

**Meier, David**

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**From:** Clare Chandler [Clare.Chandler@maf.govt.nz]  
**Sent:** Friday, 25 March 2011 9:39 AM  
**To:** submissions  
**Cc:** Stockwell, Dean  
**Subject:** MAF submissions on A1046 and A1049  
**Attachments:** A1046 Fd from GM soy DAS-68416-4 1st Ass Sub March 2011.doc; A1049 Fd from GM high oleic acid soybean MON87705 Sub March 2011.doc

Dear Sir/madam

Please find attached our submissions on these applications. The signed copies have been posted to the Wellington office.

regards

Clare

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25 March 2011

Project Officer Application A1049  
Food Standards Australia New Zealand  
PO Box 10559  
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WELLINGTON 6036

FS350-117-1049

Dear Sir/Madam

## **Application A1049 – Food Derived from Herbicide-tolerant, High Oleic Acid Soybean Line MON87705 – Assessment Report**

Thank you for the opportunity to comment on this application. The Ministry of Agriculture and Forestry (MAF) has the following comments to make.

### **Safety Assessment**

Genetic modification - The genetic modification to alter the fatty acid composition of the soybean employs gene regulation pathways that have not been manipulated previously (to the best of our knowledge) to produce commercialised genetically modified crops.

Section 3.2 of the Safety Assessment Report describes the genetic modification. The mechanisms and techniques of the genetic modification are complex, and the rationale for adopting the two T-DNA segment approach used for this modification is only partially explained in the Safety Assessment Report. A full explanation would require considerable understanding of the genetic processes on the part of the reader, but it is our view that greater explanation of homologous recombination, why it was employed, and RNA interference mechanisms (as natural processes), would enhance the report. This would show that these novel aspects have been appropriately addressed.

Novel protein - As stated in the FSANZ report, the only novel protein is the CP4 EPSPS enzyme. The amount of CP4 EPSPS that could be obtained directly from MON87705 soybean seed was insufficient for analysis, so the protein was expressed in *E.coli*. Analyses were undertaken to determine the equivalence of the plant and bacterial expressed protein, so that the bacterial surrogate could be used in further safety evaluations of the novel protein. However, these further studies are not included in the Safety Assessment Report. It is MAF's view that this section of the report should be expanded, to clarify why the equivalence of the bacterial and plant derived CP4 EPSPS proteins were established, and the relevance of this to the safety assessment.

## Nutrition Assessment

MAF notes that a dietary intake assessment for the changes in fatty acid intakes (particularly oleic and linoleic acids) has not been presented in the report for the Australian and New Zealand population. Rather, information is reported from the United Kingdom and the United States. This is in contrast to the report prepared for Application A1018 – Food derived from High Oleic Acid Soybean Line DP-305423-1, where an analysis of the dietary impact was presented. MAF considers that the nutritional impact for the Australian and New Zealand populations should be reported in the Approval Report for A1049 (we do note a reference to the modelling undertaken for A1018 in section 5.3.3 of the Safety Assessment Report, perhaps this statement could be incorporated into the Nutritional Impact Section as well).

We do note however, when comparing the reports for A1018 and A1049, that the proposed food uses are not the same. A1018 states that the modified oil will be used for cooking and deep frying, whereas the current application states that the intended use is in margarines, and oil for domestic use, and is not suitable for commercial cooking purposes. It is not clear why the oils would have different end uses, when the fatty acid profile is similar. Furthermore, the dietary modelling assessment for A1018 has been conducted excluding the impact of margarine as a source of oleic acid. This difference, along with comment made above concerning the use of overseas dietary intake assessments, suggests that the Nutrition Assessment could be expanded on in the Approval Report.

MAF also notes that the range of fatty acids reported for A1049 is not as comprehensive as that provided in the reports for A1018. For example, the A1049 report does not have data on C17:0 and C17:1 (levels of these fatty acids were increased slightly in soybean oil from Line DP-305423-1 - A1018). MAF is interested to know if further data is available from the applicant for this application (and could therefore be included in the Approval Report). We do note that Section 5.3.3 of the Safety Assessment Report reports that only the nine fatty acids reported in table 8 (should read table 4?), are above the limit of quantitation. MAF considers that this limit should be reported in the Approval Report.

Yours sincerely

Jenny Reid  
**Manager Food Safety**  
**Science, Information & Risk Directorate**