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Public Submission on

APPLICATION A1041:
FOOD DERIVED FROM SDA SOYBEAN LINE MON87769
2nd ASSESSMENT REPORT

Thank you for the opportunity to make a submission on this Application for GM crop approval. MADGE asks that the application be rejected on the following grounds:

1. FSANZ has not applied scientific method in the review of the safety of the crop

FSANZ makes the following claim on its website:

"Paper reviews are a standard scientific method of evaluation used by regulators around the world…"
http://www.foodstandards.gov.au/consumerinformation/gmfoods/frequentlyaskedquestionsongeneticallymodifiedfoods/part2safetyassessmen4658.cfm

By describing such reviews as standard scientific method we understand that FSANZ is likewise promoting itself to the public as conducting its reviews according to standard scientific method.

It is typical that reviews in science address issues related to a wide range of potential biases, such as funding bias, outcome bias, publication bias and dissemination bias.

In the case of this GM crop there are profound and established biases related to development costs, and profit incentives. I would like to alert FSANZ to the fact that Monsanto has taken out forward-looking patents on the anticipation of approval of this crop. These represent a capacity to capture not just income but food in the marketplace.

Some of the patents coming up on Google Patents under the search term "Monsanto SDA soy", or on Google Scholar under the search term "Patent Monsanto SDA soy"

Patent: Omega-3 Enriched Cereal, Granola, and Snack Bars; Monsanto Technology LLC ; Filed Apr. 24, 2009; US 2010/0272875 A1 Oct. 28, 2010
http://www.google.com.au/patents?id=aVcCAQAAEBAJ&printsec=abstract&zoom=4&source=gbs_overview_r&cad=0#v=onepage&q&f=false

Patent: Spread Formulations Including Stearidonic Acid; Monsanto Technology LLC; Filed Apr. 16, 2009; US 2010/0266746 A1 Oct.21, 2010
http://www.google.com.au/patents?id=gTbYAAAAEBAJ&printsec=abstract&zoom=4&source=gbs_overview_r&cad=0#v=onepage&q&f=false

Patent: Methods of Feeding Pigs and Products Comprising Beneficial Fatty Acids; Monsanto Company; Filed Jan. 29, 2009; US 2009/0196950 A1 Aug. 6, 2009
http://www.google.com.au/patents?hl=en&lr=&vid=USPATAPP12362102&id=Kg7UAAAAEBAJ&oi=fnd&dq=Patent:++Monsanto+SDA+soy&printsec=abstract#v=onepage&q&f=false

Patent: Poultry Meat and Eggs Comprising Beneficial Fatty Acids; Monsanto Company; Filed Mar. 16, 2009; US 2010/0233313 A1 Sep. 16, 2010
http://www.google.com.au/patents?id=FMbWAAAAEBAJ&printsec=abstract&zoom=4&source=gbs_overview_r&cad=0#v=onepage&q&f=false

Patent: Food Compositions Incorporating Stearidonic Acids; Monsanto Technology LLC; Filed Jul. 1, 2009; US 2010/0021608 A1 Jan. 28, 2010
http://www.google.com.au/patents?id=4dDLAAAAEBAJ&printsec=abstract&zoom=4&source=gbs_overview_r&cad=0#v=onepage&q&f=false

Patent: Aquaculture Feed, Products, and Methods Comprising Beneficial Fatty Acids; Monsanto Company; Filed Jan. 29, 2009; US 2009/0202672 A1 Aug. 13, 2009
http://www.google.com.au/patents?id=DAzUAAAAEBAJ&printsec=abstract&zoom=4&source=gbs_overview_r&cad=0#v=onepage&q&f=false

Patent: Food Compositions Incorporating Additional Long Chain Fatty Acids; Monsanto Technology LLC; Filed Jan. 3, 2008; US 2010/0173061 A1 Jul. 8, 2010
http://www.google.com.au/patents?id=9iTSAAAAEBAJ&printsec=abstract&zoom=4&source=gbs_overview_r&cad=0#v=onepage&q&f=false

Patent: Meat Products with Increased Levels of Beneficial Fatty Acids; Monsanto Technology LLC; Filed Nov. 21, 2008; US 2010/0291267 A1 Nov. 18, 2010
http://www.google.com.au/patents?id=8IXdAAAAEBAJ&printsec=abstract&zoom=4&source=gbs_overview_r&cad=0#v=onepage&q&f=false

These biases are further magnified by the research restriction biases related to patent ownership – that there is no work on products from this GM crop apart from those conducted by the patent owner.

- Unlike standard scientific reviews FSANZ did not discuss or evaluate the quality and reliability of the data it was assessing from any perspective of bias.

Furthermore the public needs to be aware that there are biases that we need to appreciate exist at FSANZ. FSANZ are paid somewhere in the range of $60,000 - $150,000 to conduct this review. This payment allows them to employ staff to help Monsanto 'jump the queue' for a quick review for approval. This presents a classic 'funding bias' risk within the organisation itself.

There are also personal biases that have also been well documented. These may relate to past work history, economic, religious and political beliefs, academic or

career prospects, personal financial responsibilities and the need maintain steady employment, the values one places on other people's children, how parenting should be conducted and views on the risks one should carry through life; even the value one places on the right of companies to have their products tried in the marketplace for the money invested.

Where it may be the case that only one person at FSANZ reads thoroughly through all of the material (if that), on behalf of a population of 22 million people, the personal bias takes on a profound and unacceptable risk.

- FSANZ routinely fails to address payment or personal bias risks.

- On the basis that this review has been so profoundly unscientific as to not address nor consider the impact of the clear and present biases, nor even to reference their possible presence, we request that this GM crop not be approved.

2. FSANZ has not conducted thorough assessments of safety nor nutritional implications.

FSANZ makes the following claim on its website:

"FSANZ conducts a thorough safety assessment of all GM foods before they are allowed in the food supply."
http://www.foodstandards.gov.au/consumerinformation/gmfoods/frequentlyaskedquestionsongeneticallymodifiedfoods/part2safetyassessmen4658.cfm

2.1 In our brief submission to the first round, referring only to the safety assessment document we noted:

> "1. FSANZ listed 27 references in its safety assessment document that it did not cite. This looks like reference padding and it does not add to the credibility of the FSANZ assessment process. Also, FSANZ failed to reference 16 citations in the same document. MADGE does not have the confidence that FSANZ has applied serious scientific process necessary for the review of the safety of this crop, and asks that approval be withheld until a more credible assessment is conducted."

FSANZ did not give any explanation for the lax unscientific referencing of its document when replying in the second round assessment. It did not amend its Safety Assessment document for the second round assessment, so as to represent material of a quality expected in the most elementary work of science.

For this second round assessment we would like to make the following notes about failure to conduct a thorough assessment of nutritional implications.

2.2 This is a document of few references. There was a reference referred to but not listed. It was "(Heart Foundation, 2008)". Ordinarily I wouldn't complain about a singular omission of a non-systemic type, but it is a reference that I haven't been able to access. The Heart Foundation put out a position statement on fish, fish oils and omega-3 PUFAs[1], which I'm supposing is the correct reference, but the actual review[2] has been unavailable to me through the web, and to date, through the Heart Foundation. It is important to see the basis for the well-publicised advice of such a quasi-authority with many declared industry links, particularly if FSANZ is referencing the advice.

2.3 Table 2 of the nutritional implications document contained several errors.

2.3.1 In respect of the "Miles et al. (2004)" study there are three rows of numbers, all identical. Two of the rows of numbers (8) are wrong. They are not the numbers reported by the study. I make mistakes and errors of omission in what I write; I may be the worst proof reader on the planet. But did anyone at all within FSANZ look at these numbers, or is this whole document the work of just one person (apart from, possibly, a typist) of behalf of 22 million consumers? This cannot be described as thorough.

2.3.2 In respect of the "Harris et al. (2008)" study the placebo group was given Soy Bean Oil (SBO) not "ALA" as written in column two of the table. Please check the methodology section. The ALA present in the soybean oil amounted to 1.7g per day. This was not an 'additional' element as wrongly described on page 808 and mis-tabled and mis-analysed in the following pages. The participants were given far more than just the ALA (being the rest of the oils in SBO, including LA). This study was deceptive or in error in how it presented its results, whether by design or lax logic. It was a study funded by Monsanto where most of the authors came from, but the lead author was described as coming from "Sandford Research in Sioux Falls". In the subsequent Lemke Monsanto paper he was described as "a scientific advisor to and received research support from Glaxo-SmithKline and Monsanto Company, is part of GlaxoSmithKline's Speakers' Bureau, and has ownership in OmegaQuant, LLC". One of the trials for the Lemke study was conducted at the "Sioux Valley Clinic Clinical Research Center (Sioux Falls, SD; now named Sanford Clinical Research Centre)". It is imperative that FSANZ apply a fierce scrutiny to the material presented where research with such obvious interests exists. This cannot be described as 'thorough'.

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[1] Position statement. Fish, fish oils, n-3 polyunsaturated fatty acids and cardiovascular health (updated November 2008)
http://www.heartfoundation.org.au/HEALTHY-EATING/FATS/Pages/omega-3.aspx

[2] Colquhoun D, Ferreira-Jardim A, Udell T, Eden B and Nutrition and Metabolism Committee of the National Heart Foundation of Australia: Fish, fish oils, n-3 polyunsaturated fatty acids and cardiovascular health: a review of the evidence, in Australia NHFo. Sydney, NHFA, 2007.

2.3.3 In respect of the "Wu et al. (1999)" study, Table 3 of the study where the numbers appeared to have come from reported on outcome measured in plasma, rather than erythrocytes as reported in the FSANZ Table 2 of the nutritional implications document.

2.4 Table A1 of the FSANZ nutritional assessment document contained errors. In respect of the "Harris et al. (2008)" study previously mentioned in point 2.3.2 there are errors under the heading "Treatment groups". The SDA group received SDA oil and SBO oil in capsules. It did not receive any additional ALA according to the methods. The 2.42g/day [2.43?] of ALA was a consequence of receiving these oils in which many other design relevant products were incorporated. Likewise the EPA group did not receive an additional 1.7g/day [1.69?] of ALA. It received EPA in capsules and SBO in which ALA was a consequence. The SBO group as previously mentioned received SBO packets and capsules, a component of which was ALA, reported in total(?) to be 1.7g/day [1.76? – they may have disgarded the ALA in the SBO capsules]. Getting this point clear is highly relevant for the analysis under point 5 below.

3. FSANZ failed to comply with its own stated requirements for studies by GM crop developers to be conducted with Good Laboratory Practice "… in accordance with internationally established scientific principles and guidelines" as stated by FSANZ on its website.

We referred to this in our previous submission, FSANZ noted our comment but gave no explanation or reply. We re-note the comment here:

"2. MADGE has counted 17 studies received by FSANZ from Monsanto to support their application. Only 5 of these studies reported compliance with Good Laboratory Practice associated with US regulation. None of these studies mentioned compliance with OECD standards, and the FSANZ made no mention of their compliance in its assessment. This food safety assessment overrides this 13 April 2010 statement by the FSANZ CEO:

"It is a requirement that the data relied upon to establish the safety of a GM food be generated according to internationally accepted quality assurance guideline (i.e. approved methodology and Good Laboratory Practice (GLP)) and that this has been subjected to external scrutiny (i.e. independent audit and documentation trail). [..] Studies that do not make the grade will not be accorded any weight in the safety assessment"

Most of the Monsanto studies should not have been given any weight in this assessment, and this includes studies investigating potential allergencity. The data provided is insufficient according to FSANZ's stated standards, and this crop should not be approved."

4. Likewise, at the first round we noted that FSANZ failed to comply with recommendations in the Auditor General's report as described below. The crop

should not be approved while FSANZ is failing to comply with its legal obligations. We asked that FSANZ redo the assessment document according to the recommendations made by the Auditor General, and request this again here.

> "3. In this assessment FSANZ failed to comply with the Auditor General's recommendations made in its ANAO Audit Report No.15 2010–11. MADGE requests that FSANZ redo this first assessment document complying with the Auditor General's recommendations so the public can make an appropriate assessment of FSANZ process in their assessment of the food safety of the crop."

5. The nutritional implications of this crop have been insufficiently considered and the GM crop should not be approved.

I challenge the findings that SDA converts to EPA at the efficiency ratios described, if at all. The Lemke, Harris, Miles and Wu studies[3] did not control for the LA/ALA ratio or alternatively described, Omega-6:Omega-3 ratio.

[NB: James and Ursin of "James 2003" are share inventors of an SDA patent jointly assigned to Monsanto Technology LLC and the Royal Adelaide Hospital]

In the absence of SDA many studies have demonstrated an improved conversion of ALA to EPA through alteration of the LA/ALA ratio in the oil diet. This is achieved and reported through the simple addition of an oil such as flaxseed to the diet. FSANZ seems to be aware of this effect because it cited "Jones and Kubow 2006" reporting that an excess of O6 (typically LA) can reduce the metabolism of O3 PUFA's. FSANZ however did not seem to follow through the consequences of this citation into examining the studies they cited from this aspect.

O6:O3 Ratio Effect

None of these studies had a comparative l LA/ALA control on the SDA tests. In the Lemke study the control participants received 8.4 g/100g fatty acids of LA and only 1g of ALA. The EPA participants received 7.8g of LA, 1g of ALA and 1g of EPA. The SDA participants received 3.5g of LA (1.1g of O6 GLA), 1.6g of ALA (4.2g of O3 SDA). That is, the SDA participants had a very low O6:O3 intake ratio in the study compared to the other trial groups. Reducing the O6:O3 intake ratio has been shown in numerous studies to push ALA through to EPA, in the complete absence of any additional SDA in the diet.

There is a lot of conjecture over what change to the ratio produces the best effect, whether to increase O3, reduce O6, increase both but O6 to a lessor extent etc. However the fact that a reduced ratio changes the conversion of ALA that has been described as 'rate-limited' through to EPA.

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[3] [NB: James and Ursin of "James 2003" are share inventors of an SDA patent jointly assigned to Monsanto Technology LLC and the Royal Adelaide Hospital. "Treatment and Prevention of Inflammatory Disorders; US Patent No.: US 7,163,960 B2]

FSANZ cited the "Pawlosky RJ" study as a sole example of very limited conversion of 0.2% ALA to EPA. However Harnack et al 2009 reported conversions up to 17% in hepatic cells in vitro with a 1:1 O6:03 ratio, comparable with that used in the Lemke SDA trial if the longer chain O3's and O6's are included. Barcelo-Coblijn et al 2008[4] reported a 77% increase in erythrocyte EPA over 12 weeks from 3.6g flax oil/d, and Young et al 2004[5] reported a 56% increase in serum phospholipid EPA over 12 weeks from 36g flax oil/d. An analysis of the O6:O3 ratios in control and test groups shows it to be a present variable. These studies had smallish numbers in these trial groups but so did Pawlovsky. I don't recall the in-study dietary recommendations to be out of line with those in the studies put forward in this application. I can't completely explain the Pawlovsky result, but certainly the participants had extraordinarily high O6:O3 ratio in plasma, though other studies suggest this might be a regular observation. The Australian study by Hoyos et al 2008[6] reported a negative association between dietary n-6 PUFA and plasma n-3 in children.

There is something very subtle about when, why and how our bodies pick up the conversion of ALA through to the longer chain PUFAs, as highlighted by the Harnack et al 2009 study. Harnack measured the regulation of enzymes involved in conversion down to the level of transcription. She reported that transcription in hepatocytes is affected by the O6:O3 ratio. She also reported that conversion went through to DHA in this case.

There is a genetic, possibly epigenetic, likely hormonally affected mechanism for LCPUFA conversion and we don't seem to have a lot of understanding about it. While the crude '*you look a bit short in O3, have a bit more and we'll patent it*' may seem to be a simple and obvious solution, it does imply a deep lack of respect of the complexity and nuances of how our bodies actually work. This form of 'correctional' approach may, along many other crude nutritional 'adjustments', end up creating other problems. There is what seems to be a simple solution, the advice to eat a natural diet of the type experienced in the last thousands of years of our existence on the planet.

It is a feature of the studies provided in support of this GM SDA crop that there was no reported conversion to DHA, the fatty acid with the predominant reputation for health benefit. Females are reported to produce this fatty acid

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[4] American Journal of Clinical Nutrition, Vol. 88, No. 3, 801-809, September 2008; **Flaxseed oil and fish-oil capsule consumption alters human red blood cell n–3 fatty acid composition: a multiple-dosing trial comparing 2 sources of n–3 fatty acid[1,2,3] ;** Gwendolyn Barceló-Coblijn, Eric J Murphy, Rgia Othman, Mohammed H Moghadasian, Tarek Kashour and James K Friel
http://www.ajcn.org/content/88/3/801.long

[5] © INRA, EDP Sciences, 2005 DOI: 10.1051/rnd:2005045; **Effect of randomized supplementation with high dose olive, flax or fish oil on serum phospholipid fatty acid levels in adults with attention deficit hyperactivity disorder** Genevieve S. YOUNGa, Julie A. CONQUERa*, René THOMASb
http://www.tohtoritolonen.fi/files/pdf/young_2005.pdf

[6] *Asia Pac J Clin Nutr 2008;17 (4):552-557;* **Effect of omega 3 and omega 6 fatty acid intakes from diet and supplements on plasma fatty acid levels in the first 3 years of life;** Camilla Hoyos BAppSci(Hons)1, Catarina Almqvist PhD1,2,3, Frances Garden BAppSci4, Wei Xuan PhD1, Wendy H Oddy PhD5,6, Guy B Marks PhD1,2,3, Karen L Webb PhD2;
http://apjcn.nhri.org.tw/server/APJCN/Volume17/vol17.4/Finished/2_1096_Hoyos_552-557.pdf

more readily than males, suggested to be hormonally driven but it seems a mystery in general.

SDA Efficiency Ratios and Conversion

FSANZ did address the conversion of SDA to EPA. After some discussion there seemed to be a determination that ~17% converted through to EPA. Regard was still given a 30% conversion reported by James 2003 using ethyl ester capsules, but with a quite strong O6 restriction and provision of alternative food products.

I have noticed an apparent problem in the FSANZ logic. Despite acknowledging an undetermined partial conversion in Section 2.2.2 of the Nutritional Implications document, in Section 2.2.3 FSANZ wrote that the conversion of SDA to the longer chain omega-3s is nearly 100%. This statement was made on the basis that the Wu, James, Harris and Lemke studies found little change in their before and after SDA measurements. Miles and James couldn't find it anywhere else they looked, but neither reported looking in participant faeces. There were probably other places they didn't look, such as in the liver, kidneys and urine. Perhaps FSANZ meant that ~17% was taken into the body, of which nearly 100% was converted, and that 83% went down the toilet unexamined.

However FSANZ has given recognition of the O6 intake and O6:O3 ratios, so it seems it would be a logical consequence for FSANZ to acknowledge that part or all of the conversion is due to this variable, rather than to the inclusion of SDA in the diet. This would put the efficiency substantially below 17%.

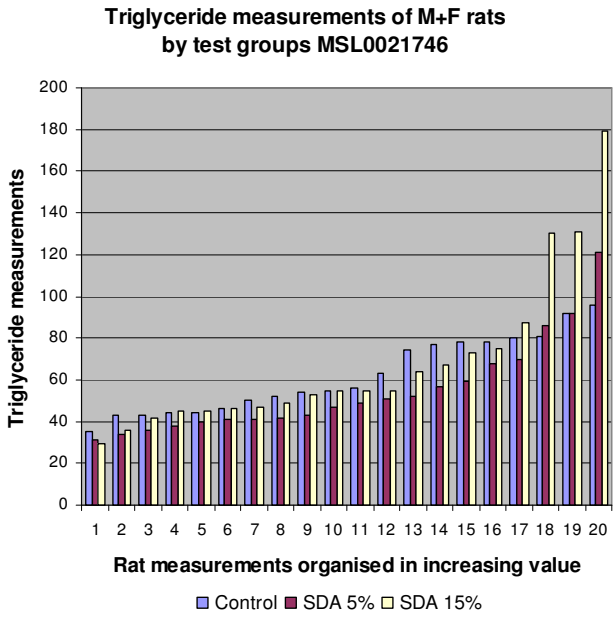
I'm wondering, subject to further clarifying study, if the SDA is going to turn out to be little more than a gimmick. SDA is not a part of our regular diet in any quantities. Over the millenniums of human existence we have not bred a plant for the sole purpose of consumption to be high in SDA. Is it a possibility that it is an irrelevant and perhaps un-utilized fatty acid in the human diet?

What did they feed the animals?

Does it seem a little bit strange to FSANZ that Monsanto went to the trouble of testing GM SDA soy oil on rats, tested GM SDA soy meal on rats and chickens, yet did not measure any variables related to the purported O3 feature of the product? Monsanto reported no significant differences in animal production and various health features of the animals, but isn't this meant to be a nutrition product? Wouldn't they cut up a sacrificed rat's heart/brain to see of there is some additional DHA deposition around the heart which are the supposed highly beneficial effect of consuming the very long chain PUFAs? But no! I wonder why not. Thus I wonder, on an issue more related to the safety assessment, what they fed the animals. When the testing bodies report that they didn't comply with Good Laboratory Practice because they didn't put the materials through full analysis, how do we know what material they actually tested on the animals? Monsanto labels a packet, and that's it? How does FSANZ account for the potential for misconduct in such a case? Has FSANZ ever requested

material meant to be archived as a Good Laboratory Practice requirement to verify what Monsanto does?

Increase of Trans Fatty Acids



Omega 3's are purported to have beneficial affects on adverse blood fats, however trans-fatty acids are purported to have negative affects. They have been reported to be a factor affecting the likelihood and incidence of High Triglycerides. In the SDA soy meal study Monsanto measured triglycerides in 20 rats (10M, 10F) of each test group. Probably still within the range of chance in such a small group, but worth a second look, are these three findings of high triglycerides in the highest SDA soy test group.

In the human study Lemke isolated a High Triglyceride group of participants on whom to conduct a further TG test, but were a little bit vague about the purpose of this. The group sizes were small and there were withdrawals, particularly in the GM SDA soy group. Completers in the control group: 7 out of 9, EPA group 9 out of 10, and GM SDA group 9 out of 14. The statistical variation in the groups was very large and statistical conclusions were unable to be drawn. I don't think the test provides sufficient evidence for a null effect on triglycerides from the Trans-fatty acids in the oil, or from some other effect related to the genetic modification of the crop. I think an appropriately sized test should be conducted to see if people with high triglycerides may be affected by this product.

On another matter the Lemke study had been supposedly set up to reach statistical power at 68 completers. There were quite high withdrawals though and power was not reached. The results are not conclusive. Bad luck again or not but there were a lot of withdrawals in the GM SDA group. Completers in the control group: 65 out of 87, EPA group 62 out of 84, GM SDA group 54 out of 81.

There doesn't seem to be a justification for a health claim for this product, even assuming a GM crop with data supplied by the commercial company of interest could ever be determined to be safe on the basis of studies that failed to comply with the minimum standards to protect against lab fraud.

- It isn't at all certain that the SDA is used for conversion to EPA and DPA. A simple reduction in omega 6 oils in comparison to omega 3 oils may be all this product is achieving, which is also readily achievable through non-GM existing oils that don't carry the untested safety risks and the patented food ownership issues which may themselves present a barrier to production and trade.
- The human conversion of the GM SDA oil into DHA was not noted.
- The effect of the additional TFAcids has not been sufficiently evaluated.
- New consumer research says that dieters are more likely than non-dieters to choose unhealthy foods that are labeled as healthy http://bit.ly/gNoJ7p This places an extra burden of responsibility on behalf of people who may be most in need of protection from additional TFA's, in consideration of whether products containing the GM SDA oil should carry a health claim. This assumes of course that the GM SDA soy is free of risk from the usual uncertainties of the transgenic techniques.
- There were no other beneficial findings related to cholesterol, LDL, HDL or TG.
- Lastly, it seems odd to make a health claim directly against its soy oil comparator. Should we conclude that the soy oil that people are consuming in processed products in Australia is not very beneficial? This is a just conclusion. After spending so much time considering the O6:O3 alone I can't help having the impression that FSANZ has approved a lot foods that present dietary danger, without accompanying warning signals. When ~67% of a population of 22 million is overweight/obese, dietary issues can't be considered as simple matters pertaining to individual circumstance.

On the safety assessment

6. FSANZ noted but did not respond to this MADGE point at the first round of submissions. Please can FSANZ come up with an explanation for all of the proteins that were recognized by antibodies that were meant to be specific for the two intended GM proteins:

   "5. The protein characterization tests showed specifically raised antibodies reacting with a wide range of proteins, not only the intended proteins. Even if these proteins were aggregates and degradation products of the intended proteins the EFSA scientific opinion above says these novel products represent separate risks of allergenicity. Please explain why FSANZ ignored these novel products, despite particular reference to them. MADGE requests that each of the protein products that were recognized by the specific antibodies be identified and tested.

   We alert FSANZ to Section 1 of the ANNEX:ASSESSMENT OF POSSIBLE ALLERGENICITY of the Codex Alimentarius Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants, CAC/GL 45-2003, being

"All newly expressed proteins in recombinant-DNA plants that could be present in the final food should be assessed for their potential to cause allergic reactions.""

FSANZ has not treated these identified proteins with sufficient seriousness.

7. We are not satisfied with the FSANZ answer 10.3.6.1 to this point in our first round submission

> "4. On a more technical issue, describe what FSANZ has done to determine whether the chimeric sequences in this crop are capable of immunostimulatory activity, as discussed in the European Food Safety Authority's "Scientific Opinion on the assessment of allergenicity of GM plants and microorganisms and derived food and feed" EFSA Journal 2010; 8(7):1700, giving particular attention to the codon-altered gene originally sourced from Neurospora crassa. "

I didn't ask about whether the proteins were produced as intended as a result of the codon changes, but by the way, did Monsanto provide a full confirmatory analysis that the protein produced in the plant is the same as that hypothesized? Indeed did they actually supply any evidence that the sequence in the plant being put forward for regulatory approval was the same as that used in the transformation event. I don't think I received any data on this.

On FSANZ's point "vaccines research has no relevance to food", I ask to FSANZ to consider all the GM plant vaccine work which is being conducted. Apparently we are going to be able to eat our vaccines in the future. Google it – sorry I can't, nearly submission time.

FSANZ suggested that an immunostimulatory CpG oligonucleotide couldn't provoke immune response to food, on the basis that we would consume these with high frequency in nature. FSANZ should consider that the sequence is described as chimeric and patented because it does not exist in nature. Thus this answer is insufficient. We would like some investigative work into the risk of the chimeric sequence acting as an immunostimulant.

8. We are not satisfied with the FSANZ answer 10.3.7 to this point in our first round submission

> "6. The EFSA scientific opinion above indicated that the SGF and SIF digestibility tests are inappropriate for low-acid, low-pepsin infant gastrointestinal systems. Describe what FSANZ has done to determine the infant gastrointestinal safety of this GM crop, in light of the newly collected scientific opinion on the issue."

I would like to bring this study[7] to FSANZ's attention:

[7] doi:10.1016/j.reprotox.2011.02.004; **Maternal and fetal exposure to pesticides associated to genetically modified foods in Eastern Townships of Quebec, Canada Reproductive Toxicology;** Aziz Aris (a,b,c,*), Samuel Leblanc (c); http://www.biosafety-info.net/article.php?aid=774%C2%A0

It detected the Cry1Ab protein in pregnant women just before they gave birth, and in the cord blood of their newly born infants. FSANZ has clearly, on Monsanto's recommendation, assumed full digestion of GM proteins, in this case insecticidal toxins, would take place, and has been wrong. I ask FSANZ to reconsider its assessment methods in relation to the supposed digestion of proteins. They are clearly inadequate.

Once again, time defeats me. Please offer me lenience for the grammatical and typographical errors in this unread piece.

Yours faithfully,

Madeleine Love
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