

Comments from the Victorian Departments of Health and Human Services and Economic Development, Jobs, Transport and Resources

Due date of submission – 26 October 2017

The Victorian Departments of Health and Human Services and Economic Development, Jobs, Transport and Resources (the departments) welcome the opportunity to provide comments on Application A1143 – Food derived from DHA Canola Line NS-B50027-4 (the Application).

The Application seeks permission for food derived from a new genetically modified (GM) canola (*Brassica napus*) line, NS-B50027-4 (DHA canola). DHA canola has been modified to introduce, into the seed, the pathway for producing the omega-3 long chain polyunsaturated fatty acid (n-3 LC PUFA) docosahexaenoic acid (DHA) from oleic acid.

From the FSANZ assessment report it is understood that:

- The purpose of the Application is to provide a sustainable and land-based source of n-3 LC PUFAs, particularly eicosapentanoic acid and DHA, to meet increased human consumption and reduce demand from aquaculture.
- Canola seeds are processed into oil and meal. Canola oil is the primary food product used for human consumption, used directly in cooking or as an ingredient in manufactured food products. Canola meal is primarily used as animal feed, however it has been identified as a potential alternative source of protein for human consumption. Whole canola seeds are not commercially available in retail settings but may be added to commercially-produced bread products.
- It is the Applicant's intention to commercially cultivate DHA canola in Australia and an application for commercial release has been submitted to the Office of the Gene Technology Regulator. The Applicant also intends to pursue commercial plantings in other canola-growing countries such as Canada and the United States.
- *Agrobacterium*-mediated transformation was used to insert DNA encoding expression cassettes for genes in the DHA pathway, along with a gene encoding resistance to the herbicide glufosinate, into the canola plant at two insertion sites.
- The two insertion sites contained no DNA from the plasmid backbone and were found to be genetically stable in the plant genome over generations.
- The eight introduced proteins were assessed for potential toxicity and allergenicity. Bioinformatic analysis did not find any biologically relevant identities with known toxins or allergens. In addition, the introduced proteins were found to be as potentially susceptible to digestion as the vast majority of dietary proteins, and would be inactivated at high temperatures.
- Theoretical open reading frames generated by the insertion event were also assessed for the potential to encode toxic or allergenic proteins using bioinformatics analysis, and were found not to share biologically relevant homology with known toxins or allergens.
- DHA canola seeds are significantly higher in total trans fatty acids when compared to conventional canola. Despite this, the increased levels are considered comparable to other retail vegetable oils such as soybean, sunflower and rice oils.
- Any food derived from DHA canola which contains novel DNA or novel protein will be required to be labelled as 'genetically modified', such as whole seeds and canola meal from DHA canola. While DHA canola oil is unlikely to contain novel DNA or novel protein, the product will have a different nutritional profile when

compared to conventional canola, therefore FSANZ proposes products containing DHA canola oil as an ingredient would also require the mandatory 'genetically modified' statement.

- Application A1124- Alternative DHA-rich Algal Oil for Infant Formula Products reviewed studies of this DHA derived from *Schizochytrium* sp. in relation to infant health. As there are no studies available on the use of DHA canola oil and infant health, FSANZ proposes to **not** permit the use of oil derived from DHA canola in infant formula products.

The departments support the progression of this application at this stage but wish to note certain matters:

- The voluntary addition of DHA to food may be considered beneficial to support public health due to the presence of data which indicates low levels of DHA intake. An analysis of the 2011-2012 National Nutrition and Physical Activity Survey demonstrated that approximately 80 per cent of Australians are not meeting the omega-3 long chain polyunsaturated fatty acids recommended intakes for optimal health¹.
- FSANZ has indicated fortification through genetic modification is increasing and yet there has been a lack of analysis of the consequences of this means of fortification and how it should be considered relative to traditional forms of fortification. Victoria raised this matter with the Food Regulation Standing Committee (FRSC) at its meeting on 22 September 2017 and suggested that the relevant Policy Guidelines (Fortification of Food with Vitamins and Minerals, and Addition of Substances other than Vitamins and Minerals) should be reviewed to consider new food fortification technologies. It is understood from that meeting that the FSANZ FRSC member supported the need to review the Policy Guidelines.

¹ Meyer BJ. Australians are not Meeting the Recommended Intakes for Omega-3 Long Chain Polyunsaturated Fatty Acids: Results of an Analysis from the 2011–2012 National Nutrition and Physical Activity Survey. *Nutrients*. 2016; 8(3):111.