

ADVISORY COMMITTEE ON NOVEL FOODS AND PROCESSES**EFFECT OF GM SOYA ON NEWBORN RATS****Issue**

Members are asked to note recent correspondence received in relation to the Committee's statement on this study, and to consider whether they wish to respond to any of the issues raised.

Background

1. At the previous meeting in November 2005, the Committee considered the results of a preliminary study into the effects of raw GM soya flour on the offspring of rats (ACNFP/74/8). The Committee agreed to draw up a formal statement indicating that there were several possible explanations for the reported results and that no conclusions could be drawn without further information. The statement (**Annex 1**) was issued on 5 December via the Committee's website (www.acnfp.gov.uk).
2. No further information has been received from Dr Ermakova, other than confirmation that the identify of the GM and non-GM soya samples was confirmed by PCR analysis. However, the Secretariat has recently received correspondence from two organisations in relation to this statement. The first, from the Soil Association, asked for all studies used in the GM approval process to undergo peer review prior to evaluation by the relevant advisory committees. This correspondence and the Secretariat's reply are attached at **Annex 2**.
3. Dr Brian John (GM Free Cymru) has also contacted the Committee concerning the paper published by Brake and Evenson (2004)¹, which is mentioned in the final paragraph of the statement. Dr John's emails are attached at **Annex 3**.

Committee Action Sought

4. The Committee is asked to consider the attached correspondence and to consider whether it wishes to amend its current statement or respond to any of the issues that have been raised.

Secretariat
January 2006

Annexes attached

Annex 1: ACNFP Statement: "Effect of GM soya on newborn rats" (5 December 2005).
[http://www.acnfp.gov.uk/acnfppapers/gmissues/acnfpgmsoya](http://www.acnfp.gov.uk/acnfpapers/gmissues/acnfpgmsoya)

Annex 2: Email from the Soil Association and the ACNFP Secretariat's response

Annex 3: Emails from Dr Brian John (GM Free Cymru)

¹ attached as Annex 3 to the previous paper ACNFP/74/8

ADVISORY COMMITTEE ON NOVEL FOODS AND PROCESSES

ACNFP Statement: "Effect of GM soya on newborn rats" (5 December 2005).

This document has been published on the ACNFP website at:

<http://www.acnfp.gov.uk/acnfppapers/gmissues/acnfpgmsoya>

**Secretariat
January 2006**

ADVISORY COMMITTEE ON NOVEL FOODS AND PROCESSES

Email from the Soil Association and the ACNFP Secretariat's response.

**Secretariat
January 2006**

Document 2a: Email from the Soil Association to ACNFP

Date: 17 January 2005

Title: Russian GM rats study - ACNF statement

Dear ACNFP.

We have seen your statement on the Russian rat study which notes that the current report has not been "through the normal peer review process preceding scientific publication". As this point has been one of the key criticisms of the current approval process for new GMOs, as such quality control is particularly important when the data is from the company that developed the GMO, we now ask and expect that the UK and EU approval process will ensure that all studies used in the GM approval process will now undergo such 'normal peer review' prior to the ACNFP's/EFSA's consideration of the findings and conclusions for decision-making. (The statements by the biotechnology companies that the ACNFP's/EFSA's consideration of the data constitutes a 'peer review' is clearly unacceptable as the functions are totally different - quality control versus decision-making; the two stages must both be carried out and kept separate).

We look forward to your response,

Yours sincerely
Gundula Azeez

Policy manager
Soil Association

Document 2b: Email from ACNFP to the Soil Association

Date: 23 January 2005

Title: Re: Russian GM rats study - ACNF statement

Dear Gundula,

Thank you for your email commenting on the ACNFP's recent statement. The Committee's comment about peer review was to emphasise that this study is unpublished in the scientific literature and has not, to our knowledge, previously been subjected to independent assessment. Hence, anyone wishing to draw conclusions about the safety of GM soya from this work needs to satisfy themselves that they have considered all the likely explanations for the reported results.

As the ACNFP has indicated, the study has an unusual design and its expert advice is that additional information about the experiment is needed before any conclusions can be drawn. As the statement indicates, the ACNFP will consider this study again if we receive further information from the researchers, or if a full report is published.

The ACNFP's comment therefore has no implications for the GM approvals process. The Food Standards Agency will continue to ensure that the information that is being assessed about GM foods and their safety is made publicly available, with the smallest number of exceptions for material that is commercially confidential.

Best wishes,
Sandy Lawrie
Secretary to ACNFP

ADVISORY COMMITTEE ON NOVEL FOODS AND PROCESSES

Emails from Dr Brian John (GM Free Cymru).

**Secretariat
January 2006**

Document 3a: Email from Dr Brian John (GM Free Cymru) to Professor Mike Gasson (ACNFP Chairman)

Date: 21 January 2005

Title: Urgent: The relevance of the Ermakova feeding study for GM food safety

Dear Prof Gasson,

We have seen the statement published by ACNFP on 5th December, following the meeting of your Committee on 24th November (1). Quite frankly, we are appalled by the complacency of this statement, and by the patronising and dismissive attitude which you display towards the work of an honest scientist seeking to contribute a GM research item which is quite clearly in the public interest. Dr Ermakova is of course perfectly aware of the shortcomings of her study, and it is by no means perfect, but to suggest that it is somehow inferior to the Brake / Evenson study is disingenuous and even dishonest.

You will be aware that your statement is already being cited by FSA, the Welsh Assembly and even by Monsanto in support of the view that GM foods are perfectly harmless.

You say this:

"...Dr Ermakova's findings are not consistent with those described in a peer-reviewed paper published in 2004. In a well controlled study no adverse effects were found....."

<http://food.gov.uk/multimedia/pdfs/acnfpgmsoya.pdf>

The following points are relevant, and have been made by a number of scientists who have looked at both studies:

1. Brake and Evenson had a completely different - and highly specific - focus in their GM soya study (testicular development in young male rats) and aspects of their study were very poorly described. The authors may know a lot about sperm and testes analytical techniques, and male fertility issues, but it does not follow that they are experts in nutritional studies.
2. Ermakova used rats while Brake and Evenson used mice.
3. Ermakova was focussing on female reproduction and the growth of offspring of both sexes. We are trying to find out what happened to the female offspring in the B and E study -- we know that they were culled early, and we suspect that they may have been treated as irrelevant.
4. The two research groups used RR soybeans from two totally different sources. Ermakova gave its source in contrast to B and E who did not (apart from saying that it was by a seed dealer and taken from the middle of fields in South Dakota). Ermakova used whole (undefatted) soybeans as a paste and gave it to the rats in addition to the normal rat chow while B and E used extruded and dried meals and formulated diets with these, incorporating about 21% of the transgenic soya into the diet but without specifying how much conventional soya was put into the control diet. Neither of the two groups specify the amount of diet consumed by their respective animals. Basically, both studies lack essential nutritional details, and this is particularly true of the B and E study.
5. You say that the B and E study was "well controlled". Where is the evidence for this? On the contrary, because of the poor nutritional design of the study (or lack of a study design), the authors' conclusions probably cannot be justified. We have no idea what happened to their male mice once they were born; there is no feeding protocol, no data, no weights, no feed intake, and no data on growth patterns related to feed intake.

6. In a comparison of the biological properties of animals any differences in feed intake can have immeasurably greater effect than whether the animals are fed GM- or non-GM feed. Without strict pair-feeding of a group of animals of very similar starting weights one has virtually no chance of finding significant differences. So when B and E say that the testicular development of their male mice was not influenced by feeding them on GM soybean or non-GM soybean they have wasted a lot of money, work and effort to come to a conclusion that would not stand up to proper scientific scrutiny.

7. As indicated above, Brake and Evenson are not experts in animal nutrition, and their published output shows that they are specialists in fertility issues and reproduction. It is therefore foolish to assume that their 2004 study is somehow "superior" to that of Ermakova simply because it was peer-reviewed prior to publication. The peer review process is not in itself a guarantee of either scientific rigour or meaningful results.

8. As far as the Brake and Evenson affiliations are concerned, South Dakota Agricultural Experiment Station does a large amount of field testing of Roundup Ready soya for Monsanto and compares yield etc with conventional soya. So there are clearly very close relations with at least one GM multinational. We do not know where their research grant money comes from, since the trail is very difficult to follow. But caution about "sponsor pressure" would certainly be in order.

9. Ermakova was so surprised by her own results re offspring mortality rates that she repeated the experiment three times, with similar results. This is not the action of a slapdash or biased scientist. She also asked histologists to perform analyses of some of the organs of "Non-GM" rats and "GM rats". They investigated testes and liver and found great changes in the cells of these organs similar to those found by the Italian scientist M.Malatesta.

What we are saying is this: there are even more problems and uncertainties associated with the Brake / Evenson study than there are with the Ermakove study. Will you please therefore take the following actions?

(a) withdraw or substantially revise your statement, with a recognition that the B and E study is NOT "well controlled".

(b) issue an unequivocal statement to the effect that the B and E study cannot be used to support the thesis that GM soya is safe for inclusion in either animal feed or human foods.

(c) advise FSA to commission immediate and urgent research into the health effects of GM soya in view of the major concerns that are now emerging in the literature (2).

We remind you that the integrity of ACNFP is at stake here; how many warnings about GM soya do you need to receive before you pay any attention to them? (3) In the view of many observers, your committee is already criminally negligent in failing to promote or commission new research into GM food health and safety. Please do not tell us that such research is the responsibility of EFSA. As you know full well as a member of the GMO Panel, that body will do nothing. It has long since lost the trust of consumer and environmental organizations, and is widely seen as corrupt.

May we also remind you that your personal integrity is at stake here. Some years after your involvement in the Pusztai fiasco, you are once again associated with an attempt to belittle a crucially important piece of work. Black pots and kettles come to mind. As you will know, we have accused the Royal Society of fraudulently citing the review paper which you wrote with Derek Burke during its campaign to destroy the academic reputation of Arpad Pusztai in 2001; it was implied that your paper contained "new research" when it patently did not (4). We are not aware that you did anything to correct this piece of scientific fraud, which was widely repeated and reported in the media -- which means that you yourself are implicated.

It is therefore crucial that ACNFP is now seen as honest and impartial in the matter of GM food safety, and indeed that it should always err on the side of precaution where there is doubt. We look forward to receiving your assurance that you will take the actions requested.

Please bring this letter to the attention of your Committee meeting on 25th January as a matter of urgency.

Yours sincerely,

Dr Brian John
GM Free Cymru

NOTES

1. See below for the full statement.
2. It is an ongoing disgrace that neither FSA nor EFSA has ever attempted to repeat or improve the 1999 Pusztai / Ewen research, and both bodies have consistently refused to commission any studies into GM food health and safety. However, independent studies on the health effects of GM food have recently been commissioned by the Government of Western Australia:
http://www.non-gm-farmers.com/news_details.asp?ID=2574
3. See for example:
<http://www.gmwatch.org/archive2.asp?arcid=5989>
<http://pubs.acs.org/cgi-bin/abstract.cgi/jafcau/2005/53/i23/abs/jf050594v.html>
<http://news.independent.co.uk/environment/article337253.ece>
<http://www.gmwatch.org/archive2.asp?arcid=6104>
<http://www.inmotionmagazine.com/ra02/geff14.html>
<http://www.gmwatch.org/archive2.asp?arcid=6104>
<http://www.seedsofdeception.com/Public/Newsletter/NovDec05DangerousImmuneResponses/index.cfm>
<http://www.seedsofdeception.com/Public/Newsletter/Oct05RatsDieWhenMothersEatGMSoy/index.cfm>
4. The Gasson and Burke paper, 'Scientific perspectives on regulating the safety of genetically modified foods', (Nature Reviews - Genetics 2 217-222, 2001), has been widely quoted as showing that the research findings of Dr Arpad Pusztai were superceded by subsequent research into GM food safety. It shows nothing of the sort. This is the fraudulent Royal Society citation: "the only way to clarify Dr Pusztai's claims would be to refine his experimental design and carry out further studies to test clearly defined hypotheses focused on the specific effects reported by him. Such studies, on the results of feeding GM sweet peppers and GM tomatoes to rats, and GM soya to mice and rats, have now been completed and no adverse effects have been found (Gasson & Burke, 2001)". Dr Pusztai has repeatedly pointed out that neither the Gasson-Burke paper, nor the papers they cite, may be used to support the contention of "no adverse effects". Neither has his research design been refined and/or repeated.

Document 3b: Email from Dr Brian John (GM Free Cymru) to Professor Mike Gasson (ACNFP Chairman)

Date: 23 January 2005

Title: Urgent: Further information on the Ermakova and B&E feeding studies

Dear Prof Gasson and colleagues,

Urgent: Further information on the Ermakova and B&E feeding studies

Further to our letter of a couple of days ago, we have now received another assessment of the work done by Brake and Evenson. We hope that this assessment might help you in your deliberations. These are the papers:

J Agric Food Chem. 2004 Apr 7;52(7):2097-102

Evaluation of Bt (*Bacillus thuringiensis*) corn on mouse testicular development by dual parameter flow cytometry.

Brake DG, Thaler R, Evenson DP.

Food Chem Toxicol. 2004 Jan;42(1):29-36

A generational study of glyphosate-tolerant soybeans on mouse fetal, postnatal, pubertal and adult testicular development.

Brake DG, Evenson DP.

Comments

"My thinking is that it is ridiculous to claim that negative results (on tissue/organ damage) with mice, somehow make positive results with rats invalid. Years of studies such as the cancer feeding studies have always taken positive studies seriously even though there are many instances where chemicals cause cancer in either rats or mice but not in both. I find it shocking that qualified scientists might make claims that obfuscate positive findings that endanger people.

Turning to the two mouse studies, both follow testicular cell kinetics using flow cytometry but they do not look into instances of chromosome damage or rearrangement. Agents that cause, say, dominant lethality, were not even considered. Even if the diet did not visibly affect testicular development it is my understanding that many genotoxic agents may not disrupt cell kinetics. Hydroxyurea, used as a positive control in the studies as a chemical that disrupts cell kinetics, is a chemical used in cancer chemotherapy. However, micro nuclei were studied in neither report even though they are more sensitive indicators of gene damage. It is safe to say that the gross cell kinetic studies reported are useful but full studies of genotoxicity are needed.

Extrapolation of the two mouse studies to humans and concluding "Bt is not harmful to human reproduction" is a stretch, and cannot be taken seriously from a scientific point of view. The statement should have been removed in the review process -- it is clearly there simply for public relations purposes."

May we also respectfully remind you of the profound ethical and behavioural responsibilities placed upon you and your fellow committee members, as outlined in the following extracts? Sadly, we do not see much communication of uncertainty in the ACNFP proceedings; nor do we see much evidence of respect for the Precautionary Principle. We ask you to consider the following, if you are not already familiar with it:

From Special Report

"Crop Spraying and the Health of Residents and Bystanders"

(Royal Commission on Environmental Pollution)
<http://www.rcep.org.uk/pesticides/Crop%20Spraying%20web.pdf>
and part 5 at:
<http://www.rcep.org.uk/pesticides/Chapter5.pdf>

5.37 We recommend that the advice to Ministers from technical and scientific advisory committees should take account of all the criteria employed regarding risk and precaution, the choices available, and the likely impacts on those affected by the decisions being recommended. This information needs to be reflected explicitly when communicating risk management decisions to the public. The meaning of such terms as 'adequate protection' should be clearly defined and communicated. Areas of scientific uncertainty, ignorance and indeterminacy need to be recognised and their nature described explicitly. It should be clear how uncertainty has been managed within the assessment, for example, through the use of probabilistic analysis (see 3.53), uncertainty factors, etc. The effect of uncertainty on the estimate of risk should be clear.

5.43 We recommend that advice passed to Ministers from expert committees and statements to the public should properly reflect the full range of opinion within such committees.

5.47 We recommend that in consultations and in dialogue with the public concerning pesticides, as in other areas of uncertainty, science should not be positioned without argument as being beyond doubt. It should be presented in a manner that is open about the level of risk and uncertainty involved.....

Again, we ask that this letter is brought before your Committee on 25th January. We hope that the material contained within it will be of assistance to you in your deliberations.

Yours sincerely

Dr Brian John
GM Free Cymru

Document 3c: Email from ACNFP to Dr Brian John (GM Free Cymru)

Date: 23 January 2005

Title: ACNFP correspondence: Ermakova feeding study

Dear Dr John

Thank you for your emails dated 21 and 23 January regarding the Ermakova feeding study. These will be brought to the attention of Committee when it meets on Wednesday 25 January.

Your emails imply that you have evaluated information from this study that has not been reviewed by the ACNFP, as you refer to three repeat experiments and to results of histological analysis.

As mentioned in the December statement, the ACNFP will consider any further information that can be obtained about this work. The information we have received to date is set out in the Annex to the agenda paper from the November meeting. Dr Ermakova's report indicates two experiments (totalling 6 pregnant rats given GM soya, 3 given non-GM soya, and 6 controls) and contains no results of pathological investigations.

I would be grateful if you could indicate the source of this additional information and/or provide copies.

Yours sincerely

Colin Ross
ACNFP Secretariat

Document 3d: Email from Dr Brian John (GM Free Cymru) to ACNFP

Date: 23 January 2005

Title: Re: ACNFP correspondence: Ermakova feeding study

Dear Dr Ross

The information from Dr Ermakova which we cite is contained in correspondence between her and various colleagues, and from discussions held in Frankfurt in December. I am trying to find out what extra information she can provide. Perhaps you should contact her yourself for details, since you already have your lines of communication open?

In any case, the reliability (or otherwise) of what she says should have no bearing on the rather dodgy interpretation which you and your colleagues appear to have placed on the Brake / Evenson papers.

Best wishes

Brian John