

**PUBLIC INFORMATION SHEET FOR  
DIRECT USE AS FOOD AND FEED, OR FOR PROCESSING**

**PROPOSAL FOR DIRECT USE AS FOOD  
AND FEED, OR FOR PROCESSING  
EPA+DHA Canola Event LBFLFK**

1. **Applicant's Name**  
BASF Philippines, Inc.  
on behalf of BASF Agricultural Solutions Seed US LLC
2. **Applicant's Address**  
Units 3 & 4, Upper Penthouse, CTP ASEAN Tower  
Block 3 Lot 2, Spectrum District, Fillinvest Corporate City  
Alabang, Muntinlupa City - 1781, Metro Manila
3. **Telephone Number/ Facsimile Number, E-Mail Address of the Applicant**  
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Email Address: danahjean.campano@basf.com
4. **Name of Responsible Officer/Authorized Representative**  
Ronnie Belarmino/Responsible Office  
Danah Jean Campano/Authorized representative
5. **Description of the Regulated Article for Direct Use**  
LBFLFK canola contains genes that impact the content of omega-3 long-chain polyunsaturated fatty acids in the seeds and also contain a gene conferring tolerance to imidazolinone herbicides. The fatty acid trait is conferred by the introduction of a metabolic pathway consisting of ten genes such as: PsD12D, OtD6D, TpD6E, PpD6E, TcD5D, PirO3D, PiO3D, OtD5E, TcD4D, and PID4D. These genes encode the following proteins to produce the long-chain omega-3 fatty acids eicosapentaenoic acid (EPA) and docosahexanoic acid (DHA): delta-12 desaturase (D12D(*Ps*)), delta-6 desaturase (D6D(*Or*)), delta-6 elongase (D6E(*Tp*)), delta-6 elongase (D6E(*Pp*)), delta-5 desaturase (D5D(*Tc*)), omega-3 desaturase (O3D(*Pir*)), omega-3 desaturase (O3D(*Pi*)), delta-5 elongase (D5E(*Or*)), delta-4 desaturase (D4D(*Tc*)), and delta-4 desaturase (D4D(*Pi*)). The herbicide tolerance is conferred by the introduction of an acetohydroxyacid synthase gene (*AtAHAS*) with two amino acid substitutions (S653N, A122T).
6. **If to be Imported, Country(ies) of Origin of the Regulated Article**  
USA
7. **Brief Summary of Potential Effects on Human and Animal Health and the Environment**  
Event LBFLFK was produced using biotechnology to introduce newly expressed proteins. More specifically, recombinant DNA (T-DNA) containing genes encoding fatty acid desaturase and elongase proteins and a herbicide-resistant acetohydroxy acid synthase protein was introduced into the conventional canola variety Kumily using *Agrobacterium rhizogenes*.  
A thorough safety assessment was conducted. No adverse effects were observed for newly expressed proteins. The safety of LBFLFK canola was confirmed based on multiple, well-established lines of evidence including:
  - A molecular characterization of the introduced DNA in LBFLFK canola to demonstrate two intact, stable copies of the intended T-DNA insert at two loci within the canola genome.
  - An assessment of the introduced proteins in LBFLFK canola to demonstrate that there are no associated safety concerns.
  - A compositional assessment of harvested grain and processed fractions to confirm compositional equivalence except for the intended introduced EPA+DHA trait.
  - A review of the changes of the fatty acid profile of LBFLFK canola compared to conventional canola and other dietary fatty acids sources, including a nutritional safety and exposure assessment to demonstrate the safety of the oil produced.Overall, no adverse effects on the health of humans or animals are expected from the consumption of LBFLFK canola products under normal conditions of use.

**8. Brief Summary of Potential Benefits**

Canola LBFLFK is intended for cultivation as a specialty canola variety within North America, with processing into oil and meal fractions either in the United States or Canada. As a specialty canola with a fatty acid profile containing the long-chain polyunsaturated fatty acids (LC-PUFAs) EPA and DHA, the oil produced from LBFLFK canola will be sold specifically as a source of dietary omega-3 LC-PUFAs. The oil will be incorporated as an Ingredient into consumer food items per United States GRAS (Generally Recognized as Safe)- affirmed categories and inclusion levels for oil containing EPA and DHA. Refined oil derived from EPA+DHA canola may also be used as a dietary supplement to provide an alternate source of omega-3 LC-PUFAs. As a feed product, the oil will be used as an aquafeed input ingredient to provide omega-3 LC-PUFAs to farmed aquatic species. Currently, omega-3 LC-PUFAs in aquaculture diet formulations are typically sourced from marine sources, such as fish oil, but supplies of these sources are limited.

EPA+DHA canola event LBFLFK also has tolerance to treatment with the herbicide active ingredient - Imazamox, which provides an additional option to weed control for canola farmers.

**9. Countries Where Approvals Have Been Granted (for FFP)**

To date, LBFLFK Canola has been extensively assessed of its safety and granted approvals for food and feed uses in countries namely: Australia, Canada, Mexico, New Zealand and USA.


**10. Brief Summary on Socio-economic, Cultural and Ethical considerations**

This application of BASF Philippines Inc. is intended to secure a biosafety permit for the direct use as food and feed, or for processing of LBFLFK canola in the Philippines. In addition to its uses as a food ingredient, Canola oil can already be used in aquafeed operations to supplement the limited supply of oil available from marine sources, which is primarily fish oil. However, replacing fish oil with canola or other vegetable oils has reduced the levels of long-chain omega-3 fatty acids available in farmed fish. It has been recommended to substitute fish oil with alternative sources of EPA and DHA to support the aquaculture operations that are the primary consumer of fish oil. It is noted that although LBFLFK Canola is not to be cultivated or propagated in the Philippines, the use of its oil will provide sustainable and stable access to a new source of omega-3 fatty acids, so as to better meet demands for LC-PUFAs in aquafeed operations and better ensure consumer access to these fatty acids in all markets.


The public is hereby invited to submit their comments to the BPI Director (within 15 days from date of publication) on the Proposal for the direct use as food and feed, or for processing of LBFLFK canola.

Director  
Bureau of Plant Industry  
San Andres, Malate, Manila  
E-mail [bpibiotech@buplant.da.gov.ph](mailto:bpibiotech@buplant.da.gov.ph)

Approved for Publication:

  
**GERALD GLENN F. PANGANIBAN, Ph.D.**  
Director  
Bureau of Plant Industry  
Date: July 06, 2023

SUBSCRIBED AND SWORN TO BEFORE ME  
THIS 06 JUL 2023 AT ROSALES, PANGASINAN

  
**ATTY. ROBERTO E. CADAYAN**  
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UNTIL JUNE 30, 2024  
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JAN. 03, 2023  
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**PAMPUBLIKONG IMPORMASYON PARA SA DIREKTANG PAGGAMIT  
BILANG PAGKAIN, PAKAIN SA HAYOP, O PARA SA PAGPOPROSESO**

**PANUKALA PARA SA DIREKTANG PAGGAMIT  
BILANG PAGKAIN, PAKAIN SA HAYOP O PARA SA PAGPOPROSESO  
EPA+DHA Canola Event LBFLFK**

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**4. Pangalan ng Kaukulang Opisyal/Awtorisadong Kinatawan**

Ronnie Belarmino/Kaukulang Opisyal  
Danah Jean Campano/Awtorisadong Kinatawan

**5. Deskripsyon ng Artikulo para sa Direktang Paggamit**

Ang LBFLK canola ay nilagyan ng mga gene na makakaapekto sa taglay na omega-3 long-chain polyunsaturated fatty acids sa buto ng canola at mayroon din itong gene na nagdudulot ng tolerance sa herbisidyong imidazolinone. Ang pagbabago sa katangian ng fatty acid ay resulta ng introduksyon ng isang metabolic pathway na nagtataglay ng sampung genes katulad ng PsD12D, OtD6D, TpD6E, PpD6E, TcD5D, PirO3D, PiO3D, OtD5E, TcD4D, at PiD4D. Ang sampung genes na ito ay gumagawa ng iba't-ibang protina upang makabuo ng long-chain omega-3 fatty acids eicosapentaenoic acid (EPA) at docosahexanoic acid (DHA). Ang mga protinang ito ay ang mga sumusunod: delta-12 desaturase (D12D(*Ps*)), delta-6 desaturase (D6D(*Ot*)), delta-6 elongase (D6E(*Tp*)), delta-6 elongase (D6E(*Pp*)), delta-5 desaturase (D5D(*Tc*)), omega-3 desaturase (O3D(*Pir*)), omega-3 desaturase (O3D(*Pi*)), delta-5 elongase (D5E(*Ot*)), delta-4 desaturase (D4D(*Tc*)), and delta-4 desaturase (D4D(*Pi*)). Ang tolerance sa herbisidyo ay resulta ng introduksyon ng acetohydroxyacid synthase gene (*AtAHAS*) na mayroong dalawang amino acid substitutions (S653N, A122T).

**6. Kung ma-Import, Bansa /mga bansang Pinagmulan ng Regulated Article**

USA

**7. Maikling Buod ng Potensyal na Epekto sa Kalusugan ng Tao at Hayop at sa Kalikasan**

Ang event na LBFLFK ay ginawa sa pamamaraan ng bioteknolohiya upang ang canola ay magtaglay ng mga bagong protina. Partikular dito ang paggawa ng recombinant DNA (T-DNA) na naglalaman ng genes na nag-eencode ng mga sumusunod na protina: fatty acid desaturase, elongase, at acetohydroxy acid synthase; ang mga ito ay inilagay sa Kumily barayti ng canola gamit ang *Agrobacterium rhizogenes*.

Nagsagawa ng masusing pagsusuri sa kaligtasan ng canola LBFLFK. Walang masamang epekto ang naobserbahan para sa mga bagong taglay na protina. Ang kaligtasan ng LBFLFK canola ay napatunayan base sa marami at well-established na mga ebidensya kabilang ang:

- Pagsasagawa ng molecular characterization para sa inilagay na DNA sa LBFLFK canola upang ipakita ang dalawang buo at matatag na mga kopya ng T-DNA insert sa dalawang loci sa loob ng canola genome.

- Pagsusuri sa mga inilagay na bagong protina sa LBFLFK canola upang ipakita na walang mga kaugnay na masamang epekto sa kaligtasan.
- Pagsasagawa ng compositional assessment sa inaning butil at pagproseso ng ilang bahagi ng butil upang kumpirmahin ang pagkakapareho sa conventional na canola, maliban sa introduksyon ng katangian ng EPA + DHA.
- Pagsusuri sa mga pagbabago ng fatty acid profile ng LBFLFK canola, kumpara sa conventional canola at iba pang mga pinagkukunan ng dietary fatty acids, kabilang sa pagsusuri ang nutritional safety at exposure assessment upang ipakita ang kaligtasan ng langis na mula sa LBFLFK canola.

Sa kabuuan, walang masamang epekto sa kalusugan ng tao o hayop ang inaasahan mula sa pagkonsumo ng LBFLFK canola products sa ilalim ng normal na kondisyon ng paggamit.

#### **8. Maikling Buod ng Potensyal na Benepisyo**

Ang LBFLFK canola ay ginawa upang itanim bilang isang specialty canola sa North America, na lipo-proseso para sa langis at meal fractions, alinman sa Estados Unidos o Canada. Bilang isang specialty canola na may isang profile ng fatty acid na naglalaman ng long chain polyunsaturated fatty acids (LC PUFAs) EPA at DHA, ang langis na nakuha mula sa LBFLFK canola ay ibebenta bilang isang mapagkukunan ng pandiyeta na omega 3 LC PUFAs. Ang langis ay isasama bilang sangkap sa mga consumer food items, ayon sa United States GRAS (Generally Recognized as Safe) affirmed categories at inclusion levels para sa langis na naglalaman ng EPA at DHA. Ang refined na langis na nagmula sa EPA + DHA canola ay maaari ring magamit bilang dietary supplement upang magbigay ng isang kahaliling mapagkukunan ng omega 3 LC PUFAs. Bilang isang feed product, ang langis ay gagamitin bilang isang aquafeed input, sahog upang magbigay ng omega 3 LC PUFAs sa farmed aquatic species. Sa kasalukuyan, ang omega-3 LC-PUFAs sa aquaculture na ginagamit sa diet formulation ay karaniwang mula sa marine sources, katulad ng fish oil, ngunit limitado ang mga pinagkukunan nito.

EPA + DHA Canola event LBFLK ay mayroon ding tolerance sa mga herbisidyo na may active ingredient na imazamox, na nagbibigay ng karagdagang pagpipilian ng mga magsasaka para sa weed control.

#### **9. Mga Bansa kung Saan Nabigyan ng pag-apruba (para sa FFP)**

Sa kasalukuyan, ang LBFLFK Canola ay sumailalim sa masusing pagsusuri upang masigurado ang kaligtasan nito. Ito ay nabigyan ng approval para sa paggamit bilang pagkain at pakain sa hayop sa mga bansang sumusunod: Australia, Canada, Mexico, New Zealand at USA.


#### **10. Maikling Buod sa sosyo-ekonomiya, Kultura at Etikal na konsiderasyon**

Ang application ng BASF Philippines Inc. ay nagnanais na mabigyan ng biosafety permit para sa direktang paggamit bilang pagkain, pakain sa hayop, o para sa pagpoproseso ng LBFLFK Canola sa Pilipinas. Karagdagan sa paggamit nito bilang isang sangkap ng pagkain, ang langis ng Canola ay maaari nang magamit sa mga aquafeed operations upang madagdagan ang limitadong supply ng langis mula sa mga pinagkukunan sa dagat, pangunahin dito ang fish oil. Subalit, kung ang paggamit ng fish oil ay mapapalitan ng canola oil o iba pang mga langis na galing sa gulay, ito ay magdudulot ng kabawasan sa taglay na long-chain omega 3 fatty acids na nakukuha sa farmed fish. Inirerekomenda na magkaroon ng alternatibo o substitute sa fish oil na mapagkukunan ng EPA at DHA upang suportahan ang aquaculture operation na pangunahing gumagamit ng fish oil. Bagama't hindi itatanim o pararamihin ang LBFLFK canola sa Pilipinas, ang paggamit ng langis nito ay magbibigay ng sapat at matatag na mapagkukunan ng omega 3 fatty acids, upang mas matugunan ang mga demand para sa mga LC-PUFA sa aquafeed operations at mas matiyak ang access ng consumer sa mga fatty acid na ito sa lahat ng merkado.

Ang publiko ay inimbitahang isumite ang kanilang mga komento sa BPI Director (sa loob ng 15 araw mula sa petsa ng paglalathala) sa Panukala para sa direktang paggamit bilang pagkain, pakain sa hayop, o para sa pagpoproseso ng LBFLFK canola.

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