

FACT SHEET

APPLICATION FOR APPROVAL FOR RELEASE OF PRODUCTS OF MON 87705 SOYBEAN FOR SUPPLY OR OFFER TO SUPPLY FOR SALE OR PLACING IN THE MARKET

NBB REF NO: JBK(S) 600-2/1/7

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 87705 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 87705 soybean. This means that MON 87705 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 87705 soybean is not intended for cultivation in Malaysia.

3. How has MON 87705 soybean been modified?

Monsanto Company has developed biotechnology-derived MON 87705 soybean with an improved fatty acid profile that result in enhanced nutritional characteristics and glyphosate tolerance trait. This improved oil is produced in the soybean through the technique of RNA interference (RNAi)-mediated gene suppression of FATB and FAD2, two key enzymes in the fatty acid biosynthetic pathway. Suppression of the FATB enzyme results in a decrease in the levels of saturated fats (16:0 palmitic acid and 18:0 stearic acid), while suppression of the FAD2 enzyme results in an increase of monounsaturated oleic acid (18:1) and associated decrease in polyunsaturated linoleic acid (18:2). MON 87705 soybean also produces a 5-enolpyruvylshikimate-3-phosphate synthase (CP4 EPSPS) from *Agrobacterium* sp. strain CP4, which confers tolerance to glyphosate, the active ingredient in Roundup® agricultural herbicides.

4. Characteristics of MON 87705 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.

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 and tempeh. Soybean also is the most commonly grown oilseed in the world.

Other than that, soybean meal is used as a supplement in feed rations for livestock. Soybean meal is the most valuable component obtained from processing the soybean, accounting for roughly 50-75% of its overall value. By far, soybean meal is the world's most important protein feed, accounting for nearly 65% of world supplies. 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.

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b. Donor organism

Agrobacterium sp. strain CP4 is the source of the *cp4 epsps* gene. The gene segments configured to suppress *FATB* and *FAD2* gene expression are endogenous to soybean and no new functional enzyme is produced.

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

MON 87705 soybean contains *FATB1-A* and *FAD2-1A* suppression gene segments to suppress endogenous *FATB* and *FAD2* genes, thereby producing the desired fatty acid phenotype of decreased saturated fatty acid, increased oleic and decreased linoleic fatty acids. MON 87705 soybean also contains the *cp4 epsps* gene derived from *Agrobacterium* sp. strain CP4, which encodes the CP4 EPSPS protein.

d. Safety of the Expressed Proteins

RNAi-based suppression of *FATB* and *FAD2* genes in MON 87705 soybean is mediated by *Double-stranded RNA* (dsRNA) molecules. These dsRNAs are found commonly in eukaryotes, including plants, for endogenous gene suppression and are composed of nucleic acids. Nucleic acids have a long history of safe consumption and are considered generally recognized as safe (GRAS) by The Food and Drug Administration of the United States Department. There is no evidence to suggest that dietary consumption of RNA is associated with toxicity or allergenicity. Additionally, RNAi technique is a naturally occurring process that is believed to occur in all plants and animals. RNAi has been harnessed by breeders to improve conventional crops and some biotechnology-derived crops that have been approved for cultivation.

Information and data from studies also support the safety of the CP4 EPSPS protein and demonstrate that this protein is unlikely to be an allergen or toxin. This is based on the

assessment of the donor organism, *Agrobacterium* sp. strain CP4, which is not a known human or animal pathogen and there are no reports of allergies derived from the organism. The CP4 EPSPS protein also represents one of many different EPSPSs found in nature; the CP4 EPSPS and native plant EPSPS enzymes are functionally equivalent except for their tolerance to glyphosate. CP4 EPSPS protein has a history of safe use as the active ingredients in many biotechnology-derived food and feed crops.. Examination of the CP4 EPSPS amino acid sequences against a bioinformatics database showed a lack of significant structural similarity between the CP4 EPSPS protein and known allergens or pharmacologically active proteins. In addition, studies using CP4 EPSPS protein have demonstrated that the protein was digested rapidly in simulated gastric fluid, and ingestion of the protein did not cause acute toxicity in mice. These data are consistent with the conclusion of safety for CP4 EPSPS protein.

5. Assessment of Risks to Human Health

No significant health hazards are currently associated with this product. MON 87705 soybean is substantially equivalent to conventional soybean, which have no specific detrimental health effects.

a. Nutritional Data

Soybean seed and forage derived from MON 87705 are compositionally and nutritionally equivalent to those of the conventional soybean, except for the intended changes in fatty acid levels. No statistically significant differences were observed in the eight anti-nutrient component comparisons between MON 87705 and the conventional control.

b. Toxicological Information

There is 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

Agrobacterium sp. strain CP4 which is ubiquitous in the environment and has lack of reports of allergies derived from the organism.

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 87705 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 87705 soybean and food and feed products derived from it have been assessed as being as safe as its conventional 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 and subsequently 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. Handle as any soybean seed product. No special storage procedures are required for this product. Store as any soybean seed product.

d. Disposal Consideration

MON 87705 is equivalent to conventional soybean with the exception of intended changes in fatty acid levels and glyphosate tolerance. Waste from MON 87705 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 6 February 2020 and written submissions are required by that date. Submissions must be addressed to:

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Ministry of Water, Land and Natural Resources
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Please include your full name, address and contact details in your submission.