

**CORRESPONDENCE WITH Dr BRIAN JOHN, GM-FREE CYMRU  
(19 December 2009 and 12 January 2010)**

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19 December 2009

Dear Secretariat,

ACNFP negligence in the GM scrutiny / approvals process

We will be grateful if you will bring this letter to your next Committee meeting as a matter of urgency.

We are writing to express our grave concern about three very serious recent developments in GM science, which all indicate (so far as we can see) major deficiencies in the ACNFP scrutiny and assessment process. Your Committee is supposed to be the scientific watchdog that draws the attention of the FSA, the Government and the public to the risks associated with GM crops and foods. But from our examination of the ACNFP web site, and Committee minutes etc, we can see no sign that three serious health and safety issues have been given the degree of scrutiny which we all have a right to expect.

The three cases are as follows:

1. MON810. So far as we can see from a perusal of ACNFP opinions and minutes over the past decade or so, the Committee has repeated, over and again, that MON810 is as safe as its conventional counterpart and that it is substantially equivalent to the line from which it was bred. Furthermore, when asked about safety concerns raised by other countries (eg Italy and Austria) it has always dismissed these concerns out of hand and has refused to revise its opinion. Now it has transpired that German feeding studies on cattle, conducted in 2005-2008, and using MON810 in feed, which have been heavily promoted to the media as showing "that feeding with transgenic maize does not have any impact on the food chain" and that "transgenic maize has no impact on lactating cows" (1), are essentially worthless. A close examination of the original German-language study (2009) by Greenpeace and Testbiotech (2) has revealed that the study had so many shortcomings in its experimental design, in the conduct of the feeding trials, and in the analyses of results, that we have to conclude that there has been research manipulation. At the very least, it now has to be concluded that the trial data do NOT support the conclusions published by the researchers. A positive EFSA overall opinion on MON810, fulfilling the requirements of Articles 6 and 18 of Regulation (EC) No 1829/2003, and confirming the conclusions of the original safety assessment, was adopted on 15 June 2009 (and published on 30 June 2009. This positive assessment was based in part upon the "clean bill of health" given

by the German feeding study research team. In the spring of this year, did ACNFP review this study with a view to reassessing its conclusions on the safety of MON810 in animal feed? We can see no evidence in Committee minutes that it did -- and in our book that constitutes negligence (3).

2. LY038 and LY038 x MON810. On 30th April 2009 Renessen / Monsanto pulled two applications for high-lysine maize varieties following requests from EFSA for additional studies and for a clarification of their experimental data (4). EFSA had also asked -- for the first time -- for adherence to the Codex rules relating to GM and comparator studies. This unprecedented action by EFSA followed irresistible pressure from a number of EU states, arising from deep concerns about the content of the applicant's supporting dossiers. The Monsanto dossiers included rigged research and false assumptions in the reported experiments; a failure to offer any test results based on cooked or processed corn; a failure to test the whole GM plant in feeding trials; confusing and contradictory characterizations of the GM varieties and proteins; a fraudulent mixing of GM strains during trials; a pooling of crop data so as to mask undesirable effects in experiments; feeding trials too short to reveal true physiological changes in animal tissues; and the choice of an irrelevant, unrelated corn variety as the control group for comparison with the GM lines, with the clear intention of hiding potentially serious differences in composition or side effects on animals. On the basis of a careful review of the dossiers, scientists at Canterbury University's Centre for Integrated Research in Biosafety (INBI) warned that the new corn was not safe for humans when cooked. They also expressed concerns about unpredictable health effects, increased levels of toxins in high-lysine corn, and possible allergies and links to cancer. In the face of these strongly-stated health and safety concerns Renessen / Monsanto simply refused to provide additional information that might (or might not) have proved their products to be safe. We have seen the summary of comments received from the member states, and we have to ask why, when many other EU regulatory authorities raised safety concerns about LY038, there was NO comment on the dossier from ACNFP or the UK government. We can only assume that ACNFP did not even bother to look at the applications from Renessen, or that they scanned them and found no problem. Again, therefore, we have to accuse ACNFP of gross negligence.
3. MON810, MON863 and NK 603. Researchers from CRIIGEN and Universities of Caen and Rouen have highlighted a number of new sex and often dose dependent side effects linked with the consumption of these three GM varieties (5). Their study of the 90-day feeding trials data of these GM maize varieties clearly underlines adverse impacts on kidneys and liver, the dietary detoxifying organs, as well as different levels of damage to heart, adrenal glands, spleen and haematopoietic system. The raw data held by Monsanto relating to feeding trials on rats was not opened to independent evaluation or peer review, and some of it was hidden behind the "Commercial in Confidence" rules; and yet EFSA, ACNFP and other regulators simply accepted the Monsanto assurances that there were no signs of health damage, leading to the international authorization of these three GMOs in different parts of the world. That represents a corporate failure to apply proper scrutiny. CRIIGEN has pointedly denounced the past

opinions of EFSA and others who have drawn faulty conclusions on the basis of safety tests / feeding trials conducted for just 90 days on rats. While criticizing their failure to examine the detailed statistics, CRIIGEN has also emphasized the conflict of interest and incompetence of these committees to properly assess dossiers or raw data. The CRIIGEN researchers concluded that all 3 of the GMOs studied contain novel pesticide residues that will be present in food and feed and may pose grave health risks to those consuming them. They have, therefore, called for immediate prohibition on the import and cultivation of these GMOs and have strongly recommended additional long-term (up to 2 years) and multi-generational animal feeding studies on at least three species to provide true scientifically valid data on the acute and chronic toxic effects of GM crops, feed and foods. Has ACNFP made plans to consider this CRIIGEN paper as a matter of urgency, with a view to revising its opinions on MON810, MON863 and NK603 and any stacked varieties bred from them? We trust that we will receive from you positive assurances that all three of these matters will be given careful consideration without delay. We further ask for fully reasoned and scientifically based responses to the evidence presented in these cited papers -- which makes it clear that there is systematic and ongoing malpractice in the conduct of scientific experiments by Monsanto and others in pursuit of their desired GM approvals.

We look forward to hearing from you in the near future.

Yours sincerely,  
Dr Brian John  
GM-Free Cymru

#### NOTES

(1) "Final Report on Research Projects A/05/12, "Use of transgenic maize (MON810) in dairy cows: breakdown, transfer and potential interactions of DNA and Bt protein in cattle", TU Munich, Bayerische State Institute of Agriculture (LFL) and Wissenschaftszentrum Weihenstephan für Food, land use and environment, by Heinrich H.D. Meyer, Hubert Spieker, Frieder Black, Patrick Guertler, Vijay Paul, Kerstin Steinke, Wolfgang Preißinger, Christiane Albrecht, Steffi Wiedemann, 2009.

(2) Risk Reloaded Risk analysis of genetically engineered plants within the European Union -- A report by Testbiotech e.V. Institute for Independent Impact Assessment in Biotechnology

[www.testbiotech.org](http://www.testbiotech.org)

October 2009 by Christoph Then and Christof Potthof.

Then, C. (2009) "Bayerische Fütterungsstudie der TU München zu Gen- Mais weist Mängel auf", Greenpeace Germany e.V., April 2009

Bavarian GM Maize feeding study by the Technical University of Munich has shortcomings

(3) GERMAN MON810 FEEDING TRIAL RESULTS ARE WORTHLESS Did the researchers manipulate the trial so as to obtain their desired "no harm" result?

[http://www.gmfrecymru.org/news/Press\\_Notice10Dec2009.htm](http://www.gmfrecymru.org/news/Press_Notice10Dec2009.htm)

(4) Monsanto pulls GM corn LY038 amid serious food safety concerns Applicant's dossiers contained wide-ranging fraudulent research

[http://www.gmfrecymru.org/news/Press\\_Notice9Nov2009.htm](http://www.gmfrecymru.org/news/Press_Notice9Nov2009.htm)

<http://www.stuff.co.nz/national/3020246/Europe-balks-at-GE-corn-in-NZ> Jack Heinemann: "Hope not Hype", see Chapter 4 <https://sites.google.com/site/therightbiotechnology/>

(5) Vendômois JS, Roullier F, Cellier D, Séralini GE. A Comparison of the Effects of Three GM Corn Varieties on Mammalian Health. *Int J Biol Sci* 2009; 5:706-726.

<http://www.biolsci.org/v05p0706.htm>

[http://www.gmfrecymru.org/news/Press\\_Notice14Dec2009.htm](http://www.gmfrecymru.org/news/Press_Notice14Dec2009.htm)

Three Major GMOs Approved for Food and Feed Found Unsafe

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12 Jan 2010

Dear Dr John,

Thank you for your email of 19 December concerning the safety assessment of GM maize.

The assessment of GM food and feed applications under EC regulation 1829/2003 is the responsibility of the European Food Safety Authority and the ACNFP does not routinely duplicate EFSA's assessments. Neither the ACNFP (for food) nor the Advisory Committee on Animal Feedingstuffs (for feed) have been asked to advise the Agency on the published EFSA opinion, which is based on a complete review of the available evidence.

There is no obligation for Member States to comment to EFSA on dossiers that are submitted under regulation 1829/2003. As in other areas of regulation and pre-market assessment in the food area, evaluations are the responsibility of EFSA, and most Member States choose not to duplicate EFSA's assessments at national level. The Food Standards Agency has not asked the ACNFP for advice on the application dossiers for LY038 maize and LY038 x MON810 maize.

The ACNFP next meets on 10 February and I can confirm that the recent paper that you mentioned, concerning 3 varieties of genetically modified maize, will be included on the agenda.

Yours sincerely,

Sandy Lawrie  
Secretary to ACNFP