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## **Response to publication by Carman et al 2013 reporting on a pig feeding study**

Dr Judy Carman and co-authors have published 'A long-term toxicology study on pigs fed a combined genetically modified (GM) soy and GM maize diet' in the Journal of Organic Systems (Journal of Organic Systems, 8 (1), 2013 ).

The publication describes the results of a feeding study conducted in a commercial piggery in the United States of America in which two groups of pigs were fed a mixed feed of corn and soybeans comprised of either GM or non-GM varieties.

The Office of the Gene Technology Regulator has examined this publication in consultation with Food Standards Australia New Zealand (FSANZ) and relevant regulatory agencies from other countries. All agencies have reached the conclusion that this study is of poor quality and does not provide any grounds for reconsideration of existing GM crop or GM food approvals or assessment processes.

### **Relevance to Australia**

None of the GM crop varieties used in the study have been approved by the Gene Technology Regulator for growing in Australia.

However products from these GM crop varieties are approved for food and feed use in many countries including Australia. FSANZ is responsible for setting standards for the safety, content and labelling of food, including GM food. Details of [GM food approvals](#) can be found on the FSANZ [website](#). FSANZ has also provided a [response to the Carman et al publication](#) on its website.

### **Main claims in the publication**

The study authors claim that pigs fed a GM diet had a higher rate of severe stomach inflammation and higher uterine weights compared to pigs fed the control (non-GM diet), and thus raise concerns about the use of GM food and feed.

No differences were noted for the majority of parameters measured, including feed intake, weight gain, mortality, various blood measurements, number or nature of illnesses and a range of visual indicators of pathology.

### **Response to the study and its claims**

There are many problems with the study design, execution, data analysis and reporting that severely limit its value.

The GM and non-GM diets were not sufficiently characterised or standardised, such that any diet-related findings cannot be attributed to the GM status of the feed. For most of the study period all animals of each group were kept together, meaning that there was no replication within the groups and only limited statistical analysis is possible. There was only a single GM diet so no dose-response relationship can be determined.

Animal husbandry during the study appears to have been poor, with the majority of animals suffering from pneumonia, and the mortality rate was high (13%-14%) for both groups. Not

every internal organ intended for analysis was obtained from every animal, so values are reported for different numbers for each organ and each diet group.

The information presented does not support the authors' claims of a link between GM feed and stomach inflammation. The reporting of stomach inflammation is based on gross visual appearance (reddening) alone; however this is not sufficient to confirm inflammation, which would require microscopic examination. Various factors may lead to reddening of the stomach, including stress of the animals prior to slaughter. Some unusual statistical analysis was also applied in relation to the reported stomach inflammation. A more standard statistical approach, in which all data for stomach inflammation is analysed together rather than singling out an individual, arbitrary level of inflammation, does not suggest any significant difference between the two groups for this measure. It should also be noted, compared to the non-GM diet group, that twice as many pigs in the GM diet group were recorded as having no stomach inflammation (although this is also not statistically significant for this small number of animals).

Similarly, there is no basis for attributing differences in mean uterine weight to diet. The analysis of uterine weight which suggests a difference excluded one measurement from a pig in the non-GM diet group on the basis that it was an 'extreme outlier'. The excluded value is the highest measured uterus weight of all animals in either group (by % body weight). If all values are included in the analysis there is very little difference in mean uterine weight. Even if there were a statistical difference in uterine weights between the two groups, there is no supporting evidence to suggest this is a result of the GM diet. This could simply reflect the sexual maturity or reproductive cycle of individual pigs, which are known to affect uterus weight greatly, but were not taken into account in this study.

Thus the data do not support the authors' claims, and the publication does not bring into question previous regulatory assessments or approvals.

The OGTR will continue to monitor the scientific and other literature for any new information in relation to GM crops and GM foods, and assess this information for its potential to impact on regulatory approvals.