

ADVISORY COMMITTEE ON NOVEL FOODS AND PROCESSES

EFFECTS OF THREE GMOs ON THE HEALTH OF MAMMALS

**Issue**

Members are invited to note a recently published article comparing the data from three feeding trials of three different GM maize varieties.

**Background**

1. Recently, the raw data from three 90-day GM feeding studies carried out by, or on behalf of, Monsanto have been made publically available. These studies formed part of the safety Dossiers submitted to EFSA for the authorisation of the respective GMOs. The three GMOs in question are NK603 (glyphosate herbicide tolerance), MON810 (Cry1Ab expression leading to insect resistance) and MON863 (Cry3Bb1 expression leading to insect resistance). These types of GM maize are all authorised in the EU for food and feed use. MON810 maize is also approved for cultivation in the EU and has been grown commercially in a number of Member States (not including the UK).
2. These data have been reanalysed by researchers at CRIIGEN (Comité de Recherche et d'Information Indépendantes sur le génie Génétique), a French NGO that promotes alternatives to GM technology and pesticides. The resulting paper (Spiroux de Vendomois et al.; **Annex 1**) provides a critique of the 3 feeding studies carried out for Monsanto, including the experimental design, data collection and statistical analysis (sections 2.1 - 2.4) and reanalyses the available data using a number of non-parametric statistical tests.

**Study design**

3. Groups of 20 rats (10 male, 10 female) were fed each diet (11% and 33% GM maize; control, near isogenic or parental maize lines and 6 other non-GM (reference) maize lines. Approximately 80 different biochemical parameters in serum and urine were measured at 5 and 14 weeks of feeding and whole body and organ weight parameters measured at the end of the experiment (14 weeks). These studies were carried out according to the relevant OECD protocol (OECD 408).

## Results and conclusions

4. The current publication is an extension of a previous study by the same group at CRIIGEN on MON863 (Seralini et al., 2007), which was previously brought to the attention of the ACNFP by the Secretariat (ACNFP/83/9). The 2009 publication initially compiles all the significant differences observed for all 3 GM maize varieties and compares them with the results obtained by Monsanto (paper annex table E, p723). They then discuss the results and analysis of the datasets where relative differences are over 5% (table 1, p710; table 2, p712).
5. The authors claim that the majority of the statistically significant differences observed that are associated with the liver and kidney for the 3 GM maize varieties are sex specific, with males being more susceptible with NK603 (18 of 23 significant effects), but females with MON810 (11 of 15 significant effects). The results are less clear cut with MON863, with 16 of the total of 34 significant effects in males and 18 in females. However, for parameters associated with kidney function 9 of 16 males show statistically significant differences compared with 4 of 18 females. This trend is reversed for parameters associated with liver function where 5 of 16 males show statistically significant differences compared with 9 of 18 females. It was not clear how the authors had determined that these sex specific differences were significant and not due to random variation.
6. The authors conclude that the results of their analysis suggest that all 3 GM varieties, “induce a state of hepatorenal toxicity”, which they attribute to, “new pesticides (herbicide or insecticide) present specifically in each type of GM maize”; while not ruling out the possibility of, “unintended effects due to the mutagenic properties of the GM transformation process”.
7. The paper has been the subject of comments from several sources:
8. The Scientific Committee of the French High Council on Biotechnology has issued an opinion relating to this paper (**Annex 2**) which concludes;

“the study by Spiroux de Vendômois *et al.*, 2009, like a preceding study (Séralini *et al.*, 2007), presents no admissible scientific element likely to ascribe any haematological, hepatic or renal toxicity to the three re-analysed GMOs.”
9. Food Standards Australia New Zealand (FSANZ) has also responded to the paper (**Annex 3**), concluding that;

“Reliance solely on statistics to determine treatment related effects in such studies is not indicative of a robust toxicological analysis. There is no corroborating evidence that would lead independently to the conclusion that there were effects of toxicological significance. FSANZ remains confident that the changes reported in these studies are neither sex- nor dose-related and are primarily due to chance alone.”.
10. FSA ‘in house’ experts are also of the opinion that, while the statistical tests used could, taken in isolation, be appropriate for the analysis of such datasets, they

did not agree with the conclusion that the data “strongly suggests that these GM maize varieties induce a state of hepatorenal toxicity” (**Annex 4**).

11. The Commission has referred the paper to the EFSA GMO Panel and the opinion of the Panel will be communicated to the Committee in due course.
12. Monsanto has also published a response to the paper on its website.

### **Correspondence from GM-Free Cymru**

13. The CRIIGEN paper was one of several points raised recently in correspondence from Dr Brian John, of GM-Free Cymru, regarding the role of the ACNFP (**Annex 5**), in which Dr John specifically requested that this study be brought to the Committee’s attention. Dr John also criticises the Committee for its evaluation of certain GM food and feed dossiers submitted for EU authorisation. The Secretariat has responded to Dr John, pointing out that there is no obligation for Member States to comment to EFSA on dossiers that are submitted under the GM food and feed regulation 1829/2003 and the Food Standards Agency does not duplicate EFSA’s assessments at national level.

**Secretariat**  
**February 2010**

### **Annexes attached:**

**Annex 1:** Spiroux de Vendomois et al. (2009) Int. J. Biol. Sci., 5, pp706-726  
<http://www.biolsci.org/v05p0706.htm>

**Annex 2:** Unofficial translation of the Opinion of the Scientific Committee of the French High Council on Biotechnology

**Annex 3:** Response from FSANZ  
<http://www.foodstandards.gov.au/educationalmaterial/factsheets/factsheets2009/fsanzresponseto0904647.cfm>

**Annex 4:** Comments from FSA internal experts

**Annex 5:** Correspondence with Dr Brian John, GM-Free Cymru  
(19 December 2009 and 12 January 2010)



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Opinion of the French High Council of the Scientific Committee of  
Biotechnology

*(This is an unofficial English translation prepared for the Food Standards Agency. The original French text is published at <http://www.ogm.gouv.fr>.)*

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Response from FSANZ

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