

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.
- Public protest meant UK supermarkets removed most GM food from sale in 1999. The rapid increase in anaphylaxis (severe allergy) in children aged 0-4 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 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.



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.

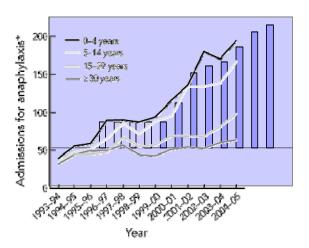
There has been a dramatic increase in all grades of food allergy in Australia¹, across all age groups², over the last decade. MADGE is concerned that GM foods may be contributing to this increase.

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...

The CSIRO GM pea example³:

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.

Anaphylaxis Admissions vs GM Crop Approvals



Anaphylaxis Graph:
Paediatric food allergy trends in a communitybased specialist allergy practice, 1995-2006,
Raymond J Mullins, MJA Vol. 186 No. 12 pp 618621 * 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/gmfo
ods/gmcurrentapplication1030.cfm

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.



Guidelines for Allergenic Assessment

Codex Alimentarius has issued Guidelines⁴ 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 scientists⁵⁶⁷. 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 assessment⁹.

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 allergenic¹¹

The GM process generally creates other disturbances in the plant DNA, and many new proteins may be created that have not even been identified¹². Contrary to the scientific knowledge at the time these crops were developed, we now know that

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 missing¹.

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 places³.

In 2001 researchers reported that there was a large section of unidentifiable DNA after one of these extra pieces of code⁴.

In 2003 part of that code was identified as belonging to non-GM soy – the rest has not been identified⁵.

- 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

one gene (section of DNA) can code for multiple proteins¹³.



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 allergenic² 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 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 uncovered¹⁵".

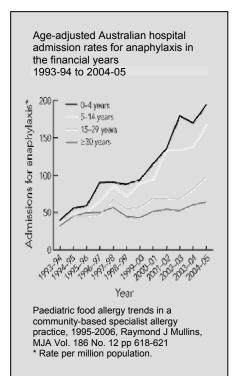
It would be interesting to discover if there is any post-market surveillance on GM food happening anywhere in the world. To date MADGE has heard of none.

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?

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 allergy¹⁶.





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 website¹⁷.

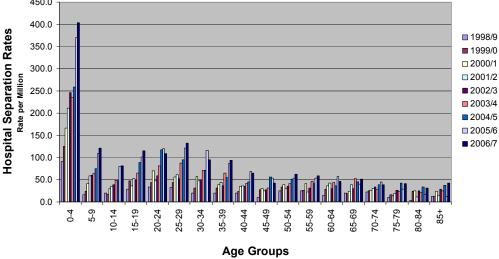
Two diagnosis codes¹⁸ are of particular interest...

- 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.

Hospital Separation Rates

T78.0 Anaphylactic shock due to adverse food reaction, and T78.1 Other adverse food reactions, not elsewhere classified Rates per million Source: AIHW National Hospital Morbidity Database



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 contrary¹⁹. Even evidence provided by at least one GM company shows they know there is protein in refined canola oil²⁰. 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 ingredients²¹.

Food approvals began formally around 1998/9. Seven crops are listed as being approved in the year $2000 - \sin \alpha$ of these were created by Monsanto²². 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 1996²³ 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 1996²⁵. We also know that at least 12 food crops producing different novel proteins were being grown world wide in 1996²⁶. 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 Australia²⁷. From 1996 Australia had 40,000 hectares of GM cotton growing²⁸ Did GM cottonseed oil first enter the market in 1996? Did cottonseed oil from the extensive test crops enter the market before that?

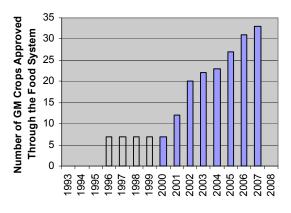
Under a new Standard A18 adopted in July 1998, GM foods were prohibited unless 'approved'. The approval requirements came into force on 13 May 1999, but GM foods currently on the market were exempted provided an application for approval was received on or before 30 April 1999.

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

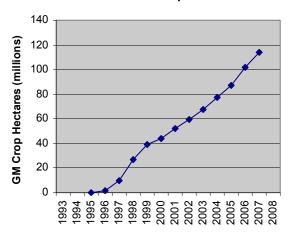
We have disregarded GM additives in this rough graph of formal crop approvals by Food Standards Australia New Zealand (FSANZ – formally ANZFA)²⁹.

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

GM Crop Food Approvals



World GM Crop Hectares





is estimated that they occupy 8.4% of arable land³⁰, 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 allergens³¹, and the European Food Safety Authority has taken note³².

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 period³³ 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

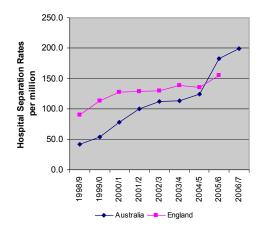
In England GM food was sold, including whole foods such as tomatoes, but there was a massive outcry and removal of GM foods from some supermarkets that culminated mid 1999³⁵. By 2001 the rapidly increasing incidence of anaphylaxis in the 0-14* age group had stabilized (see graph "Hospital Separation 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.

Hospital Separation Rates England vs Australia 0-14* vear olds

0-14* year olds
T78.0 Anaphylactic shock (food)
T78.1 Other adverse food reactions
Rates per million
Source: AIHW National Hospital M orbidity Database



Norway

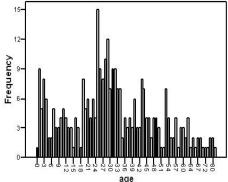
In Norway there were two rounds of public 'Consensus Conferences' in 1996 and 2000 on the GM issue³⁶. Norway has very restrictive trade policies on GM food, animal feed and contamination³⁷. US soybeans were disallowed in Norway from 1996, and all food and feed produced from genetic engineering – including products that no longer contain detectable

traces of agricultural products derived from biotechnology – must be labelled³⁸. So far no GMO products have been approved as food or as ingredients in food³⁹.

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 group⁴⁰.

"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."

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.



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



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.

References

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

Separation, patient day and average length of stay statistics by principal diagnosis in ICD-10-AM, Australia, 1998-99 to 2006-07; T78.0 Anaphylactic Shock due to adverse food reaction + T78.1 Other adverse food reactions, not elsewhere classified; http://www.aihw.gov.au/cognos/cgi-bin/ppdscgi.exe?DC=Q&E=/ahs/pdx0607

Transgenic Expression of Bean r-Amylase Inhibitor in Peas Results in Altered Structure and Immunogenicity; J. Agric. Food Chem. 2005, 53, 9023-9030 9023; PRESCOTT VE et al

Guideline for the conduct of food safety assessment of foods derived from recombinant-DNA plants; CAC/GL 45-2003; www.codexalimentarius.net/download/standards/10021/CXG_045e.pdf

The use of the "Substantial Equivalence" criteria and associated untested hypotheses/claims has been broadly criticized – begin with Genetic Roulette; Jeffrey Smith; ISBN 978-0-646-48131-9

Suggestions for the Assessment of the Allergenic Potential of Genetically Modified Organisms; Spök A et al; Int Arch Allergy Immunol 2005;137:167-180



- Reviewers of the CSIRO study questioned whether a typical GM crop safety assessment would have picked up the problem with the GM peas. Immunogencity of GM peas Review of immune effects in mice fed on genetically modified peas and wider impacts for GM risk assessment; Rudolf Valenta and Armin Spök; 2008; Bundesamt für Naturschutz (BfN) Federal Agency for Nature Conservation; http://www.bfn.de
- 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.
- 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.
- 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
- 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.
- 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.
- In Roundup Ready soybeans, the NOS terminator was ineffective in ending transcription, and may have helped process the RNA in four variants.
- Identification and analysis of functional elements in 1% of the human genome by the ENCODE pilot project; ENCODE project consortium; Nature. 2007 Jun 14;447(7146):799-816
 - The ENCODE project aimed to look at the function of 1% of Human DNA around 300 scientists from 35 groups and 80 organisations took 4 years to look see what DNA does. They found that every bit is used, 'genes' overlap, prompting other investigators to come up with an alternative definition for a gene...
 - "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
- SENATE STANDING COMMITTEE ON COMMUNITY AFFAIRS ESTIMATES (Budget Estimates) WEDNESDAY, 4 JUNE 2008 pp134-136 http://www.aph.gov.au/hansard/senate/commttee/S10859.pdf
 - $\frac{http://www.foodstandards.gov.au/newsroom/factsheets/factsheets2002/faqsongmfoods6august163}{2.cfm}$
- Paediatric food allergy trends in a community-based specialist allergy practice, 1995-2006; Mullins RJ; MJA, Volume 186, Number 12, 18 June 2007
- http://www.aihw.gov.au/cognos/cgi-bin/ppdscgi.exe?DC=Q&E=/ahs/pdx0607
- Principal Diagnosis Separations statistics by ICD10 codes 1998/9 2006/7
- Proteins in Refined Oil

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- 1. Awazuhara, H., Kawai, H., Baba, M., Matsui, T., Komiyama, A. (1998). Antigenicity of the proteins in soy lecithin and soy oil in soybean allergy. *Clin. Exp. Allergy*, 28: 1559-1564.
- 2. Crevel, R. W. R., Kerkhoff, M. A. T., Koning, M. M. G. (2000). Allergenicity of refined vegetable oils. *Food Chem Toxicol*, 38:385-393.
- 3. Errahali, Y., Morisset, M., Moneret-Vautrin, D. A., Kanny, G., Metche, M., Nicolas, J. P., Fremont, S. (2002). Allergen in soy oils. *Allergy*, 57(7):648-649.
- 4. Hoffman, D. R. and Collins-Williams, C. (1994). Cold-pressed peanut oils may contain peanut allergen. *J Allergy Clin Immunol*, 93(4):801-802.
- Klurfeld, D. M. and Kritchevsky, D. (1987). Isolation and quantitation of lectins from vegetable oils. LIPIDS, 22(9):667-668.



- 6. Nordlee, J. A., Neimann, L. M., Hefle, S. L., Taylor, S. L. (2002). Determination of proteins in soybean oil from distinct processing steps. Abstracts of the IFT Annual Meeting.
- Olszewski, A., Pons, L., Moutete, F., Aimone-Gastin, I., Kanny, G., Moneret-Vautrin, D. A., Gueant, J. L. (1998). Isolation and characterization of proteic allergens in refined peanut oil. Clin. Exp. Allergy, 28:850-859.
- 8. Paschke, A., Zunker, K., Wigotzki, M., Steinhart, H. (2001). Determination of the IgE-binding activity of soy lecithin and refined and non-refined soybean oils. *J Chromatogr B Biomed Sci Appl*, 756(1-2):249-254.
- 9. Peeters, K. A. B. M., Knulst, A. C., Rynja, F. J., Bruijnzeel-Koomen, C. A. F. M., Koppelman, S. J., (2004). Peanut allergy: sensitization by peanut oil-containing local therapeutics seems unlikely. *J Allergy Clin Immunol*, 113:1000-1001.
- Reeves, R. M. (1999). Letter from Institute of Shortening and Edible Oils to Joint FAO/WHO Expert Committee on Food Additives, Food and Nutrition Division. Unpublished data analytical results for protein in oil.
- Skinner and Haynes. (1998). Seed crushers and oil processors association report as reported in: WHO
 Food Additive Series 44 and in EFSA Notification.
- 12. Tattrie, N. and Yaguchi, M. (1973). Protein content of various processed edible oils. *Journal of the Institute for Cancer, Science Technology and Alimentation*, 6:289-290.
- 13. Teuber, S. S., Brown, R. L., Haapanen, L. A. D., (1997). Allergenicity of gourmet nut oils processed by different methods. *J Allergy Clin Immunol*, 99:502-507.
- The FSANZ (then ANZFA) Final Risk Assessment Report attached to the Final Risk Analysis Report document reported that the Monsanto Roundup Ready Canola crop line contained 0.290 ppm of protein in the refined oil
- Australian Pilot Survey of GM Food Labelling of Corn and Soy Food Products; The TAG Working Group on GM Food Labelling; June 2003
- Genetically modified foods and their approval status; Food Standards Australia New Zealand (FSANZ); http://www.foodstandards.gov.au/foodmatters/gmfoods/gmcurrentapplication1030.cfm
- FULL ASSESSMENT REPORT AND REGULATORY IMPACT ASSESSMENT SUBJECT: A338 FOOD DERIVED FROM GLYPHOSATE-TOLERANT SOYBEANS http://www.foodstandards.gov.au/ srcfiles/A338FAR.pdf
- FINAL RISK ANALYSIS REPORT APPLICATION A363 Food produced from glyphosate-tolerant canola line GT73; http://www.foodstandards.gov.au/srcfiles/A363%20draft%20IR.pdf
- 25 ISAAA Briefs; http://www.isaaa.org/RESOURCES/PUBLICATIONS/BRIEFS/default.html
- Global Status of Transgenic Crops in 1997; Clive James; Chair ISAAA board of Directors; http://www.isaaa.org/RESOURCES/PUBLICATIONS/BRIEFS/05/download/isaaa-brief-05-1997.pdf. The crops were Herbicide Tolerant Soybeans, Insect Resistant Corn, Herbicide Tolerant Canola, Herbicide Tolerant Cotton, Insect Resistant Cotton, Herbicide Tolerant Corn, Virus Resistant Tomatos, Herbicide Tolerant Hybrid Technology Canola, Insect Resistant Potato, Delayed Ripening Tomato
- Global Review of the Field Testing and Commercialization of Transgenic Plants: 1986 to 1995; The First Decade of Crop Biotechnology; Clive James and Anatole F. Krattiger, ISAAA; http://www.isaaa.org/RESOURCES/PUBLICATIONS/BRIEFS/01/download/isaaa-brief-01-1996.pdf
- Table 9. Global GM plantings by country 1996-2005 ('000 hectares); GM Crops: The First Ten Years Global Socio-Economic and Environmental Impacts; Graham Brookes and Peter Barfoot; PG Economics Ltd., UK
 - http://www.isaaa.org/RESOURCES/PUBLICATIONS/BRIEFS/36/download/isaaa-brief-36-2006.pdf
- Genetically modified foods and their approval status; Food Standards Australia New Zealand (FSANZ); http://www.foodstandards.gov.au/foodmatters/gmfoods/gmcurrentapplication1030.cfm
- GM Crops Around the World an accurate picture June 2008; GM Freeze; citing www.nationmaster.com and ISAAA; http://www.gmfreeze.org/uploads/GM crops land area final.pdf



- 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
- Opinion of the Scientific Panel on genetically modified organisms [GMO] on a request from the Commission related to the Notification (Reference C/NL/98/11) for the placing on the market of herbicide-tolerant oilseed rape GT73, for import and processing, under Part C of Directive 2001/18/EC from Monsanto; The European Food Safety Authority (ESFA) Journal (2004) 29, 1-19, Section 4.3 Conclusions
- cat. no. 4102.0 Australian Social Trends, Data Cube; Released at 11.30am (Canberra time) 23 July 2008; Table 1 Family and community, National Summary, 1997-2007;
- ³⁴ Australia

Australian Bureau of Statistics, "Breastfeeding in Australia, Electronic delivery", www.abs.gov.au/Ausstats/abs@.nsf/ Maternal and Child Health Services Annual Reports, Office For Children, Department of Human Services, State Government of Victoria. 2000/1-2004/5 at www.office-for-children.vic.gov.au/children/ccdnav.nsf/childdocs/-fee555C5D757CA2BCA256E18006497D4-ED1E2431B9EB4892CA256E2000088BF8-AE9FB320272ADFE6CA256E20000882FF?open">www.abs.gov.au/children.vic.gov.au/children/ccdnav.nsf/childdocs/-fee555C5D757CA2BCA256E18006497D4-ED1E2431B9EB4892CA256E2000088BF8-AE9FB320272ADFE6CA256E20000882FF?open

England

Infant Feeding Survey 2005; Bolling, Grant, Hamlyn, Thornton; "A survey conducted on behalf of The Information Centre for health and social care and the UK Health Departments by BMRB Social Research"; The Information Centre; (ISBN: 1-84636-124-9, www.ic.nhs.uk, email: enquiries@ic.nhs.uk)

Norway

Directory for Health and Social Affairs. "Dietary survey among infants, 1998", www.ssb.no/english/subjects/03/01/kostspe_en/art-2003-03-28-01-en.html

- 35 GM Foods in the UK between 1996 and 1999: comments on "Genetically Modified Crops: Risks and Promise" by Gordon Conway; John R Krebs; Ecology and Society, Vol. 4, No. 1, Art. 11 http://www.ecologyandsociety.org/vol4/iss1/art11/
- 36 CONSENSUS CONFERENCES ON GENETICALLY MODIFIED FOOD IN NORWAY; Alf J. Mørkrid; OECD 2001 http://www.oecd.org/dataoecd/53/56/2537449.pdf
- ³⁷ USDA Foreign Agricultural Service GAIN Report Global Agriculture Information Network http://www.fas.usda.gov/GainFiles/200303/145884831.pdf
- ³⁸ 2008 report on Norway from the Office of the United States Trade Representative; http://www.ustr.gov/assets/Document_Library/Reports_Publications/2008/2008_NTE_Report/asset_upload_f ile589_14676.pdf
- The Norwegian Food Standards body: Mattilsynet www.mattilsynet.no
 "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."
- The Norwegian National Reporting System and Register of Severe Allergic Reactions to Food; Lovik M et al; Norsk Epidemiologi 2004; 14(2): 155-160