conduct**[6]

Therefore MADGE Australia is asking for:

- **The immediate suspension of the importation and sale of NK603**
- **A freeze on GM approvals** by FSANZ while a review of all past and pending GM crop approvals takes place.
- **Full labelling** of all ingredients derived from a GM crop or process including all products from animals fed GM feed

What are GM crops?

Genetically Modified Crops are plants created through particular gene-splicing techniques. This includes **transgenics**, where **genes are moved between different species i.e. from bacteria to plants.**

Genes used in GM may come from bacteria, viruses, animals and plants. This is **entirely different to the natural breeding** that has been used for thousands of years.

GM crops have been changed in two main ways so they can:

1. **survive being sprayed with weedkiller** (herbicide tolerant). **NK603 is this type of GM corn.** It is sprayed with Roundup to kill weeds but allow the crop to survive. **The rats in Seralini's study were fed levels of Roundup permitted as residues in US crops and drinking water.**

2. **kill certain insects** that eat them (insect resistant). The GM toxins produced in the plants can't be washed off

The most widely grown **GM crops** are: **corn, soy, canola, sugarbeet and cotton.** They become **ingredients in many processed foods** and are also **fed to animals.**

PUBLIC HEALTH AND SAFETY IS BEING PUT AT RISK BY GENETICALLY MODIFIED CROPS.

Michelle Simon - Appetite for Profit:

"Our concentrated food system driven by insatiable profit, combined with a broken regulatory system held hostage by powerful economic interests."[7]

FSANZ's role is to provide expert advice on food **based on the best available science to the** body that approves food standards, **the Forum.**

Food Standard 1.5.2, allows the consumption of GM ingredients and food in Australia.

"Substantial equivalence" is not scientific

The Standard requires a "mandatory pre-market approval (including a food safety assessment)".[8] **The basic principle of FSANZ's assessment of GM crops is that they are "substantially equivalent" to non-GM crops.**[9] This is the key concept in assessment of GM foods worldwide and is laid out in CODEX, the international food standards setting body, guidelines.[10]

An Expert Panel Report on the Regulation of Food Biotechnology, prepared by the Royal Society of Canada in 2001 said "The panel finds the use of "substantial equivalence" as a decision threshold to exempt GM agricultural products from rigorous scientific assessment to be **scientifically unjustifiable and inconsistent with precautionary regulation of the technology."**[11]

The Expert Panel suggested instead GM crops should undergo rigorous scientific assessment, which had been designed by experts in open consultation. They recommended that the analysis of studies should be done by "arms-length" experts who "report their decisions and rationale in a public forum".[12]

"Substantial equivalence" can only be meaningful if GM food has undergone transparent and detailed testing to prove it is so. **Currently this concept is used to allow GM-derived foods to escape adequate toxicity, reproductive and multi-generational testing.**

Feeding studies?

The process of genetic modification causes unpredictable changes to the GM crop's DNA. They include mutations at the site of the GM gene insertion, deletions and rearrangements of the existing DNA and the accidental introduction of DNA. "The frequency of transformation-induced mutations and their importance as **potential biosafety hazards are poorly understood."**[13]

It has been argued **"well-conducted feeding trials are one of the best ways of detecting such unpredictable changes."**[14] FSANZ does not require any feeding trials in its pre-market approval of GM crops.
No regulatory agency anywhere in the world requires long-term GM feeding studies. Most studies are 90 days or less. Reproductive and multi-generational feeding trials are also not required.

Many feeding trials have shown statistically significant differences between animals fed GM and non-GM feed. Regulators and industry have dismissed these differences as "not biologically significant", "within the range of normal variation" or "within the range of biological variation". There is no definition or measurable endpoints for these terms therefore they "are a matter of opinion, not science." [15]

FSANZ's uses flawed GM company data to assess GM crops:

FSANZ has dismissed studies published in peer-reviewed journals, Internet publications and conferences that show problems with GM foods.[16] In contrast FSANZ accepts, without criticism, unpublished studies done by GM companies as the basis for their approvals of GM derived foods.[17]

FSANZ regard it as **"... the responsibility of companies that have developed GM foods to demonstrate the safety of that food** and to supply FSANZ with the raw data from scientific studies to prove this."[18]

FSANZ does no independent testing of GM-derived foods.

The Auditor-General Audit Report No 15 2010-11 (ANAO)[19] into FSANZ analyzed ten of FSANZ's accepted applications. The report does not say how many were of GM crops. They found "gaps in the supporting data identified in Table 3.3 were because either the information was not provided by the applicants; or **FSANZ has not documented whether the requirements were met."**... "an applicant may provide supporting documentation or **scientific studies that could be incorrect or incomplete**, whether this is intentional or not."[20]

Public health and safety is being put at risk

CASE STUDY

Case study –FSANZ and the Office of the Gene Technology Regulator's (OGTR) approval of GM canola GT73

MADGE spent 18 months analyzing the raw data FSANZ and the OGTR used to approve the planting and eating of Monsanto's GM Roundup Ready canola, GT73.[21] In a chicken feeding study sent to the OGTR **Monsanto reported a commercial animal feed they used as a comparison (control) was contaminated with GM.**

GM RR canola (GT73) used in a trout feeding study was grown 1.5m away from non-GM canola, which was to be used as a control. **The GM and non-GM canola are extremely likely to have cross-contaminated each other.** A separate GM canola line (GT200) was grown next to the GM (GT73) line and could have contaminated it as well.

This contamination makes the feeding trials scientifically worthless, if all animals are being fed GM contaminated feed what is point of the studies?

Monsanto reported to the US Food and Drug Administration (FDA) that their GT73 line "may be" contaminated with GT200. The GT200 line has not been approved for planting in Australia but it seems a likely contaminant of the GM RR GT73 canola we are growing and eating here.[22]

FSANZ and the OGTR failed to notice problems with the trials and the manner in which they were conducted even though they were given the raw data from Monsanto. FSANZ should have requested trials be redone with uncontaminated feed. The OGTR should have conducted tests to ensure Australia is not growing GM canola contaminated by an unapproved GM line (GT200).

These are only some of the problems MADGE found when reviewing Monsanto's data.

Case study – FSANZ approval of DOW's 2,4-D herbicide-tolerant CORN DAS-40278-9

On 19th August 2011, FSANZ approved a new **GM corn** line DAS-40278-9, which has been developed to be **tolerant to the herbicides 2, 4-D and quizalofop-P-ethyl.**[23]

It was developed by Dow AgroSciences to help farmers deal with their increasing "superweed" problems. Most GM crops in the US are routinely sprayed with Roundup but now the weeds are no longer dying. Therefore older herbicides like 2,4-D are being used to kill these "superweeds".

2,4-D is one of the chemical components of Agent Orange and has been **linked to birth defects and cancers.**

Dow conducted an **acute toxicity trial** on 5 male and 5 female mice. **The mice were given 2 doses of a GM protein one hour apart and observed for 2 weeks.** The AAD-1 protein used in the study was not obtained from the GM crop but was produced in a bacterial system. It was not derived from Sphingobium, which is the source of the gene used in this GM corn, instead it was taken from a different bacteria Pseudomonas. There are concerns it may perform differently to the protein produced by the GM crop.

When they were examined "one male mouse had **signs of an ulcer in the stomach**, and one female mouse had a **dark area in the cerebrum of the brain".**

FSANZ wrote, **"These findings were considered to be incidental and unrelated to treatment."**

FSANZ concluded that the Safety Assessment **did not identify any public health and safety concerns** and that food from herbicide-tolerant corn line DAS-40278-9 is equivalent to that from other commercially available corn cultivars in terms of its **safety for human consumption and nutritional adequacy.**

Queensland Health Protectorate submission said **"....FSANZ has relied significantly on Dow AgroSciences Study Reports** to progress this Application. Accordingly we remain concerned that the **scientific safety assessment could be viewed as not being independent."**[24]

FSANZ is in the process of approving DOW's Herbicide-tolerant Soybean DAS-44406-6

This GM soy will be sprayed with three herbicides: 2,4-D, glufosinate ammonium and glyphosate (Roundup).

Public submissions close mid-November 2012. The Forum will be asked to scrutinize FSANZ's approval late Feb 2013. If no review is requested, it will be gazetted early May 2013.

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DOW's 2,4-D herbicide-tolerant corn

Michelle Maisto "as a parent it's my moral and even legal responsibility to exercise caution and skepticism and when in doubt to err toward good sense. When small, vulnerable lives are at the heart of a matter, to do anything less would be criminal." [25]

CASE STUDY

Case study – FSANZ approval of GM corn NK603

The study **"Long term toxicity of a Roundup herbicide and a Roundup-tolerant genetically modified maize"** by Seralini ,et al, (2012) was recently published in the **peer-reviewed journal, Food and Chemical Toxicology.**[26]

Rats were fed Monsanto's GM corn NK603, NK603 treated with Roundup or Roundup in their drinking water. NK603 is an herbicide tolerant GM corn designed to be sprayed with Roundup. **The rats were fed levels of Roundup permitted as residues in US crops and drinking water.** The trials lasted two years. There was a control group of rats to which the GM and/or Roundup fed rats were compared.

Female rats in the GM and/or Roundup fed groups developed mammary tumours. Male rats developed liver and kidney disease. GM and/or Roundup treated rats began dying much earlier than rats not fed these substances. A male rat fed GM corn died at 120 days. The first death of a male control rat was a year later. Around the 550th day six female rats had died compared to only one control female.[27]

Dr Michael Antoniou, molecular biologist at King's College, London said "It shows an extraordinary number of tumours developing earlier and more aggressively (in the GM/Roundup fed rats) – particularly in female animals. **I am shocked by the extreme negative health impacts."**[28]

We have been eating this GM corn NK603 since 2002 when it was approved by FSANZ. It is not grown here but would have been imported as an ingredient for processed food. FSANZ approved it based on:

- **A 9-day acute toxicity trial** where mice were given single doses of a purified GM protein.
- **The assumption that** because the **GM protein** didn't appear similar to known allergens it **would not be allergenic.**
- **The assumption that** although there were differences in the GM corn's fatty acids and amino acids **it was "compositionally equivalent to unmodified corn varieties".**[29]

The EU approved this NK603 GM corn after a 90-day feeding trial conducted on behalf of Monsanto. They used 400 rats for the trial. 80 were fed GM corn but only 40 of these rats were subjected to blood tests.[30] **Was data from only the healthiest animals used?** Monsanto included this trial in the documents sent to FSANZ for approval even though FSANZ did not require it.

In 2010 Seralini reanalyzed the data from this Monsanto study. His analysis was published in the International Journal of Biological Sciences.[31] It found "side effects linked with GM maize consumption, which were sex- and often dose-dependent. Effects were mostly associated with the kidney and liver."

Who regulates the Regulators?

FSANZ has said they will ask Seralini et al to provide the original data and "undertake a comprehensive analysis in order to determine if amendment to the current approval of NK603 maize is required."[32] **FSANZ has previously dismissed Seralini's peer-reviewed 2010 paper, as well as peer-reviewed studies by others.**[33] MADGE Australia has found no ombudsman or other body able to review the scientific basis on which FSANZ allowed flawed data from Monsanto to be used to approve GM canola GT73.

The European Food Safety Authority (EFSA) claims it does not need to re-evaluate the safety of the GM maize because Seralini's study is "of insufficient scientific quality to be considered as valid for risk assessment." EFSA is the body that originally approved NK603. They have argued against the need for mandatory feeding trials and claim that, if they are done, 90-day trials are sufficient. These claims have been disproved by Seralini's research. **If EFSA supports the Seralini study it would condemn many of its own previous decisions.**[34]

The US Food and Drug Administration (FDA) have, at the time of writing, made no statement. Perhaps this is because it does not have a mandatory GM food safety assessment process. It does not carry out or commission safety tests on GM foods. They have a voluntary programme for pre-market review of GM foods. At the end of the process the FDA sends a letter to the company releasing a GM food noting that the company has concluded its GMO is safe and that the company is responsible for placing only safe foods on the market.[35]

The regulation of GM crops relies on the unscientific concept of "substantial equivalence" and inadequate, usually unpublished, trials mainly done by the GM companies themselves. **When issues of safety are raised the same groups who have approved GM foods on these inadequate grounds are asked to judge studies that challenge the basis of their previous decisions.** This cannot possibly be seen as being either scientifically or ethically appropriate.

Who regulates the Regulators?

Coordinated attacks on science, scientists and journalism

The Seralini study was subject to coordinated attack on the day it was released. The Science Media Centres put out press releases and quoted scientists critical of Seralini and his work.[36] Considering the potential threat to public health the media coverage was slight, superficial and did not seem to be aware that Seralini's is the only, long term, peer-reviewed toxicity study on this GM corn and its associated herbicide.

The global network of **Science Media Centres** present themselves as an "independent, not-for-profit service for the news media, giving journalists direct access to evidence-based science and expertise."[37] Their **funders include** learned societies but also "some of **the biggest names in the biotech industry such as Monsanto and Syngenta**, as well as the industry's global lobby CropLife International."[38] Many of the **scientists they quote are directly involved in the biotech industry.**[39]

Seralini's team and others have rebutted the criticisms of the study[40] yet this has not been widely reported either. **Australians are likely to be eating corn, potentially NK603, everyday;** in cornflakes, corn chips, taco shells and many other processed foods. **It is striking that a study showing harm to animals of this magnitude is barely being reported.**

When problems are discovered with GM foods and crops, the scientists and journalists involved are subject to attack. Examples include:

- **Ignacio Chapela endured an intensive internet-based campaign to discredit him** after he reported on the GM contamination of Mexican maize. "This campaign was reportedly masterminded by the Bivings Group, a public relations firm specializing in viral marketing – and frequently hired by Monsanto".
- Distinguished biochemist **Arpad Pusztai, was subject to "a gag order, forced retirement, seizure of data, and harassment** by the British Royal Society" after his research showed GM potatoes harmed rats.
- **Andres Carrasco, Professor of Molecular Embryology at the University of Buenos Aires, was threatened with physical violence** after his "research identified health risks from glyphosate, the active ingredient in Roundup"[41]
- **Journalists Jane Akre and Steve Wilson were fired** after Monsanto threatened to sue their employer, Fox News. They had researched a story about how Monsanto's GM bovine growth hormone, being injected into cows to increase milk production, has cancer causing potential.[42]

There can be no understanding of GM food and its effects if independent science and discussion is repeatedly shut down.

We are denied th

Context of GM crop development

GM crops have been developed and promoted in a context that has denied proper scientific and regulatory scrutiny. **Patents restrict independent testing** of GM crops.[43] Successive US governments have promoted the interests of the major developer of GM crops, Monsanto.[44] Regulators worldwide are relying on the flawed concept of "substantial equivalence." They have been criticized as having "enshrined protocols with little or no potential to detect adverse consequences of GMOs."[45]

The World Trade Organization (WTO) regards GM crop decisions as a potential trade issue. FSANZ's approval document on Dow's 2,4-D resistant GM corn states:

"As members of the World Trade Organization (WTO), Australia and New Zealand are **obligated to notify WTO member nations** where proposed mandatory regulatory measures are inconsistent with any existing or imminent international standards and the proposed measure **may have a significant effect on trade.** The inclusion of **food derived from corn line DAS-40278-9 in the Code would have a trade enabling effect** as it would permit any foods containing this line of corn to be imported into Australia and New Zealand and sold, where currently they would be prohibited."

e ability to choose GM-free food.

WE ARE BEING DENIED THE ABILITY TO CHOOSE GM-FREE FOOD

Elizabeth Farrelly

"nanoparticles, GM or BPA, all of which could be in your baby's banana custard and you'd never know." ..."Essentially, the government's take on what passes your lips, and mine, is "trust us." But can we?"[46]

The FSANZ website says there are mandatory labelling requirements for GM food.[47] Most people reading this would assume all GM-derived food is labelled. In fact **there are almost no GM labels on food.** This is despite the Australian Food and Grocery Council saying, if all ingredients derived from GM needed labelling, nearly every processed food on the shelves would have one.[48]

The lack of GM labelling means the public is being misled and cannot make informed choices about GM food purchases. The annual Swinburne National Technology and Society Monitor repeatedly shows the public has low levels of comfort about GM crops and animals.[49] The 2011 "Labelling Logic" food labeling review noted **"the genetic engineering of food gave rise to more submissions and more comments in consultation than any other single issue."**[50]

GM corn NK603 processed into corn oil, flour, starch and sugars and high fructose corn syrup has **escaped labeling since 2002.**[51]

2,4-D tolerant GM corn DAS-40278-9 processed into corn oil, flour, starch sugars and high fructose corn syrup **will escape labelling.**

In the past, **even polenta (ground corn) has escaped GM labelling.**[52] Corn is widely used as a feed for domestic livestock. Meat, dairy, eggs, fish and honey from GM fed animals are not labelled.

GM crops are refined into sugars, starches, oils and other ingredients used in processed food. FSANZ asserts these refined ingredients do not contain GM DNA or protein and therefore, according to standard 1.5.2, do not need to be labelled. These ingredients do contain traces of GM DNA and protein[53] and **tests are constantly improving the ability to detect GM material.**

GM crops are also fed to animals but the dairy, meat, eggs, fish and honey from these animals escape labeling. This is despite **GM DNA being found in the muscles and organs of animals eating GM.**[54] Research has also found "that there can be a **residual difference in animals or animal-products as a result of exposure to GM feed..."**[55]

GM contamination "unintentionally present" at less than 1% does not require labelling. This has resulted in **inaction from FSANZ after an infant formula tested positive to GM contamination.**[56]

GM flavours at less than 1%, processing aids and additives and food from restaurants, cafes and takeaway outlets are also unlabelled.

FSANZ has conducted only one pilot study into the labelling laws in 2003. **22% of tested samples had GM DNA. None had labels.**[57]

In contrast a New Zealand maker of soy sausages was prosecuted for labelling its sausages "non-GM" as they had 0.0088% GM present. The company pleaded guilty rather than face a legal bill of $63,000.[58]

It appears that food producers wishing to provide customers with GM-free produce are harshly punished for accidental contamination. In contrast foods detected as containing GM are allowed to escape labelling. This is entirely contrary to the public's desire for GM labelling.

The Public Health Association of Australia's (PHAA) GM policy calls for a **comprehensive monitoring and surveillance system to track the effects of GM foods.** They want a labelling system where consumers can easily identify foods containing ingredients originating from GM organisms and from animals fed GM feed.[59]

The Australian Medical Association's (AMA) submission to the "Labelling Logic" review called for full process-based labeling of GM foods similar to that of the EU. They also **called for a monitoring system so doctors can report if they think a patient may have had a reaction to a GM food.**[60]

In Europe food is labeled as GM when any ingredient has been derived from a GM plant or process. Labeling does not depend on GM residues being detectable in the final product. Europe does not label produce from animals fed GM feed.

Australia has the ability to regulate and label GM food. This may change depending on the outcome of the Trans Pacific Partnership Agreement free trade negotiations that Australia is currently a part of. The Biotechnology Industry Organization (BIO) wants a common regulatory approach to encourage trade in GM crops.[61] They also want US labelling practices. In both cases this would remove the little protection that Australia currently has.

The provisions of this Agreement will remain secret until it is signed by Parliament. **It is vital that our option to regulate and label GM food remains.**

The GM labelling requirements are in Standard 1.5.2 available at http://www.comlaw.gov.au/Details/F2012C00518
Division 2 - Labelling etc of food produced using gene technology

SOME EXAMPLES OF GM LABELLING IN UK AND AUSTRALIA/NZ		
Type of food / feed	**Food Standards Agency (FSA) UK**	**Food Standards Australia New Zealand (FSANZ)**
	Labelling required?	
Highly refined canola oil, soya oil, glucose syrup from maize starch	**YES**	**NO**
GM product used as a food ingredient, eg yeast extract	**YES**	**NO**
Feed produced from a GMO, eg Corn gluten feed, soybean meal	**YES**	**NO**
Food additive/flavouring produced from GMOs, eg lecithin extracted from GM soybeans used in chocolate	**YES**	**NO**
Food containing GM ingredients that is sold in catering establishments	**YES**	**NO**

http://www.food.gov.uk/policy-advice/gm/gm_labelling#.UHdr

CONCLUSION:

The Forum, chaired by the Honourable Catherine King, has the power to **compel FSANZ to review standard 1.5.2** Food Produced using Gene Technology. It can do this on the following grounds:

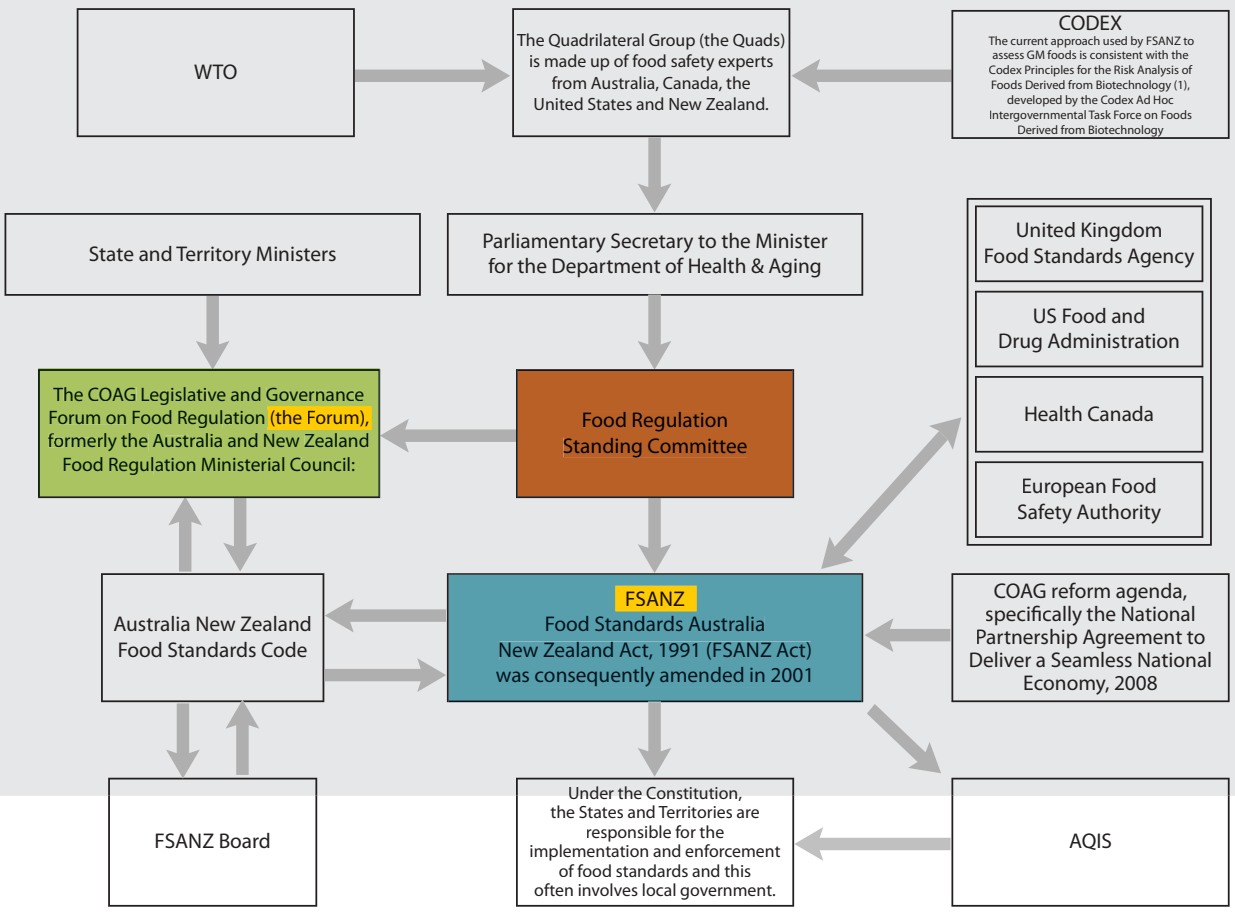
- **it is not consistent with the objectives of the legislation which establishes FSANZ**
- **it does not protect public health and safety**
- **it does not provide adequate information to enable informed choice**[62]

Public health is at risk from inadequately tested and virtually unlabelled GM food. The Forum must take immediate action to ensure:

- **The immediate suspension of the importation and sale of GM corn NK603**
- **A freeze on GM crop approvals by FSANZ while a review of all past and pending GM crop approvals takes place**
- **Full labelling of all ingredients derived from a GM crop or process including all products from animals fed GM feed.**

The current system for approving GM food is scientifically inadequate.[63] Suitable long-term feeding, toxicity, reproductive and multi-generational trials must be undertaken. Independent and non-Government experts must carry out the trials. All data and reasoning must be available to the public for review. Decisions about GM crops must only be taken once they have been proved not to threaten public health and safety. There should be no coercion to accept GM crops for trade reasons.

Australian Food Safety Regulation



GMO regulatory flow chart as described in The Auditor-General Audit Report No.15 2010-11
Performance Audit, Food Standards Australia New Zealand

Acronyms and Abbreviations

AMA	Australian Medical Association
BIO	Biotechnology Industry Organization
BPA	Bisphenol A
BfR	German Federal Institute for Risk Assessment
EFSA	European Food Safety Authority
FDA	Food and Drug Administration - US
FSANZ	Food Standards Australia New Zealand
GM	Genetic Modification
MADGE	Mothers are Demystifying Genetic Engineering
OGTR	Office of the Gene Technology Regulator
PHAA	Public Health Association of Australia
The Forum	Legislative and Governance Forum on Food Regulation
TPPA	Trans Pacific Partnership Agreement
WTO	World Trade Organization

FOOTNOTES:

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