Application to Food Standards Australia New Zealand
for the Inclusion of
DHA canola, NS-B5ØØ27-4 (OECD ID)
in Standard 1.5.2 - Food Derived from Gene Technology

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Executive Summary

Nuseed Pty Ltd is a specialised global seed company, committed to Grow Beyond Yield™ by enhancing food and feed performance throughout the value chain. A wholly owned subsidiary of Nufarm Limited (ASX: NUF), Nuseed solves critical nutrition needs with seed-based solutions. Through world-class research, expert teams, collaborative partnerships and a focus on innovation, Nuseed develops top performing hybrids with environmental benefits that drive value through the agrifood chain, solving problems and creating new market opportunities for growers, processors and end-users.

Long-chain omega-3 (LC-ω3) fatty acids, such as docosahexaenoic acid (DHA) and eicosapentaenoic acid (EPA), have established health benefits. EPA and DHA are primarily sourced from oils extracted from wild-caught fish, which consume algae containing these healthy oils. Wild fish stocks are under pressure due to increasing

demand for LC-ω3 fatty acids for aquacultural, nutraceutical and pharmaceutical applications.

There is a need for alternative, direct sources of LC-ω3 fatty acids for increased human consumption and demand from aquaculture. In collaboration with the Commonwealth Scientific and Industrial Research Organization (CSIRO), Nuseed has developed a genetically modified *Brassica napus* (canola) line, DHA canola (elite event B0050-027; OECD ID NS-B5ØØ27-4) that accumulates relevant amount of DHA in seed oil. DHA canola was produced through *Agrobacterium tumefaciens*-mediated transformation of the conventional canola cultivar AV Jade.

The introduced genetic material produces seven enzymes that convert oleic acid in canola to the final product, DHA. These enzymes can be grouped into three classes: two fatty acid desaturases from yeast, two elongases from microalgae, and three front-end desaturases from microalgae. A herbicide-tolerant selectable marker from a bacterium was used in the initial transformation/selection process, but was not used in the breeding process.

The seven introduced fatty acid biosynthesis enzymes that drive the production of DHA using seed-specific promoters were only detected in developing seed and mature seed at low levels (20-740 ng/mg total protein), while none of the DHA biosynthesis enzymes were detected in the non-seed tissues of DHA canola. No significant homologies to known and putative allergens or toxins were found with the newly expressed proteins. The rapid digestion of the full-length proteins indicates that it is highly unlikely that these proteins will pose any safety concern to human health. The protein safety evaluations of these enzymes in the DHA pathway conclude that there is a reasonable certainty of no harm resulting from DHA canola, including the introduced genes and proteins, in human foods, animal feed or environmentally.

The DHA canola would be grown and processed in the same way that commercial canola is currently grown and processed. The canola meal fraction would be utilised in the same way that commercial canola meal is currently utilised, primarily as animal feed. The oil fraction would be utilised in markets that use LC-ω3 oils, including animal/aquaculture feed, food additives, nutraceuticals and pharmaceuticals.

DHA canola has been released into the environment in Australia under Licence DIR123 from the Office of the Gene Technology Regulator (OGTR) for field trials from 2014, and in Canada from 2016. There have been no reports of harm to human health and safety or the environment resulting from field trials in Australia or overseas. The research data, including molecular, protein, agronomy and composition data, has been compiled and

presented in this application, which confirms that the only change in DHA canola was by design to the oil profile.

The DHA canola was identified to have two T-DNA inserts. The phenotypic and molecular stability of the inserts has been tested over five generations and found to be stable. No new open reading frames were created at the insert junctions and there were no significant sequence homologies with any known toxins or allergens.

No unintended changes were observed in the composition or agronomics of DHA canola when compared with its parental variety and other commercial canola varieties.

The purpose of this submission is to make an application to amend the *Australia New Zealand Food Standards Code* Standard 1.5.2 - *Food Produced Using Gene Technology* to allow for the inclusion of Food derived from DHA canola, NS-B5ØØ27-4 in Schedule 26 – *Food Produced using gene technology*. Information is included in this application that cover Part 3.1.1 and 3.5.1 of the application handbook. A submission is being made concurrently to the OGTR for a commercial release licence. Similar applications will be made to relevant agencies overseas as appropriate.