

17 January 2011

Project Officer Application A1041  
Food Standards Australia New Zealand  
PO Box 10559  
The Terrace  
WELLINGTON 6036

FS350-117-1041

Dear Sir/Madam

## **Application A1041 – Food Derived from SDA Soybean Line MON87769 – First Assessment Report**

Thank you for the opportunity to comment on this application. The New Zealand Food Safety Authority (NZFSA) has the following comments to make.

### General

This is the first application to be assessed by FSANZ for approval of a genetically modified (GM) food carrying a consumer focused nutritional modification. As such, NZFSA agrees that two rounds of public consultation are appropriate. Our review of the application has brought to our attention some interesting issues, which can be considered further in the 2<sup>nd</sup> Assessment report. All food derived from stearidonic acid (SDA) soybean will need to be labelled as genetically modified, and under the present rules in the Food Code, claims about the omega-3 fatty acid content cannot be made. This issue is discussed in more detail below.

### Comments on the Safety Assessment

We agree with the conclusion of the safety assessment report that no public health and safety concerns have been identified.

A minor point is that we consider the 2<sup>nd</sup> Assessment Report should provide comment on the insertion site in the soy genome, and confirmation that it is not part of a known functioning gene. This was raised in our submission on A1035, and the text given in the Approval Report for A1035 (Section 10.1.1.1) would be appropriate.

### Comments on the Nutrition Assessment

Soybean line MON87769 has been genetically modified to produce stearidonic acid (SDA), a source of omega-3 fatty acids. We note that the Nutrition Assessment (Supporting Document 2) addresses the nutritional implications of the intentional change to increase the SDA content of soybean oil derived from MON87769 and the consequential increase in the trans fatty acid (TFA) content of the oil.

NZFSA has the following comments on the Nutrition Assessment:

- Figure one in the Nutrition Assessment shows the metabolism of omega-3 fatty acids. We suggest that the pathway be updated in the 2<sup>nd</sup> Assessment Report to that shown in the paper by Lemke, et al (2010) cited in the Reference list in the Nutrition Assessment (1). We note that it is now recognised that it is a combination of elongase,  $\Delta$  6-desaturase, and  $\Delta$  5-desaturase enzymes that are involved in the human omega-3 metabolic pathway. It does not include a  $\Delta$  4-desaturase as previously hypothesised. Further information on this pathway is provided by Wall et al (2010) and Burdge (2006) (2,3).
- The Executive Summary and the body of the 1<sup>st</sup> Assessment Report states that “*Studies have shown that consumption of SDA can lead to higher levels of EPA and DHA in body tissues, compared with ALA*”. This statement is not made in the Nutrition Assessment Report and therefore, should be amended, as SDA can only improve levels of EPA in body tissues. None of the SDA supplementation studies reviewed in the Nutrition Assessment Report found a significant improvement in the red blood cell DHA concentrations (1,4,5).
- The supplementation of EPA has been shown to have minimal effects on DHA (6). This is because the conversion of EPA to DHA is dependent on the same  $\Delta$  6-desaturase enzyme that impairs conversion of ALA to SDA (7). It is therefore important that oil from SDA soybean is not considered as a source of DHA (for example, in infant formula products).
- The Nutrition Assessment indicates that dietary SDA at levels of 3.7 g/day or more result in a significant increase in EPA in blood plasma and in erythrocytes. NZFSA is of the view that the 2<sup>nd</sup> Assessment Report should contain some dietary modelling, to ascertain if this is a plausible intake from the use of SDA soybean oil. The SDA content is given as 22.62% of total fatty acids. Assuming the oil is 100% fatty acids this equates to 16.4 g oil. This is not an insignificant amount of oil to consume per day, particularly in the food groups that the oil is proposed to be added to.
- SDA soybean oil is proposed to be a sustainable alternative source of omega-3 fatty acids. The Nutrition Assessment would be enhanced if there was a section on existing knowledge concerning plant-based sources of long chain PUFAs. The following references provide some information (8,9).

### Labelling

NZFSA agrees that food derived from MON87769 would require labelling as 'genetically modified', due to the inherent nutritional changes.

We note that FSANZ is proposing that no additional labelling provisions should be stipulated in the 'special conditions' part of the table in standard 1.5.2. This means that any voluntary nutrition information provided on the label must comply with the Food Code rules on nutrition claims.

This therefore raises the question - how will consumers be informed that the oil is nutritionally modified? It is acknowledged that it is very difficult to communicate this information in a way can be understood by the consumer, without being at odds with the current Standard 1.2.8 which would not allow any claims as to the omega-3 content of the SDA soybean oil. It is also important to ensure that this information is communicated in a way that would not mislead consumers.

NZFSA requests that FSANZ give further consideration to this, in the 2<sup>nd</sup> Assessment Report. An informative mandatory statement (in the special conditions column), could be considered by FSANZ. Such a statement would inform consumers that there is a change in nutritional content. The nature of such a statement is of course dependent on the outcome of the Nutrition Assessment Report, so NZFSA is not able to suggest at this time what the statement would be, or if a statement would be supported. Clearly any such informative mandatory statement could only be applied to the soybean oil.

We note that if the special conditions column of the table did reference omega-3 fatty acids, this may not be considered a nutrition claim, if this is "prescribed information" under the definition of nutrition claim.

NZFSA agrees (as discussed in section 6 of the First Assessment Report) that a nutrition claim could not be made for the omega-3 fatty acid content, but that the food could make a polyunsaturated (PUFA) acid claim. A PUFA claim will not necessarily be made, particularly as this will trigger the declaration of the trans fatty acid content.

### Other comments

This application could benefit from a Food Technology Report, or a fuller discussion of the proposed food uses of the SDA soybean oil. Some issues that may be expanded on in the 2<sup>nd</sup> Assessment Report include:

- More discussion on the oils that the SDA soybean oil will replace, and the products that the oil will be used in. What is the effect on processing? Is the oil degraded?

- Will the SDA soybean oil be partially hydrogenated for some food applications, and what data is there on the changes in the fatty acid (including the TFA) profile?
- In the EU application to authorise Monsanto soybean line 87769 the proposed food groups that SDA soybean oil is proposed to be used in is very different from those stated in this application (i.e. margarine, shortening, mayonnaise). This could be clarified with the applicant.

Yours sincerely

signed

Jenny Reid  
Deputy Director  
Science

## References

- (1) Lemke SL, Vicini JL, Su H, Goldstein DA, Nemeth MA, Krul ES, et al. Dietary intake of stearidonic acid-enriched soybean oil increases the omega-3 index: randomized, double-blind clinical study of efficacy and safety. *American Journal of Clinical Nutrition* 2010;92:766-775.
- (2) Wall R, Ross RP, Fitzgerald GF, Stanton C. Fatty acids from fish: the anti-inflammatory potential of long-chain omega-3 fatty acids. *Nutr.Rev.* 2010;68(5):280-289.
- (3) Burdge GC. Metabolism of  $\alpha$ -linolenic acid in humans. *Prostaglandins, Leukotrienes and Essential Fatty Acids* 2006;75:161-168.
- (4) James MJ, Ursin VM, Cleland LG. Metabolism of stearidonic acid in human subjects: comparison with the metabolism of other n-3 fatty acids. *Am.J.Clin.Nutr.* 2003;77(5):1140-1145.
- (5) Harris WS, Lemke SL, Hansen SN, Goldstein DA, DiRienzo MA, Su H, et al. Stearidonic acid-enriched soybean oil increased the omega-3 index, an emerging cardiovascular risk marker. *Lipids* 2008;43(9):805-811.
- (6) Brenna JT, Salem Jr N, Sinclair AJ, Cunnane SC.  $\alpha$ -Linolenic acid supplementation and conversion to n-3 long-chain polyunsaturated fatty acids in humans. *Prostaglandins, Leukotrienes and Essential Fatty Acids* 2009;80:85-91.
- (7) D'Andrea S, Guillou H, Jan S, Catheline D, Thibault J, Bouriel M, et al. The same rat  $\Delta 6$ -desaturase not only acts on 18- but also on 24-carbon fatty acids in very-long-chain polyunsaturated fatty acid biosynthesis. *Biochem. J.* 2002;364:49-55.
- (8) Barcelo-Coblijn G, Murphy EJ, Othman R, Moghadasian MH, Kashour T, Friel JK. Flaxseed oil and fish-oil capsule consumption alters human red blood cell n-3 fatty acid composition: a multiple-dosing trial comparing 2 sources of n-3 fatty acid. *Am.J.Clin.Nutr.* 2008;88(3):801.
- (9) Patenaude A, Rodriguez-Leyva D, Edel AL, Dibrov E, Dupasquier CMC, Austria JA, et al. Bioavailability of  $\alpha$ -linolenic acid from flaxseed diets as a function of the age of the subject. *Eur.J.Clin.Nutr.* 2009;63(9):1123-1129.