EXECUTIVE SUMMARY

EPA+DHA canola event LBFLFK (OECD Unique ID BPS-BFLFK-2) was produced using *Agrobacterium rhizogenes*-mediated transformation of the conventional canola variety Kumily. LBFLFK canola expresses fatty acid desaturase and elongase proteins and a herbicide resistant acetohydroxy acid synthase protein. Enzyme-encoding genetic sequences and associated expression cassettes were introduced from a number of eukaryotic organisms (*Phytophthora sojae*, *Ostreococcus tauri*, *Thalassiosira pseudonana*, *Physcomitrella patens*, *Thraustochytrium* sp., *Phytophthora infestans*, *Pythium irregulare*, *Pavlova lutheri*, and *Arabidopsis thaliana*) to alter the production of specific fatty acids in canola, resulting in the production of omega-3 long-chain polyunsaturated fatty acids (LC-PUFAs) and tolerance to treatment with the herbicide active ingredient imazamox.

Canola normally produces primarily C18:1n-9 (oleic) and C18:2n-6 (linolenic) fatty acids in seeds through the combined efforts of *de novo* fatty acid synthesis, elongation, and desaturation enzymes. The introduction of seven desaturases and three elongases to develop EPA+DHA canola event LBFLFK causes production of LC-PUFAs including DHA (docosahexaenoic acid, C22:6n-3) and its biosynthetic intermediate EPA (eicosapentaenoic acid, C20:5n-3) from these endogenous fatty acids through an aerobic pathway. LBFLFK canola provides a plant-based and scalable production system for omega-3 fatty acids and will be another source of EPA and DHA for consumers as either a food ingredient or as an aquaculture feed ingredient. The herbicide tolerance trait is conferred through the introduction of a modified acetohydroxy acid synthase (AHAS) protein from the *Arabidopsis thaliana* plant.

To maintain the quality and ensure the segregation of LBFLFK canola seeds, grains, and processed products, an Identity Preservation System (IDP) will be implemented at every step of production and handling. Processing operations will be conducted either at dedicated facilities or at facilities with specific measures in place to ensure segregation from other products. Canola can be manufactured into a variety of products for human and animal consumption or for industrial purposes. As a specialty canola with a fatty acid profile containing the LC-PUFAs EPA and DHA, the oil produced from LBFLFK canola will be sold specifically as a source of dietary omega-3 LC-PUFAs. Refined oil derived from EPA+DHA canola may be used as a dietary supplement to provide an alternate source of omega-3 LC-PUFAs, pending any additional regulatory reviews required for this use. Additionally, the oil will be used as an input to aquafeed operations to provide omega-3 LC-PUFAs to farmed aquatic species. Defatted canola meal produced from LBFLFK canola will be available for use in the same applications as conventional canola meal. The primary application for canola meal is as a feed ingredient for livestock. The defatted meal produced from LBFLFK canola will not be sold as a source of omega-3 LC-PUFAs, as the oil content of the meal will be too low to make a significant contribution to the nutrition of the livestock.

All requisite domestic and international regulatory approvals, including labelling requirements based on nutritional content, will be obtained prior to use of specific products of EPA+DHA canola for food or feed purposes.

BASF Australia Ltd[1] prepared this application to amend the Australia New Zealand Food Standards Code Standard 1.5.2 (Food Produced Using Gene Technology) to allow for the

[1] - here and after referred to as 'BASF'.

inclusion of food derived from genetically modified LBFLFK canola in the Australian and New Zealand food industries. More specifically, BASF requests to allow the use of genetically modified *Brassica napus* (canola) oil derived from the transformation event LBFLFK in the Australian and New Zealand food industries. Information included in the application covers Part 3.1.1 and Part 3.5.1 of the application handbook.

The data package has been provided to FSANZ for LBFLFK canola; however, food products derived from the processed oil are not anticipated to contain novel proteins. A large body of food safety data is available on EPA and DHA LC-PUFAs themselves and health and nutrition claims related to their consumption have been formally assessed, and Standards are in place (*Food Standards Australia New Zealand Act 1991 (Cth)*, Schedule 4, Nutrition and Health Related Claims). Data requirements as per the July 2019 Application Handbook are addressed here below.

Table 1. Gazetted FSANZ Standards for Crop Lines Genetically Modified to Produce Long-Chain Fatty Acids

Crop	Events/Lines Evaluated	FSANZ Application Number
Canola	DHA canola line NS-B50027-4	A1143
Soybean	High oleic acid soybeans lines G94-1,G94-19 and G168; High oleic acid soybean line DP-305423-1; Stearidonic acid containing soybean line MON87769; Herbicide-tolerant, high oleic acid soybean line MON87705	A387; A1018; A1041; A1049
Safflower	Super High Oleic Safflower Lines 26 and 40	A1156

The canola variety used for the introduction of the EPA+DHA canola trait was Kumily, a spring cultivar of *Brassica napus* L. Therefore, this parental variety is used as the conventional counterpart in studies conducted to generate the data provided in this application.

The data and information presented in this submission demonstrate that derived products from LBFLFK are comparable to conventional canola, with the exception of the introduced proteins and the trait-associated changes in the composition of fatty acids. The safety of LBFLFK canola was confirmed based on multiple, well-established lines of evidence including:

- A molecular characterisation of the introduced DNA in LBFLFK canola demonstrated two intact, stable copies of the intended T-DNA insert at two loci within the canola genome.
- An assessment of the newly expressed proteins in LBFLFK canola demonstrated that there are no associated safety concerns.
- A compositional assessment of harvested grain and processed fractions confirmed compositional equivalence with the conventional counterpart, except for the introduced EPA+DHA traits.
- A review of the changes of the fatty acid profile of LBFLFK canola compared to conventional canola and other fatty acids sources, including a nutritional safety and exposure assessment demonstrated the safety of the oil produced.