

FACT SHEET

APPLICATION FOR APPROVAL FOR RELEASE OF PRODUCTS OF MON 87769 SOYBEAN FOR SUPPLY OR OFFER TO SUPPLY FOR SALE OR PLACING IN THE MARKET

NBB REF NO: JBK(S) 600-2/1/9

The objective of the Biosafety Act 2007 is to protect human, plant and animal health, the environment and biological diversity. Under the Biosafety Act 2007, the National Biosafety Board (NBB) is currently assessing an application for approval submitted by Monsanto Malaysia Sdn. Bhd.

1. What is the application for?

This application is to import and release MON 87769 soybean and its products.

2. What is the purpose of the import and release?

The purpose of the import and release is to supply or offer for sale/ placing on the market-for direct use as food, feed and for processing (FFP) of MON 87769 soybean. This means that MON 87769 soybean may enter Malaysia as grain, food ingredients for processing or packaging or as finished products ready for distribution, or as feed meal for animals. The MON 87769 soybean is not intended for cultivation in Malaysia.

3. How has MON 87769 soybean been modified?

MON 87769 soybean has been genetically modified to produce stearidonic acid (SDA), an omega-3 fatty acid to help meet the need for increased dietary intake of long chain omega-3 fatty acids. The development of MON 87769 involved the introduction of genes *Primula juliae* $\Delta 6$ desaturase (*Pj.D6D*) and *Neurospora crassa* $\Delta 15$ desaturase (*Nc.Fad3*) that encode for Pj $\Delta 6D$ and Nc $\Delta 15D$ proteins, respectively. The Pj $\Delta 6D$ and Nc $\Delta 15D$ proteins catalyze the synthesis of SDA. The Pj $\Delta 6D$ protein desaturates α -linolenic acid (ALA) to produce SDA, and converts linoleic acid (LA) to γ -linolenic acid (GLA); The Nc $\Delta 15D$ protein desaturates GLA to produce SDA and also converts LA to ALA, increasing the flux of ALA to SDA and lowers the substrate pool for GLA production. As a result, MON 87769 has increased levels of SDA and GLA.

4. Characteristics of MON 87769 soybean

a. Details of the parent organism

The recipient or parental plant is *Glycine max*, also known as soybean. Soybean is grown as a commercial crop in over 35 countries. Soybean is a largely self-pollinated species, although low levels of natural cross-pollination can occur. In studies with cultivated soybean where

conditions have been optimized to ensure close proximity and flowering synchrony, natural cross-pollination generally has been found to be very low.

b. Donor organism

Primula juliae, a member of the genus of plant commonly known as Primrose, is the source of the *Pj.D6D* gene. Primrose plants are frequently grown in cooler climates and are well-known in folk medicinal practices in many countries. It can also be used as a food source. The *Neurospora crassa*, a type of fungus commonly known as bread mold is the source of the *Nc.Fad3* gene. It is ubiquitous in the environment and considered a non-pathogenic organism.

c. Description of the trait(s) and characteristics which have been introduced or modified

MON 87769 contains the *Pj.D6D* gene derived from *Primula juliae* and *Nc.Fad3* gene derived from *Neurospora crassa* that encodes for the Pj Δ 6D and Nc Δ 15D proteins, respectively which catalyze the synthesis of stearidonic acid (SDA), resulting in increasing of SDA level. MON 87769 can serve as an alternate source of an omega-3 fatty acid to help meet the need for increased dietary intake of long chain omega-3 fatty acids in food and feed.

d. Safety of the Expressed Proteins

Information and data from studies demonstrate that the Pj Δ 6D and Nc Δ 15D proteins are unlikely to be an allergen or toxin. This is based on the assessment of the donor organisms, *Primula juliae* and *Neurospora crassa*, which are not known human or animal pathogens and hasd lack of reports of allergies derived from these organisms. Pj Δ 6D and Nc Δ 15D proteins have demonstrated history of safe use. The Pj Δ 6D and Nc Δ 15D proteins are similar with desaturases found in many common food sources and have been consumed for many years with no history of adverse health effects establishing a history of safe exposure for these proteins. Examination of the Pj Δ 6D and Nc Δ 15D amino acid sequences against a bioinformatics database showed a lack of significant structural similarity between the Pj Δ 6D and Nc Δ 15D proteins and known allergens or pharmacologically active proteins. In addition, studies using Pj Δ 6D and Nc Δ 15D proteins have demonstrated that the protein was digested rapidly in simulated gastric fluids, and ingestion of the proteins did not cause acute toxicity in mice. These data support the safety for Pj Δ 6D and Nc Δ 15D proteins.

e. Utilization of soybean

A major food use of soybean is as purified oil, utilized in margarines, shortenings and cooking and salad oils. It is also used in various food products including tofu, simulated milk, soybean sprouts, soymilk film (yuba), soynuts, green vegetable soybean (e.g. edamame), whereas the fermented soyfoods include soybean paste (miso), soybean sauce, natto (Japanese cuisine) and tempeh.

Other than that, soybean meal is used as a supplement in feed rations for livestock. Industrial use of soybean ranges from the production of yeasts and antibodies to the manufacture of soaps and disinfectants. A sizeable amount is also used in pet food.

MON 87769 soybean may enter Malaysia as grain, food ingredients for processing or packaging or as finished products ready for distribution, or as feed meal for animals.

5. Assessment of Risks to Human Health

a. Nutritional Data

Data obtained from compositional analyses conducted on the forage and seed of MON 87769 concluded that MON 87769 is compositionally and nutritionally equivalent to those of the conventional soybean, except for the intended fatty acid changes.

b. Toxicological Information

There are no known health hazards associated with the product. Studies have shown no toxicity toward mammals. Additionally, there are no amino acid sequences similarities to known toxins.

c. Pathogenicity

Primula juliae and *Neurospora crassa* have no known pathogenicity and allergenicity to humans, animals and non-target organisms.

6. Assessment of Risks to the Environment

The application does not cover an environmental release. The application is intended only to cover the import of MON 87769 soybean products from countries where soybean is already approved and commercially grown, and that may enter Malaysia as foodstuffs or as feed or grain for further processing.

7. What is the Emergency Response Plan?

MON 87769 soybean and food and feed products derived from it have been assessed as being as safe as its conventional non-genetically modified counterparts and there are no reports of adverse effects since its commercialization. Should adverse effects be reported and verified, appropriate follow up action would be taken to investigate these, and if verified, appropriate actions taken.

a. First Aid Measures

No special first aid measures are required in response for exposure to this product.

b. Accidental Release Measure

No special measures are required in response to an accidental release. Spilled seed should be swept, scooped or vacuumed in a manner that avoids dust generation and dust-related hazards.

c. Handling and Storage

No special handling procedures are required for this product. MON 87769 soybean may be handled and stored as any conventional soybean seed product.

d. Disposal Consideration

MON 87769 is equivalent to conventional soybean with the exception of intended fatty acid changes. Waste from MON 87769 can be treated similar to conventional soybean waste.

8. How can I comment on this application?

Any member of the public may submit their comments or queries on publicly notified information about the application. Before submission of comments or queries, the person should review the information provided. Your comments and queries on any possible impacts/risks to the health and safety of the people and the environment that may be posed by the proposed release are appreciated. The submission to the comments or queries should be prepared carefully as it will be given the same scrutiny as the application by the NBB. The submission of comments and clarifications of queries should contribute to the NBB's assessment. Even if the submission is not science-based, and focuses on cultural or other values, it should still be developed in the form of a well-founded argument.

Please note that the consultation period closes on 9 April 2020 and written submissions are required by that date. Submissions must be addressed to:

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Please include your full name, address and contact details in your submission.