

FACT SHEET
APPLICATION FOR APPROVAL FOR RELEASE OF PRODUCTS OF MON 87701 SOYBEAN
FOR SUPPLY OR OFFER TO SUPPLY FOR SALE OR PLACING IN THE MARKET

NBB REF NO: JBK(S) 602-1/1/46

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 87701 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 87701 soybean. This means that MON 87701 soybean may enter Malaysia as grain, food ingredients for processing or packaging, as finished products ready for distribution, or as feed meal for animals. The MON 87701 soybean is not intended for cultivation in Malaysia.

3. How has MON 87701 soybean been modified?

Monsanto has developed genetically modified insect-protected soybean MON 87701 that produces the Cry1Ac insecticidal crystal (Cry) protein (δ -endotoxin) derived from *Bacillus thuringiensis* (*B.t.*) subsp. *kurstaki*. The Cry1Ac protein provides protection from feeding damage caused by targeted lepidopteran pests. The *cry1Ac* gene was transferred into the genome of soybean cells using *Agrobacterium tumefaciens*-mediated transformation method.

4. Characteristics of MON 87701 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 insect resistant.

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

Bacillus thuringiensis (*B.t.*) subsp. *kurstaki* is the source of the *cry1Ac* gene. It is a gram-positive bacterium commonly found in soil.

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

The Cry1Ac protein provides protection from feeding damage caused by targeted lepidopteran insects. It is anticipated to reduce or replace current insecticide applications to control lepidopteran pests in tropical and subtropical soybean production regions where these insects cause significant plant damage and yield loss.

d. Safety of the expressed proteins

Information and data from studies demonstrate that the Cry1Ac protein is 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 there are no reports of allergies derived from the organism. Examination of the Cry1Ac amino acid sequences against bioinformatics databases showed a lack of significant structural similarity between the Cry1Ac protein and known allergens or toxins. In addition, studies using Cry1Ac protein have demonstrated that the protein was digested rapidly in simulated digestive fluid and ingestion of the protein did not cause acute toxicity in mice. These data are consistent with the conclusion of safety for Cry1Ac 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 87701 concluded that MON 87701 is compositionally equivalent to conventional soybean with regards to levels of nutrients. Comparisons between MON 87701 and the conventional soybean showed no statistically significant differences in six 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. Toxicological 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 sequence 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 87701 soybean products from countries where MON 87701 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 87701 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 seeds 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 87701 soybean may be handled and stored as any conventional soybean seed product.

d. Disposal Consideration

MON 87701 is equivalent to conventional soybean with the exception of insect tolerance. Waste from MON 87701 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 National Biosafety Board (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/on that date. Submissions must be addressed to:

Director General,
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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.