

FACT SHEET
APPLICATION FOR APPROVAL FOR RELEASE OF PRODUCTS OF MON 87708 SOYBEAN
FOR SUPPLY OR OFFER TO SUPPLY FOR SALE OR PLACING IN THE MARKET
NBB REF NO: JBK(S) 602-1/1/47

The objective of the Biosafety Act 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 87708 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 87708 soybean. This means that MON 87708 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 87708 soybean is not intended for cultivation in Malaysia.

3. How has MON 87708 soybean been modified?

Monsanto has developed genetically modified herbicide tolerant soybean MON 87708 that produces the DMO protein derived from *Stenotrophomonas maltophilia*. The DMO protein provides tolerance from dicamba herbicide application. The *dmo* gene was transferred into the genome of soybean cells using *Agrobacterium tumefaciens*-mediated transformation method.

4. Characteristics of MON 87708 soybean

a. Details of the parent organism

The recipient of the gene or parental plant is *Glycine max*, commonly known as soybean. The soybean has been genetically modified to be tolerant to dicamba herbicide.

Soybean is grown as a commercial crop in over 35 countries. Soybean is also the most commonly grown oilseed in the world. In 2013, approximately 284.1 MMT (millions metric tons) of harvested seed were produced, representing 56% of the world's oilseed production.

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

Stenotrophomonas maltophilia is the source of the *dmo* gene. It is a gram-negative bacterium commonly found in aquatic environments, soil and plants.

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

The DMO protein provides tolerance from dicamba herbicide application, allowing the use of dicamba herbicide on the crop, in addition to glyphosate herbicide. It is anticipated to enable

an improved integrated weed management program to control a broad spectrum of weed species including weeds resistant to several herbicide families.

d. Safety of the Expressed Proteins

Information and data from studies demonstrate that the DMO protein is unlikely to be an allergen or toxin. This is based on the assessment of the donor organism, *Stenotrophomonas maltophilia*, which is ubiquitous in the environment and has lack of reports of allergies derived from the organism. Examination of the DMO amino acid sequences against bioinformatics databases showed a lack of significant structural similarity between the DMO protein and known allergens or pharmacologically active proteins. In addition, studies using DMO protein have demonstrated that the protein was digested rapidly in simulated digestive fluid. Ingestion of the protein did not cause acute toxicity in mice. These data support the safety for DMO protein.

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.

5. Assessment of Risks to Human Health

a. Nutritional data

Data obtained from compositional analyses conducted on the forage and seed of MON 87708 concluded that MON 87708 is compositionally equivalent to conventional soybean with regards to levels of nutrients. Comparisons between MON 87708 and the conventional soybean showed no statistically significant differences in four of the eight anti-nutrient components. The anti-nutritional components that showed statistically significant differences were assessed and found to be not meaningful from a food and feed perspective.

b. Toxicology information

There are no known health hazards associated with the product. It is not known to be capable of causing allergic sensitization. Studies have shown no toxicity toward mammals. Additionally, there are no amino acid sequences similarities to known toxins.

c. Pathogenicity

Stenotrophomonas maltophilia 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 87708 soybean products from countries where MON 87708 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 87708 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 action 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 and storage procedures are required for this product. MON 87708 soybean may be handled and stored as any conventional soybean seed product.

d. Disposal Consideration

MON 87708 is equivalent to conventional soybean with the exception of dicamba herbicide tolerance. Waste from MON 87708 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 22 May 2019 and written submissions are required before or on that date. Submissions must be addressed to:

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