

FACT SHEET

APPLICATION FOR APPROVAL FOR RELEASE OF PRODUCTS OF MON 87751 SOYBEAN FOR SUPPLY OR OFFER TO SUPPLY FOR SALE OR PLACING IN THE MARKET

NBB REF NO: JBK(S) 600-2/1/8

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 87751 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 87751 soybean. This means that MON 87751 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 87751 soybean is not intended for cultivation in Malaysia.

3. How has MON 87751 soybean been modified?

Monsanto has developed genetically modified insect resistant MON 87751 soybean that produces Cry2Ab2 and Cry1A.105 insecticidal proteins. Cry1A.105 is a modified Cry1A protein. The Cry2Ab2 and Cry1A.105 proteins provide protection from feeding damage caused by targeted lepidopteran insect pests. The *cry* genes were transferred into the genome of soybean using *Agrobacterium tumefaciens*-mediated transformation method.

4. Characteristics of MON 87751 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

Bacillus thuringiensis is the source of the *cry1A.105* gene and the *cry2Ab2* gene is derived from *Bacillus thuringiensis* subsp. *kurstaki*.

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

MON 87751 contains the *cry1A.105* and *cry2Ab2* coding sequences derived from *Bacillus thuringiensis* which is a common soil bacterium. The Cry1A.105 and Cry2Ab2 proteins are active against lepidopteran insect pests.

d. Safety of the Expressed Proteins

Information and data from studies demonstrate that the Cry1A.105 and Cry2Ab2 proteins are unlikely to be an allergen or toxin. This is based on the assessment of the donor organism, *Bacillus thuringiensis*, which is not a known human or animal pathogen and has lack of reports of allergies derived from the organism. Examination of the Cry1A.105 and Cry2Ab2 amino acid sequences against a bioinformatics database showed a lack of significant structural similarity between the Cry1A.105 and Cry2Ab2 proteins and known allergens or pharmacologically active proteins. In addition, studies using Cry1A.105 and Cry2Ab2 proteins have demonstrated that the protein was digested rapidly in simulated digestive fluids, and ingestion of the proteins did not cause acute toxicity in mice. These data support the safety for Cry1A.105 and Cry2Ab2 proteins.

Furthermore, Cry proteins have been used as components of topical *B.t.* microbial pesticides for over 45 years. The Cry1A.105 and Cry2Ab2 proteins are structurally and functionally related to Cry proteins that have a history of safe use as the active ingredients either in *B.t.* microbial pesticides and/or in biotechnology-derived food and feed crops.

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 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 87751 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 87751 concluded that MON 87751 is compositionally equivalent to conventional soybean.

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

Bacillus thuringiensis has 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 87751 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 87751 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 procedures are required for this product. MON 87751 soybean may be handled and stored as any conventional soybean seed product.

d. Disposal Consideration

MON 87751 is equivalent to conventional soybean with the exception of insect protection. Waste from MON 87751 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.