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23 October 2008

To: The Senate Select Committee on Agricultural and Related Industries

Re: Submission to the Inquiry on Food Production in Australia

Thank you for the invitation to make a submission to this Inquiry. As evidence I have sent two attachments to this covering letter:

- Attachment 1 - Letter to Senator Heffernan.doc
- Attachment 2 - MADGE Body of Evidence 161008.doc

When people talk about food it is implicitly assumed that the food is of nutritional and energy value, and that the food is universally safe, or generally safe and clearly labelled.

It is also implicitly assumed that consumers are able to choose what food they buy.

I submit information about the genetic engineering process of seed development and subsequent food production, and address concerns over whether the regulatory environment is sufficient to meet these implicit characteristics of food.

I am one member in a network called MADGE (Mothers are Demystifying Genetic Engineering).

To give an example of regulatory concern, I present the following information:

> Over this last year I've had the opportunity to become exceptionally familiar with the scientific process and detail of genetically engineered crop development. I am particularly familiar with Monsanto's Roundup Ready Canola, known as "GT73".
>
> I have read the assessment documents on RR Canola from the US FDA, US EPA, Canada, Japan, European Food Safety Authority, as well as Australia, and report massive discrepancy between them.
>
> I need to see what Monsanto told FSANZ (then ANZFA) about the product, and I put in a public viewing request ten weeks ago. This material is "open to the public", yet I'm still waiting.
>
> I assert that FSANZ (then ANZFA) has deliberately misled the public in its presentation of material for public viewing. As just one example, here is a selection of statements from the Roundup Ready Canola report:
>
> > The statements were made in the Final Risk Analysis Report and Attachments, available on the web under the heading "Inquiry Report - 16 October 2000 at web address **http://www.foodstandards.gov.au/_srcfiles/A363%20draft%20IR.pdf**

• P3 Executive Summary:	"[The oil] undergoes extensive processing such that **all protein and DNA are removed**."
• P7 Issues Addressed During Assessment:	"... oil is **not considered** to contain any protein (or DNA). "
• P18 Final Safety Assessment Report – Background:	"As a result of the processing steps, canola oil contains **negligible** protein."
• P25 Expression of the Novel Protein in the Plant:	"... **all** protein is **virtually** removed upon processing canola seed [...]"
• P25 Expression of the Novel Protein in the Plant:	"**Total protein present in refined oil** of 1992 field trial of GT73 - 0.29 ppm [this figure is typical of the protein levels in refined oils].

Clearly this is a series of contradictory statements, and the statement in the Executive Summary is misleading. It seems likely to have influenced decisions about labelling, and about the presentation of fair information to consumers.

This is a simple illustration of misstatement but it is echoed in all aspects of the report, no less so in the provision of misleading information on the intricate aspects of the technical process.

I assert that the FSANZ (then ANZFA) document clearly demonstrates that they did not understand the scientific process behind the products they were assessing in the report they produced. They did not appear to know what novel proteins were produced by the plant, and they wrongly interchanged the words gene and protein 8 times in their assessment document. It appears that some of the novel proteins have not even been assessed on paper.

There are some allusions to these assertions in Attachment 1 and 2. It is easy to understand the genetic engineering process so these assertions can be understood. MADGE would welcome the opportunity to Demystify the Senators using children's toys as props.

In general now, the likely food safety of GE foods cannot be determined in advance, and no post-market introduction surveillance has taken place. There is gathering disease in the population and possible links to GE foods should be investigated – see Attachment 2.

The comparative economic efficiency of the development and subsequent employment of GE crops in comparison to non-GE crops has not been determined. In 3 decades only two types of traits have been developed after enormous investments, and the food is of doubtful safety.

There also appears to be an unhealthy level of influence exerted by the Developers of existing GE crops in many areas of Australian life: corporate, scientific, educational, farming, media

My personal view is that we are at severe risk of losing our food and land sovereignty through the introduction genetically engineered crops at this stage. In addition we are a long way from being

able to come to a credible determination of food safety in respect of GE crops. We must support our farmers to resist this.

Thank you for the opportunity to present this material.

Yours faithfully

Madeleine Love

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23 October 2008

Senator the Hon Bill Heffernan
Parliament House
Canberra ACT 2600

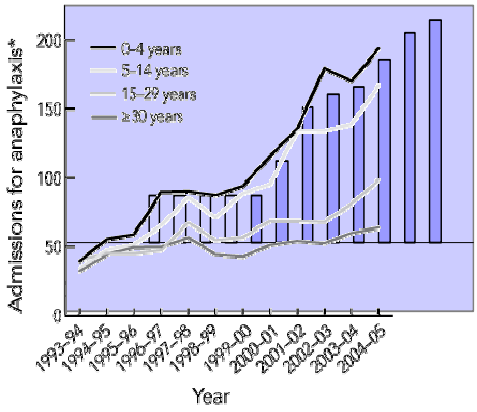
Dear Senator Heffernan

Re: GM foods and the huge rise in food allergies – 8 Questions for Senator Heffernan

1. **Would Senator Heffernan support the MADGE call for an urgent investigation into the association between the dramatic rise in food allergies in Australia and the consumption of GM foods?** (MADGE: Mothers are Demystifying Genetic Engineering)

   Please read the MADGE report at www.madge.org.au/Docs/allergy-report.pdf (see Attachment 2) detailing the Body of Evidence supporting this urgent call. The MADGE report also describes the random GM transformation techniques, and explains how GM foods can cause food allergies:

Anaphylaxis Admissions vs GM Crop Approvals



Anaphylaxis Graph:
Paediatric food allergy trends in a community-based specialist allergy practice, 1995-2006, Raymond J Mullins, MJA Vol. 186 No. 12 pp 618-621
* Rate per million population.

Food Approvals Graph:
Food Standards Australia New Zealand (FSANZ): Genetically Modified Foods & Their Approval Status, http://www.foodstandards.gov.au/foodmatters/gmfoods/gmcurrentapplication1030.cfm

   - Almost all food allergies are caused by food proteins, and the Genetic Modification of crops is about introducing novel proteins into the crop. These proteins are typically synthetic (mutated) and often not produced as expected in the plant.

   - These proteins can cross-prime other foods to become allergenic.[1]

   The report also shows how different things are for children in similarly hygienic circumstances in Norway, where no GM crops or foods have been approved, and shows how food allergy stabilized in England after GM food was labelled (most GM food escapes labelling in Australia).

2. **Could Senator Heffernan please ask the Federal Health Minister if the United States company Monsanto, convicted of "outrage" in 2002, is primarily responsible for post market monitoring of food allergies in Australian children which may be arising from Genetically Modified food?**

   - No pre-market assessment of new genetically modified foods can accurately determine if the food will be allergenic, and post-market monitoring is required to determine the effects.

   - Food Standards Australia New Zealand (FSANZ), which is overseen by the federal health minister, declares

     "*There are currently no official mechanisms within Australia and New Zealand for monitoring the long-term impacts of GM foods. In Australia and New Zealand, as in most other countries, the responsibility for post-market monitoring is covered by an ongoing duty of care on the part of the developer. The developer is expected to monitor for existing and emerging risks that may be associated with its product and notify regulatory authorities whenever new information is uncovered.*"[2]

   - Monsanto is the developer of 90% of the world's GM seeds and would be primarily responsible for post-market monitoring in Australia.

   - In 2002 Monsanto and its corporate successors were held liable on six counts including "outrage" for releasing tons of PCBs[3] into the city of Anniston and covering up its actions for decades.

     The rare claim of "outrage" typically requires conduct

     "*so outrageous in character and extreme in degree as to go beyond all possible bounds of decency so as to be regarded as atrocious and utterly intolerable in civilized society*."[4]

     The biotechnology company now known as Monsanto has claimed to have no connection to this case, but records show that it must pay any judgment Solutia (a spin-off company from Monsanto Ltd) is unable to cover.

3. **Could Senator Heffernan please ask the Federal Health Minister to detail any studies commenced by Monsanto to investigate the five fold increase in hospital admissions for severe anaphylaxis for tiny Australian children since the introduction of their GM foods in 1996?**

4. **Does Senator Heffernan consider that Monsanto Australia Ltd's associate membership of the Australian Food and Grocery Council at 1 February 2008 may be influencing the AFGC's position on the full GM labelling of foods fully or partially derived from GM sources?**

5. **Would Senator Heffernan support a review of the safety of Monsanto's Roundup Ready Canola product (GT73)?**

   - The incorrect application of the concepts 'gene' and 'protein' eight times in two vital sections of the FSANZ (then ANZFA) Assessment Report cannot be justified. The most generous judgment that can be made is that FSANZ (then ANZFA) were confused at the time of assessing this product.[5]

   - It is likely that the actual novel proteins in the Roundup Ready canola crop have not been assessed for allergenicity, even on paper. Despite this the European Food Safety Authority issued allergenicity warnings for people with red shellfish allergy in respect of this product, based on an independent study on a related protein.

   - FSANZ is preparing the Monsanto files on Roundup Ready canola for public viewing.

6. **Would Senator Heffernan support MADGE's call to hold an inquiry into the FSANZ operation?**

   MADGE asserts that FSANZ has failed its primary objective - 18(1)(a) the protection of public health and safety - in respect of GM foods.

7. **Could Senator Heffernan move to have these issues placed on the agenda of the Ministerial Council overseeing FSANZ? Agenda items close on 27 February 2009.**

8. **Could Senator Heffernan inform MADGE of the policies of their party with respect to**

   - **the safety assessment requirements of GM food (substantial equivalence or precautionary principle),**
   - **the full labelling of all GM foods directly or indirectly, fully or partially derived from GM crops and processes, and**
   - **the growing of GM crops in Australia.**

In your investigations on this topic please be aware that there are very close associations between the medical Allergy field and recombinant technology research areas. Many vaccines are developed by GM methods, and research into allergies may use GM techniques. Allergy research groups may have partnerships with biotechnology companies, and the GM industry promotes itself as a potential creator of hypoallergenic food, although success is unlikely.

Assessment by an independent epidemiological analyst is called for. With so much Australian government money invested in GM it is questionable whether an analyst funded by the Australian government could be regarded as independent.

Best wishes

Madeleine Love
Supporter of the MADGE network

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[1] The report describes the cross-priming of mice to an egg allergen by a GM pea.

GM soy is ubiquitous in our food, and it's a legume, like peanuts. A number of the allergens from soybean and peanut are homologous and cross-reactive.

The GM soy DNA was seriously disturbed when the event took place (strange bits of misplaced DNA code) and the odds of a few subtle changes in some of the 16 soy allergens are high.

[2] Is post market monitoring of GM foods undertaken?
http://www.foodstandards.gov.au/foodmatters/gmfoods/frequentlyaskedquest3862.cfm

[3] PCBs, shorthand for polychlorinated biphenyls, have been banned in the United States since 1979
http://www.washingtonpost.com/ac2/wp-dyn/A54914-2002Feb22?language=printer

[4] Monsanto Held Liable For PCB Dumping, *By Michael Grunwald*, Washington Post Staff Writer, Saturday, February 23, 2002; Page A01 http://www.washingtonpost.com/ac2/wp-dyn/A54914-2002Feb22?language=printer

[5] This is just one example of ANZFA's apparent confusion.

Here's some text lifted from the Final Risk Assessment of Monsanto's GT73 Roundup Ready Canola…

> The *gox* gene is fused to the following regulatory sequences: the 35S promoter from [a plant virus] and the 3' end of the pea […] E9 gene […]. The gene is targeted to the plastid by […] a chloroplast transit peptide of [a flower] which has been fused to the gene.

This is all wrong. The *gox* gene didn't go into the plant. The gene that went in was a synthesized, optimized, mutated version of the *gox* gene (*gox-related*). The *gox-related* gene isn't fused to those two sequences. Proteins are targeted, not genes. Peptides (small proteins) are not fused to genes.

Re-written:

> The *gox*-related gene is fused to the following regulatory sequences: a DNA coding sequence for a chloroplast transit peptide from [a flower] and the 3' end of the pea […] E9 gene […]. The 35S promoter from [a plant virus] precedes the coding sequence for the chloroplast transit peptide. The protein encoded by the gox-related gene is targeted to the plastid by […] a chloroplast transit peptide of [a flower] the coding sequence of which has been fused to the *gox*-related gene.

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MADGE calls for Investigation

GM and Allergies - Body of Evidence

Conclusion:

There is an urgent need to investigate whether GM foods are involved in the phenomenal rise in allergies and anaphylaxis in Australia.

Summary of findings:

1. A GM pea caused mice to become allergic to egg
2. The allergy tests done on this GM pea were far more thorough than any allergy test done on the GM food we are eating.
3. Our food regulator, FSANZ, does no independent safety tests. They base their safety assessments on evidence provided by the companies wanting to release GM crops and food.
4. The assessment documents are not clear about exactly what proteins the GM plants produce. There are contradictions within and between national assessment documents.
5. There is no certain way of testing for allergens.
6. Understanding of how genes and DNA work has increased rapidly and changed fundamentally. FSANZ has not reviewed the safety of previously approved GM food in light of these discoveries.
7. One study predicts that Monsanto's Roundup Ready canola (GM) could prove allergenic to people with sensitivities to red shellfish (prawns, shrimp, lobster). The European Food Safety Authority has advised that people with these allergies should be aware of the possibility of hypersensitivity.
8. FSANZ does no monitoring of the health effects of GM foods once they are on supermarket shelves. Instead FSANZ expects the companies that developed the GM foods to monitor for adverse effects and inform government regulatory authorities of any issues.
9. In Australia, rates for anaphylaxis in the 0-4 age group have increased 5-fold since 1995. GM foods first reached our plates in 1996.
10. Public protest meant UK supermarkets removed most GM food from sale in 1999. The rapid increase in anaphylaxis (severe allergy) in children aged 0-14 stabilised.
11. Norway has very restrictive policies on GM. The Australian rate of severe reactions to food in 0-4 year olds may be nine times that of Norway.

*Errata: In the section "England" on page 8 and the summary of some previous editions of this report wrongly described the age group as 0-4, rather than 0-14. Point 4 on the summary page has also been altered slightly to better reflect the main document.

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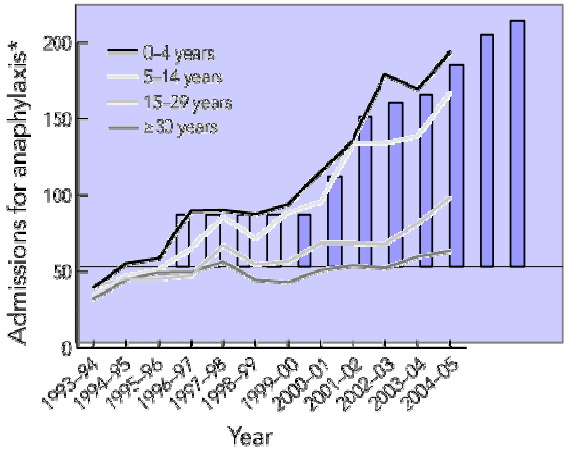
MADGE's Concern

Allergic reactions to foods are usually caused by the proteins in the food. Genetic modifications make crops produce new proteins to change the way plants behave.

There has been a dramatic increase in all grades of food allergy in Australia[1], across all age groups[2], over the last decade. MADGE is concerned that GM foods may be contributing to this increase.

The new proteins that GM plants produce could be allergens themselves, or they could cross-react with other proteins to become allergens. This is illustrated by the following study…

Anaphylaxis Admissions vs GM Crop Approvals



Anaphylaxis Graph:
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Food Approvals Graph:
Food Standards Australia New Zealand (FSANZ): Genetically Modified Foods & Their Approval Status, http://www.foodstandards.gov.au/foodmatters/gmfoods/gmcurrentapplication1030.cfm

The CSIRO GM pea example[3]:

Australia's CSIRO (The Commonwealth Science and Industrial Research Organisation) were developing a GM pea. They wanted the GM pea to produce a bean protein. They managed to get the pea DNA to incorporate some DNA code from the bean.

CSIRO asked the John Curtain School of Medical Research in Canberra to test the pea for allergenicity. They did very thorough tests.

One of the tests found that mice became allergic to an egg allergen when it was fed to them with the GM protein from the pea. They did not become allergic to the egg when it was fed with the natural protein from the bean. They were not allergic to the egg when it was fed on its own. The GM proteins made the mice susceptible to developing allergies to foods eaten with the GM food. This is called cross-priming.

Other pea proteins also became more allergenic in the GM pea, in comparison to the natural pea.

No-one knows how this happened. It has been suggested that the bean protein made in the GM pea was processed slightly differently, turning it into a cross-reactive allergen.

The risk of creating new protein allergens through the GM process is well recognised. This is why the world's "Food Standards" organization (Codex Alimentarius) advises that regulators assess the allergenic potential of each new crop.

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Guidelines for Allergenic Assessment

Codex Alimentarius has issued Guidelines[4] for how an allergy assessment of a GM crop might proceed.

These Guidelines and many of the assumptions on which the safety assessment of GM crops are based have been widely criticized by independent scientists[567]. The John Curtain tests on the GM pea are far more rigorous than those done on the GM food we are eating. GM food may be causing allergies like the CSIRO GM pea did, however since similar allergy tests haven't been done we wouldn't know.

Are GM proteins cross-priming young children to be allergic to more common allergens such as peanuts, egg and milk? No one has any idea and this is why MADGE is concerned.

Tests for Allergenicity

The 2003 Codex Alimentarius Guidelines say "At present, there is no definitive test that can be relied upon to predict allergic response in humans to a newly expressed protein…"

The tests that are done are very superficial – often just on paper – i.e. "In theory, would this protein be allergenic if the plant produced it exactly as we think it might?"[8]

In most cases, the actual new proteins produced in the seeds have not been subject to a full allergy assessment[9].

In some cases the regulators have been uncertain about which new proteins will actually be in the seeds. There are differences in the stated proteins both between and within food assessment documents.[10]

Even if the correct proteins are "assessed" this will not guarantee that the protein will not be allergenic or will not cross-prime for other risky proteins to become allergenic[11]

The GM process generally creates other disturbances in the plant DNA, and many new proteins may be created that have not even been identified[12]. Contrary to the scientific knowledge at the time these crops were developed, we now know that one gene (section of DNA) can code for multiple proteins[13].

Box 1: Monsanto's Roundup Ready Soy

In 1995 it was announced in the Crop Science journal that a Glyphosate tolerant soybean line had been developed. Portions of each end of the intended genetic code were missing[1].

When food from this crop was introduced to the UK, soy allergies went up 50%[2].

ANZFA was told that Australians may have been eating food from this crop from December 1996, but approved food from the crop for Australian consumption reportedly in 2000.

After approval, ANZFA put out a statement in July 2000 to say that Monsanto had found two extra pieces of new genetic code, in two unexpected places[3].

In 2001 researchers reported that there was a large section of unidentifiable DNA after one of these extra pieces of code[4].

In 2003 part of that code was identified as belonging to non-GM soy – the rest has not been identified[5].

1 Development, Identification, and Characterization of a Glyphosate-Tolerant Soybean Line; Padgette SR et al; Crop Sci 35:1451-1461 (1995)

2 UK York Laboratory; Genetic Roulette; Jeffrey M. Smith; p50-51; ISBN 978-0-646-48131-9

3 Application A338 - Glyphosate Tolerant Soybean GTS 40-3-2

http://www.foodstandards.gov.au/standardsdevelopment/applications/applicationa338glyphosatetolerantsoybeangts4032/index.cfm

4 Characterisation of the Roundup Ready soybean insert; Windels P et al; Eur Food Res Technol (2001) 213:107-112

5 Detection and characterization of recombinant DNA in the Roundup Ready soybean insert; Lau L-T et al; Food Control Vol.15, Issue 6, September 2004, pp 471-478

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Finally, our Food Standard's body (FSANZ) has done no testing of its own. In respect of the GM crop under assessment, the commercial company of interest is responsible for demonstrating the safety of the crop.[14]

In their Roundup Ready Canola assessment FSANZ cited 27 reports, all provided by Monsanto without independent verification.

Therefore this process has been likened to relying on the smoking industry to provide evidence that smoking is safe.

Many public submissions in the GM crop approval process have repeatedly stated the inadequacy of allergenicity assessment methods, and they've been dismissed without rational basis or ignored by FSANZ.

Box 2: Monsanto's Roundup Ready Canola

This is the GM canola planted in Victoria and NSW this year:

At one end of the 'new code', 40 rungs of the parent plant DNA 'ladder' (base pairs) are missing.[1]

At the other end of it there are 22 new rungs of the DNA 'ladder'. It is not known where they came from.[1]

The GM canola was predicted to be allergenic[2] and the European Food Safety Authority advised:

> "Since crossreactivity between GOX and tropomyosin is not ruled out completely, persons allergic to shrimp meal should be aware of the possibility of hypersensitivity reaction when working with [Roundup Ready canola]."[1]

1 The EFSA Journal (2004) 29, 1-19

2 Screening of transgenic proteins expressed in transgenic food crops for the presence of short amino acid sequences identical to potential, IgE – binding linear epitopes of allergens; Kleter and Peijnenburg; BMC Structural Biology 2002, 2:8

Post-Market monitoring of GM food

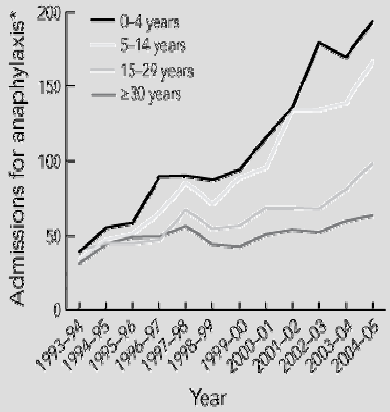
Our regulators FSANZ and OGTR do no monitoring on the long-term impacts of GM foods. Therefore there is no mechanism for identifying if allergy issues emerge. Instead the responsibility for post-market monitoring is expected to be done by the developers of GM food.

With Roundup Ready canola, Monsanto will be "expected to monitor for existing and emerging risks that may be associated with its product and notify regulatory authorities whenever new information is uncovered[15]".

It would be interesting to discover if there is any post-market surveillance on GM food happening anywhere in the world. To date MADGE has heard of none.

The issue is further compounded by the lack of full labeling of GM food. How can we tell if GM food is affecting us adversely if it is not labelled?

Age-adjusted Australian hospital admission rates for anaphylaxis in the financial years 1993-94 to 2004-05



Paediatric food allergy trends in a community-based specialist allergy practice, 1995-2006, Raymond J Mullins, MJA Vol. 186 No. 12 pp 618-621
* Rate per million population.

Data We've Collected

Mullins Pediatric study

In his study in the Medical Journal of Australia, clinical immunologist and allergy physician Dr RJ Mullens noted that there is limited published evidence for hypotheses explaining the changing prevalence in food associated allergic allergy[16].

In a thorough study examining his own clinical experience and other clinics servicing a major city (Canberra) he found that there had been a 12-fold increase in the number of 0-5 year olds seen for food allergy between 1995 and 2006, and a 5-fold increase in tip-of-the-iceberg serious allergic reaction of food-associated anaphylaxis.

To confirm that this wasn't a specific issue related to his region or clinic he evaluated Australian population and hospital morbidity data, finding similar trends for the 0-5 year olds, and noted increases across the whole population.

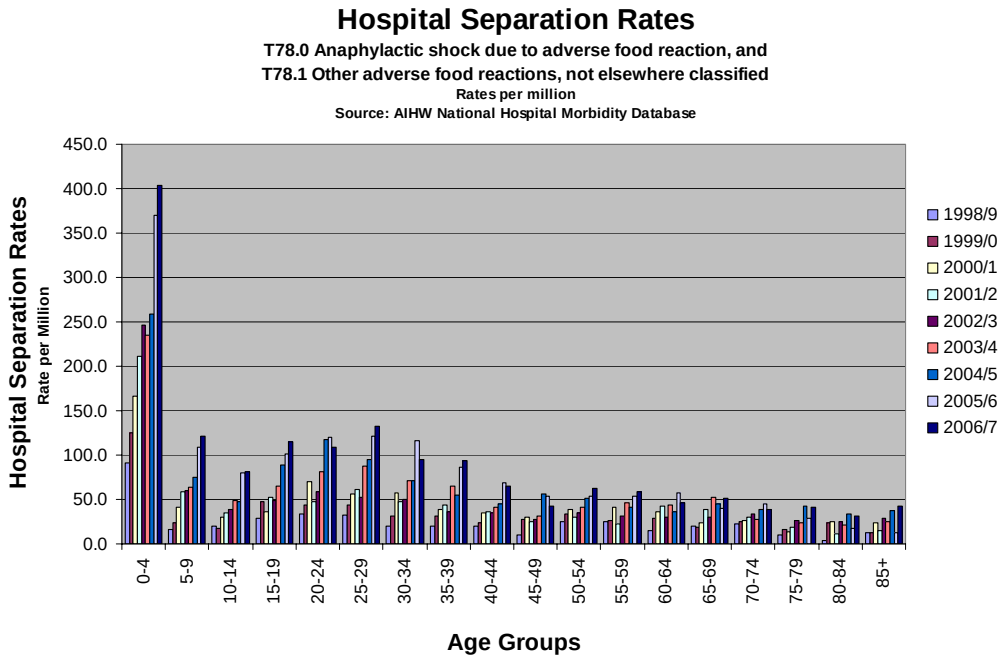
Hospitals Database material

When people leave hospital (i.e. "Separate") their diagnosis is coded into the Hospital Morbidity Database. This database is accessible through the Australian Institute of Health and Welfare website[17].

Two diagnosis codes[18] are of particular interest…

T78.0 Anaphylactic shock due to adverse food reaction
T78.1 Other adverse food reactions not elsewhere classified

There has been a three fold increase in hospital separation rates for these combined codes in the Under 50's, and a doubling in the Over 50's. Every age group has been affected.



Exposure to novel GM proteins

Part of an analysis of experience needs to look at our 'exposure' to novel GM proteins. How much has the population been eating? MADGE is trying to come up with a representative picture.

It is impossible to assess exposure with accuracy, because food containing GM ingredients has been almost completely unlabelled. Few people keep records of what they eat. To get an

idea of general exposure we need to know the range and amount of new proteins our population has been exposed to.

Labelling of GM foods has been avoided as it is claimed that refined foods don't contain proteins. Therefore it is assumed that as there are no GM proteins, labeling is unnecessary. There is a very large body of evidence to the contrary[19]. Even evidence provided by at least one GM company shows they know there is protein in refined canola oil[20]. We also know from a Foods Standards pilot study that our food has been contaminated by GM, even food that has been labelled as free of GM ingredients[21].

Food approvals began formally around 1998/9. Seven crops are listed as being approved in the year 2000 – six of these were created by Monsanto[22]. We know that we were eating unapproved GM foods before this time. Monsanto said its Roundup Ready soybeans had been imported into Australia since December 1996[23] and that its Roundup Ready canola may have been imported into Australia and New Zealand for 'several years'[24].

According to the International Service for the Acquisition of Agri-biotech Applications (ISAAA) briefs (a biotech body) commercial crops were first officially planted in 1996[25]. We also know that at least 12 food crops producing different novel proteins were being grown world wide in 1996[26]. We may have been consuming a wide variety of novel proteins, albeit in very small amounts.

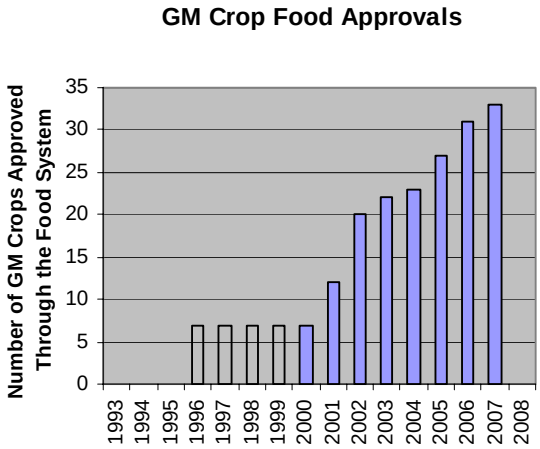
Prior to 1996 there had been an escalation in the planting of trial GM crops, including 37 GM food crop trials in Australia[27]. From 1996 Australia had 40,000 hectares of GM cotton growing[28] Did GM cottonseed oil first enter the market in 1996? Did cottonseed oil from the extensive test crops enter the market before that?

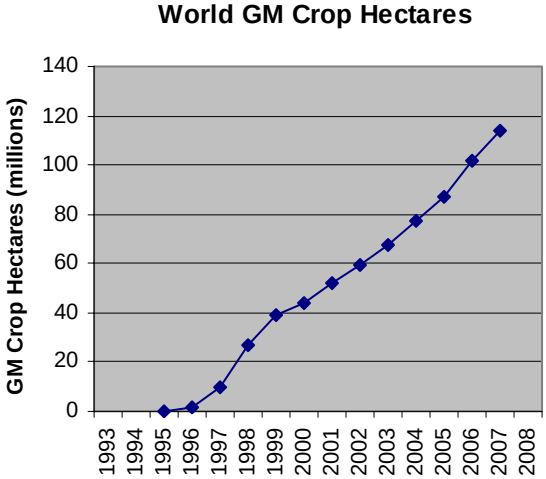
Under a new Standard A18 adopted in July 1998, GM foods were prohibited unless 'approved'. The approval requirements came into force on 13 May 1999, but GM foods currently on the market were exempted provided an application for approval was received on or before 30 April 1999.

Some food additives and processing agents are produced by genetically engineered bacteria or are derived from GM crops. This complicates the issue further.

We have disregarded GM additives in this rough graph of formal crop approvals by Food Standards Australia New Zealand (FSANZ – formally ANZFA)[29].

How much of these novel food products were we eating? It's difficult to know. The crops haven't been widely adopted, particularly in developed countries other than the USA, but it





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is estimated that they occupy 8.4% of arable land[30], although this has been challenged.

While the acreage of GM crops is small, the food products from two of these crops, soy and corn, are ubiquitous in processed food. Sixty-four percent of the world soy crop is GM – 93% of the soy crop in the USA is GM. We import soy and soy products from the USA. It is likely that these products are contaminated by GM proteins. Inadequately monitored and unlabelled GM proteins would be expected in a lot of processed food.

Prediction of allergens

Allergies have increased in line with the increase in exposure to novel GM proteins in the Australian population. An independent study has specifically predicted that some of these proteins may be allergens[31], and the European Food Safety Authority has taken note[32].

The study predicted that the *gox*-related novel protein in Monsanto's Roundup Ready canola planted in Australia may be allergenic. The *gox*-related protein was found to have an identical amino acid sequence to a known allergenic sequence of Tropomyosin. Tropomyosin is the allergen commonly found in red shellfish (shrimp, prawn, lobster etc). Roughly 500,000 Australians are estimated to be allergic to red shellfish. This is a large group of people who can recognise and avoid a prawn, but can't recognise an untested allergen in unlabelled GM canola.

The European Food Safety Authority put out a warning for people working with this product when it was reviewed for animal feed suitability in 2004.

> "Since cross-reactivity between GOX and tropomyosin is not ruled out completely, persons allergic to shrimp meal should be aware of the possibility of hypersensitivity reaction when working with GT73 [Roundup Ready Canola]."

MADGE are currently researching a different but ubiquitous GM protein with predictions of allergenicity.

Alternative hypotheses for the rise in allergies

It is argued that we are becoming cleaner and that a lack of early childhood exposure to bugs of all kinds increases susceptibility to allergic diseases. This is the Hygiene Hypothesis. However the increase in food related allergy is happening simultaneously across all age groups.

Factors in this hypothesis such as immunization, breastfeeding, cesarean section, and "parental cotton woolling" cannot explain the increase in allergy in the older age groups.

With so many mothers returning to the paid workforce over this period[33] it is unlikely that our houses are any cleaner than previously. This return to the workforce does make it more likely that children have been fed the sort of rapidly prepared processed foods which are more likely to contain GM ingredients.

It is happening at different rates across similarly hygienic and immunized developed countries. There appears to be a link with food policy in those countries.

It is difficult to compare international hospital statistics – with over 8,000 codes for 'principal diagnosis' there will be international and inter-hospital differences in diagnoses.

There are also population differences in factors thought to influence base level allergy rates. For example, breastfeeding is thought to be generally protective, particularly in the first days, and there are major differences in breastfeeding rates between developed nations. At 3 months 80% of Norwegian babies are fully breastfeeding, about 55% in Australia and 25% in England (25% of English babies are not put to the breast at all)[34].

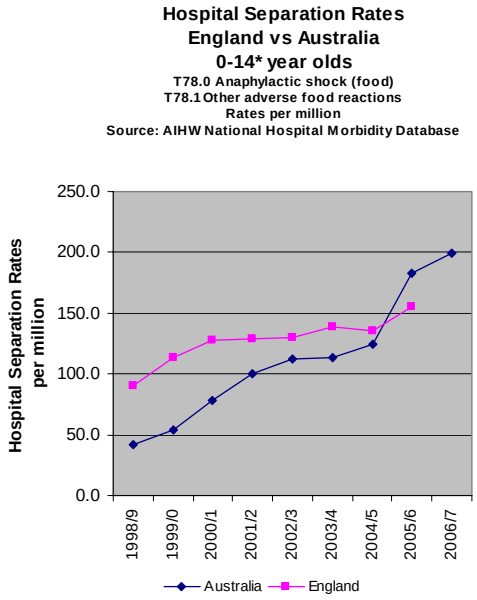
Despite these differences there are some features in the statistics that are worth noting.

England

In England GM food was sold, including whole foods such as tomatoes, but there was a massive outcry and removal of GM foods from some supermarkets that culminated mid 1999[35]. By 2001 the rapidly increasing incidence of anaphylaxis in the 0-14* age group had stabilized (see graph "Hospital Separation Rates: England vs. Australia).

By the 2005/6 year there had been a 435% increase in the number of Australian children (0-14* years) leaving hospital with a diagnosis of food anaphylaxis or other adverse food reaction (codes T78.0 and T78.1) over the 1998/9 figures, compared to the 173% increase for the same age group in England.

*Errata: Previous editions of this report wrongly described the age group as 0-4, rather than 0-14.



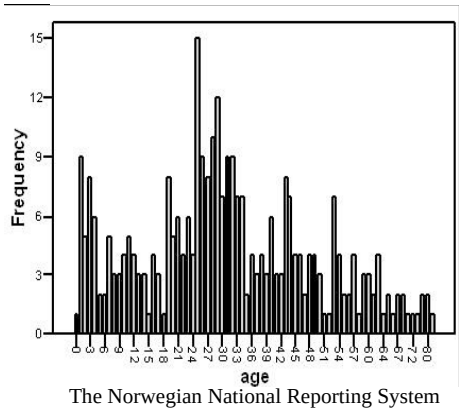
Norway

In Norway there were two rounds of public 'Consensus Conferences' in 1996 and 2000 on the GM issue[36]. Norway has very restrictive trade policies on GM food, animal feed and contamination[37]. US soybeans were disallowed in Norway from 1996, and all food and feed produced from genetic engineering – including products that no longer contain detectable traces of agricultural products derived from biotechnology – must be labelled[38]. So far no GMO products have been approved as food or as ingredients in food[39].

Figure 2: The age distribution of severe allergic reactions to food in Norway shows two peaks: 0-4 year olds and 20-35 year olds.

Unlike Australia, the Norwegian National Reporting System and Register of Severe Allergic Reactions to Food reported that the incidence of serious allergic reaction for the 0-4 year old age group is no higher than that for the young adult age group[40].

"The typical Norwegian patient with a severe allergic reaction to food appears to be a young adult, female rather than male. The offending meal is consumed at a restaurant or fast-food stand or in a private party away from home, and peanuts, nuts and shellfish are among the most common offending foods."



The Norwegian National Reporting System and Register of Severe Allergic Reactions to Food; *Norsk Epidemiologi* 2004; **14** (2): 155-160 155; Martinus Løvik1et al

MADGE
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While this group left open the possibility that they had not received notification of every severe event (MADGE is awaiting statistics from the Norwegian hospital database), it is nonetheless possible to see the dramatically different experience within the Australian population.

Australian rates of young children (0-4 years) requiring hospitalization are three times higher than young Australian adults (20-29 years). In Norway the 0-4 age group has fewer reported allergic reactions to food than the 20-29 age group.

With the numbers we have at present and assuming the severe allergy definitions are equivalent, the Australian levels of severe allergic reaction to food are:

- 9 times greater in the 0-4 age group than in Norway.
- 4 times greater in the 5-14 age group than in Norway.
- 2 times greater in the 15-59 age group than in Norway

Conclusion.

MADGE hopes this document illustrates the urgent need to investigate whether GM foods are involved in the phenomenal rise in allergies and anaphylaxis in Australia. Allergies are an immediate and measurable sign of problems with food. Could GM foods be causing less visible damage to our health that will take years to uncover?

Should GM food approved on the basis of evidence produced by the companies that developed the product be on our shelves? What monitoring have these companies done into the post-market effects of GM foods on our health? Have our Governments and regulatory agencies acted in the public interest in approving GM food for sale?

Please contact MADGE, your Federal and State politicians and your food companies and retailers if you are concerned about this issue.

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[8] The 2003 Codex Guidelines set out the following strategies

3.1 Source of the Protein – a paper test – is the source of the protein allergenic?

3.2 Amino Acid Sequence Homology – a paper/computer test – proteins are made up of smaller pieces called amino acids, and there is a test to see how similar the new protein is to sequences of known allergens

3.3 Pepsin Resistance – a test-tube test – protein (to be discussed in the next point) is tested in supposed Simulated Gastric Fluid to see if it quickly degrades, ignoring the fact that many people, including breastfeeding toddlers and adults with ulcers have a range of gastric experience and susceptibility. A test may also be done for pancreatin resistance in Simulated Intestinal Fluid.

4.0 Specific Serum Screening - If 3.1 and 3.2 indicate, serum testing may be done in a test-tube

5.0 Other Considerations – in-theory considerations of how the protein may eventually be consumed in food, and an opening to use other scientific methodology as it evolves.

[9] The proteins (if known – to be discussed in the next point) may not have come from the actual plant. They may have been artificially produced by genetically engineered bacteria in a laboratory, according to the theoretical sequence of the protein produced in the plant, without regard for the fact that there may be significant post-translational changes in the plant cell. If the proteins have come from the plant, they may not have come from the edible part of the plant – from the leaves rather than the seeds, nor from the current version of the plant.

[10] The opportunity to read retrospectively through approval documents from around the world on particular crops has shown a great deal of discrepancy between the understanding of the various national regulators on the nature of the plant and protein - of particular note is Monsanto's Roundup Ready canola GT73. Regulators depend on the information they are given by the company, but striking confusion is apparent, not just between the assessment documents, but within them. Supporters of the MADGE network are pursuing this.

[11] As earlier mentioned it is acknowledged both in the Codex Alimentarius Guidelines and in the Food Standards Australia New Zealand (FSANZ) document "GM Foods – Safety Assessment of Genetically Modified Foods" that allergens cannot be predicted with certainty. While MADGE would prefer a Precautionary approach (unsafe until proven safe), if foods from these crops are to be released on the market, there should be post-introduction surveillance, to see if people do show allergic reaction to the product, immediately, and after an appropriate period of sensitization.

[12] There are lots of ways that unintended proteins could be created. Anything that affects the DNA in the host cell could have unintended effects on the way the DNA code is used. With the help of scientists from many fields Jeffrey Smith compiled the following list in his book Genetic Roulette pp 233-236; ISBN 978-0-646-48131-9

- Inserted foreign genes might create multiple proteins, with unpredictable consequences.
- Foreign proteins may be folded improperly or become attached to other molecules, which could change their properties. Likewise, gene expression may be affected by the genetic disposition of a host organism, or even the environment.
- The process of inserting foreign genes can damage the structure and function of the host's DNA, switch genes on or off, create never-before-seen genetic sequences and render the genome unstable.
- The promoter may turn on native genes. This can create a flood of proteins with unpredictable consequences. Some scientists theorize that the promoter might even switch on dormant viruses that are deposited along the DNA.
- Studies indicate that the promoter may create a "hotspot" in the DNA, whereby the whole DNA section, or chromosome, can become unstable. This can cause breaks in the strand or exchanges of genes with other chromosomes.

- Insertion of foreign genes and their new proteins may create complex, unpredictable interactions, not well understood. Similarly, inserting two or more foreign genes into the same plant may also cause interactions that have not been studied.
- Inhalation of pollen may cause unpredicted health problems. Transfer of genes from inhaled pollen may also be possible.
- After GM soy was introduced into the UK, soy allergies sky-rocketed 50%. Current GM corn would not pass tests recommended by FAO/WHO for potential allergenicity. The EPA's Scientific Advisory Panel determined that GM protein in StarLink corn has a "medium likelihood" of being an allergen.
- Different organisms process genetic information and synthesize proteins differently.
- There are proteins with identical (active site) sequences that differ in other amino acids, and as a result, function differently.
- One amino acid can alter both the structure and the function of a protein, especially if the change occurs at the active site of an enzyme.
- The actual transgene sequences of several GM crops differ from that which was registered by the company.
- In some cases cooking does not destroy allergenicity but rather makes proteins more allergenic.
- The loss of pesticidal properties does not insure the loss of allergenic properties.
- RNA can impact gene expression, even in subsequent generations.
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"A gene is a union of genomic sequences encoding a coherent set of potentially overlapping functional products." What is a gene, post-ENCODE? History and updated definition. Gerstein MB et al; Genome Res. 2007 Jun;17(6):669-81

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"I'll try to answer you as well as I can (in English): In Norway there are very strict laws when it comes to approval and labelling of genetically modifies foods (GMO). So far no GMO products have been approved as food or as ingredients in food. But Norway imports food from countries which have approved the use of GMO products. Therefore it is very likely that GMO foods can end up in Norwegian stores."

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