

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

Submission due: 7 August 2018

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 A1156 – Food derived from Super High Oleic Safflower Lines 26 and 40 (the Application).

The Application seeks permission for food derived from two new genetically modified safflower (*Carthamus tinctorius*) lines, GOR-73226-6 or GOR-73240-2, also referred to as SHO26 and SHO40 respectively. SHO26 and SHO40 have been modified to produce very high levels of oleic acid and lower levels of linoleic acid.

From the FSANZ assessment report it is understood that:

- The purpose of the Application is to produce Super High Oleic (SHO) Safflower oil for multiple non-food and food applications, with the predominant use expected to be for non-food applications.
- The genetic modification involves the insertion of an RNA interference cassette that specifically downregulates the expression of two genes that encode proteins involved in fatty acid synthesis. Additionally, a gene encoding resistance to hygromycin has also been inserted.
- The two different lines contain the same two inserted cassettes, but are the result of two separate Agrobacterium-mediated transformation events, meaning the genomic location of the insertion is different in each line.
- Molecular characterisation confirmed the following:
 - In each line, the intact complete cassettes were inserted in single copy;
 - The genetic modification is stably inherited across different generations and in different genetic backgrounds;
 - Downregulation of the target genes was successfully achieved using the RNA interference approach;
 - Bioinformatic analysis of open reading frames generated by the genetic insertion did not yield any significant matches with known allergenic or toxic proteins.
- Any foods derived from SHO safflower which contain novel DNA or novel protein will be required to be labelled as 'genetically modified', such as whole seeds and meal from SHO safflower.
- While SHO safflower oil is unlikely to contain novel DNA or novel protein, the product will have a different nutritional profile when compared to conventional safflower, therefore products containing SHO safflower oil would also require the mandatory 'genetically modified' statement.
- FSANZ has suggested that additional labelling specifying the changes in oleic and linoleic acid content in conjunction with the 'genetic modified' statement is not required, as this information will not be informative for most consumers.

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

- The Safety Assessment Report concludes that no plasmid backbone has been incorporated into the transgenic locus of either line. However, the genome walking and sequencing results indicate that 191 base pairs of the replication of origin (RiA4) from the binary vector (pORE-CBIb) has been incorporated into the SHO26 line. While this is not likely to present a safety concern, and no part of the neomycin-kanamycin resistance gene from the vector has been transferred, this inconsistency will need to be corrected.
- Dietary intake assessment conducted by FSANZ concluded that introduction of SHO safflower would have minimal effect on oleic acid consumption and as such, would not pose a nutritional concern. However, the departments would like to highlight that nutritional concerns could include risks associated with both excess consumption, as well as insufficient nutritional intake.
 - In relation to SHO26 and SHO40, the reduced linoleic acid content should be considered in the dietary intake assessment as linoleic acid is an essential fatty acid which must be consumed through dietary sources, and therefore SHO safflower may pose a risk for insufficient linoleic acid consumption.
 - The departments understand that presently the use of safflower oil in food applications is likely to be low. However, to support a comprehensive risk assessment that considers potential future change in consumption patterns or the food system, the departments suggest that FSANZ also considers the potential impact of SHO safflower on linoleic acid consumption in the dietary assessment.