

## A. Executive Summary

GO Resources Pty Ltd (GOR) is submitting this 'Application to FSANZ for the inclusion of safflower with high oleic acid composition in standard 1.5.2 Food Produced Using Gene Technology'.

Safflower seed produces oil that predominantly contain monounsaturated fatty acid (C18:1; oleic acid) and polyunsaturated fatty acid (C18:2; linoleic acid). While both have commercial uses, it is the valuable oleic acid that is used as a replacement to petroleum-based precursors in the manufacture of plastics, lubricants and cosmetics, etc. Traditional breeding programs have developed safflower seed with oleic acid levels in the range of 75–85%, and are the highest purity sources of oleic acid in any oilseed. However, like other oilseeds, the remaining linoleic acid component, at 12-18%, is not desirable for industrial use because it is unstable and difficult to remove during oil processing. Therefore, it is desirable to develop a safflower seed that accumulates high oleic acid (C18:1), but contains very low linoleic acid (C18:2) content.

Two genetically modified (GM) safflower events (OECD Unique IDs: GOR-73226-6 and GOR-73240-2, herein referred to as Event 26 and Event 40 respectively) were developed and molecularly characterised by the Commonwealth Scientific Industrial Research Organisation (CSIRO). The events contain a construct designed to down regulate two safflower fatty acid biosynthesis genes (*CtFATB* and *CtFAD2.2*). Down regulation is achieved using RNAi technology and is targeted to the seed using a promotor from flax (*Linum usitatissimum*). Down regulation of the two safflower genes leads to accumulation of approximately 92% of oleic acid (C18:1) and very low (less than 2%) linoleic acid (C18:2) in the seed, herein referred to as Super High Oleic Acid Safflower Oil (SHOSO). The events also contain a hygromycin resistance gene that was used as a selectable marker during the transformation process. When used as a selectable marker, the hygromycin resistance gene produces a protein that protects plants from Hygromycin B, an aminoglycoside antibiotic.

GO Resources has been working with the CSIRO to characterise the events and collect relevant biosafety information to inform this and other regulatory approval applications. Characterisation has included limited and controlled release field evaluation of GM safflower lines (SHO Safflower) across safflower growing regions of Australia under licences issued by the Office of the Gene Technology Regulator (DIR121 and DIR131). In July 2017, GO Resources submitted an application to the Office of the Gene Technology Regulator for 'dealings involving intentional release (DIR) of genetically modified (GM) plants into the environment - commercial release Commercial Release licence'. The application has been designated the application number DIR158.

SHOSO derived from the safflower containing either Event 26 or alternatively Event 40 is mainly intended for the industrial oil market. However, there may be future sales into the food market therefore GO Resources is also applying to Food Standards Australia and New Zealand (FSANZ) for an amendment to the Food Standards Code (Standard 1.5.2-Food Produced Using Gene Technology). Once all regulatory approvals have been obtained, safflower varieties containing either Event 26 or Event 40 will be marketed for commercial industrial oil production.

GO Resources is committed to the responsible stewardship and management of SHOSO technology. SHOSO technology will be commercialised within a specialised, 'closed-loop' identity preserved (CLIP) quality assured management program. The CLIP program was developed by GO Resources to manage and provide traceability to the production and supply of SHO safflower planting seed to contracted GO Resources SHO safflower grain growers. The CLIP program also provides oversight and traceability of the harvested grain from the grain grower onto grain handlers, seed crushers and processors undertaking SHOSO extraction. Following crushing and processing, the oleic oil will be sold to domestic

and export market processors, with the meal being directed to use as a stock feed. (Note: The only product to be exported will be processed oleic oil. That is, no SHO safflower grain will enter the export or domestic grain markets).

Collectively, results of the molecular characterisation, agronomic assessment, and composition analysis support this application for amendment to the *Australia New Zealand Food Standards Code* to allow inclusion of GM safflower events GOR-73226-6 and GOR-73240-2 in **Standard 1.5.2-Food Produced Using Gene Technology**.