

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH PORTFOLIO

Additional Estimates 2013 - 2014, 26 February 2014

Ref No: SQ14-000101

OUTCOME: 1 – Population Health

Topic: Analysis of GM studies

Type of Question: Written Question on Notice

Senator: Siewert Rachel

Question:

In March of 2013 Heinemann, Agapito-Tenfen and Carman published a peer-reviewed evaluation of risk assessment procedures of genetically modified organisms used by regulators covering three different countries. In May 2013, FSANZ published a reply to this study on its own website

<http://www.foodstandards.govt.nz/consumer/gmfood/Documents/Heinemann%20Response%20210513.pdf>. In June of 2013, Carman et al. published a peer-reviewed study on the effects of genetically modified feed when fed to pigs. In July of 2013, FSANZ published a reply to this study on its own website

<http://www.foodstandards.govt.nz/consumer/gmfood/Pages/Response-to-Dr-Carman%27s-study.aspx>.

- a) Who made the decision to respond to these studies by publishing a critical analysis of the studies on the FSANZ website?
- b) Were the decisions to respond based on a particular policy of FSANZ? (if so please identify/provide the policy)
- c) If there is no underlying policy, what were the reasons given at the time for undertaking these responses and who provided those reasons?
- d) Was FSANZ contacted by any third parties requesting that FSANZ respond to these studies?
- e) Who authored the responses?
- f) What expertise do these persons have?
- g) Who reviewed and commented on drafts of each response?

- h) What expertise did these reviewers have?
- i) Why has FSANZ to date refused to publish the names of the authors of its analyses and their credentials? How is it possible for the public of Australia to evaluate the competing claims if it is denied access to information about the authors of the FSANZ response?
- j) Were the responses subject to the same stringent peer-review process of the published studies? Specifically,
 - (i) was the choice of referees made by someone other than FSANZ, and
 - (ii) was the response to the peer-review vetted by someone other than FSANZ and to whom FSANZ had to comply, as would be the case in a relationship between the authors of the studies and the editor of the journals in which they were published?
- k) Were the authors of the studies contacted to comment on the FSANZ response?
- l) Has FSANZ ever published an online critical analysis of a peer-reviewed study that shows no impacts or potential harm associated with a GM food? (please give details)

Answer:

- a) The decision was taken the by the relevant Food Standards Australia and New Zealand (FSANZ) Executive Manager, Chief Scientist and Chief Executive Officer, in consultation with the team responsible for Genetically Modified (GM) food safety assessment at FSANZ.
- b) Yes. In relation to GM foods, FSANZ has a clearly articulated policy to review publications that call into question the safety of approved foods, or that question the adequacy of current safety assessment approaches. A statement of this policy, along with previous responses issued under this policy, can be found at the following link: [Response to studies cited as evidence of adverse effects from GM foods.](#)
- c) Not applicable.
- d) No.
- e) Both responses were authorised by FSANZ staff involved in GM food evaluations, in consultation with the relevant Executive Manager and Chief Scientist.
- f) FSANZ staff involved in the preparation of the two responses have extensive expertise and experience in food regulation, particularly GM food safety assessments and toxicology. The staff also have experience and expertise in plant biotechnology, plant molecular virology, cell biology, biochemistry, gene regulation and veterinary pathology.
- g) Both responses were reviewed internally by the relevant scientific discipline leader, relevant Executive Manager, and the FSANZ Chief Scientist. The Heinemann response was also reviewed externally by the Office of the Gene Technology Regulator (OGTR). FSANZ sought comments from OGTR because decisions of that agency were also referred to in the paper by Heinemann et al.

- h) FSANZ staff responsible for reviewing both responses have expertise in toxicology, clinical pharmacology, molecular genetics and the safety assessment of GM food as well as extensive experience in the regulation of drugs, chemicals and food including at the international level.
- i) The documents and reports developed by FSANZ are the collaborative efforts of government employees with relevant qualifications and work experience. FSANZ provides a description of the in-house scientific expertise of FSANZ staff on the FSANZ website. FSANZ also has well-established internal peer review mechanisms, as well as mechanisms to ensure that FSANZ staff maintain an awareness and knowledge of scientific and international developments, which are detailed in FSANZ's Science Strategy, available on the FSANZ website.
- j) FSANZ followed its standard internal peer review process before publication on the FSANZ website. Given the availability of relevant in-house expertise, more extensive peer review was considered unnecessary.
 - (i) No. As the publisher of the response, FSANZ decides who the reviewers should be.
 - (ii) No. FSANZ would not publish reports until any reviewers' comments have been appropriately addressed.
- k) No.
- l) No. FSANZ monitors the studies in the peer reviewed literature and other sources that are relevant to assessing the safety of GM foods. If studies are reported that contradict previous safety assessment conclusions, FSANZ has a formal obligation to review such studies to determine if changes to a previously conducted safety assessment are warranted.