FACT SHEET

APPLICATION FOR APPROVAL FOR RELEASE OF PRODUCTS OF MON 87419 MAIZE FOR SUPPLY OR OFFER TO SUPPLY FOR SALE OR PLACING IN THE MARKET

NBB REF NO: JBK(S) 600-2/1/11

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 87419 maize 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 87419 maize. This means that MON 87419 maize 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 87419 maize is not intended for cultivation in Malaysia.

3. How has MON 87419 maize been modified?

The MON 87419 maize has been genetically modified to be tolerant to dicamba and glufosinate herbicides. MON 87419 maize contains a demethylase (*dmo*) gene that expresses a dicamba mono-oxygenase (DMO) protein to confer tolerance to dicamba herbicide and the phosphinothricin N-acetyltransferase (*pat*) gene that expresses the phosphinothricin N-acetyltransferase (PAT) protein to confer tolerance to glufosinate herbicide. The genes were transferred into the genome of maize using *Agrobacterium*-mediated transformation method.

4. Characteristics of MON 87419 maize

a. Details of the parent organism

The recipient or parental plant is *Zea mays* (maize), also known as corn. Maize has been a staple of the human diet for centuries and is grown in nearly all areas of the globe. It is the largest cultivated crop in the world followed by wheat (*Triticum* sp.) and rice (*Oryza sativa* L.) in total global metric ton production. However, unlike wheat and rice, the majority of maize produced is consumed as animal feed in the form of grain, forage, or silage.

b. Donor organism

Characteristics of *Stenotrophomonas maltophilia*

Stenotrophomonas maltophilia is the source of the *dmo* gene. It is an aerobic, environmentally ubiquitous, gram-negative bacterium commonly present in aquatic environments, soil, and plants. *S. maltophilia* has not been reported to be a source of allergens.

Characteristics of *Streptomyces viridochromogenes*

Streptomyces viridochromogenes is the source of the *pat* gene. It is a saprophytic, soil-borne bacterium widespread in the environment and is not considered pathogenic to plants, humans or other animals.

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

MON 87419 maize contains a *dmo* gene from *Stenotrophomonas maltophilia* that expresses DMO protein to confer tolerance to dicamba herbicide and a *pat* gene from *Streptomyces viridochromogenes* that expresses PAT protein to confer tolerance to glufosinate herbicide.

d. Safety of the expressed proteins

Information and data from studies demonstrate that the DMO and PAT proteins are unlikely to be allergens or toxins. This is based on the assessment of the donor organisms, *Stenotrophomonas maltophilia* and *Streptomyces viridochromogenes,* which are ubiquitous in the environment and have lack of reports of allergies derived from the organisms. Bioinformatics was to used to compare the DMO and PAT amino acid sequences against known allergens and pharmacologically active protein and the results showed a lack of significant structural similarity between the DMO and PAT proteins and known allergens or pharmacologically active proteins. In addition, studies using the DMO and PAT proteins have demonstrated that the proteins were digested rapidly in simulated gastrointestinal fluids, and ingestion of the proteins did not cause acute toxicity in mice. These data support the safety for the DMO and PAT proteins.

e. Utilization of maize

The high yield of maize makes it one of the most economical sources of metabolizable energy for food, feed and industrial products. Humans consume more maize-based food ingredients compared to whole kernel maze in spite of its great value as a source of energy. Therefore, indirect consumption is much greater than direct consumption by humans. Sweet corn and popcorn are examples of direct consumption of maize as food. The majority of maize is used to produce high fructose corn syrup for use in foodstuff. Examples of non-food products are industrial starches, maize gluten feed, and maize gluten meal.

Approximately two-thirds of the maize produced is fed to livestock, either as silage, grain, or by the use of processed feeds in the animal diet. Maize is valued for feed and food uses as it does not produce significant quantities of toxins or anti-nutritional factors.

MON 87419 maize 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 grain and forage of MON 87419 maize concluded that MON 87419 maize is compositionally equivalent to conventional maize.

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

Stenotrophomonas maltophilia and *Streptomyces viridochromogenes* are ubiquitous in the environment and lacks reports of allergies derived from the 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 87419 maize products from countries where maize is already approved and commercially grown, and that may enter Malaysia as grain, food ingredients for processing or packaging or as finished products ready for distribution, or as feed meal for animals.

7. What is the Emergency Response Plan?

MON 87419 maize 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 grains 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 87419 maize and its products may be handled and stored as any conventional maize product.

d. Disposal Consideration

The same measures for waste disposal and treatment as for conventional maize are valid for MON 87419 maize..

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 or 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 of 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 25 June 2020 and written submissions are required before/by that date. Submissions must be addressed to:

Director General,
Department of Biosafety
Ministry of Environment and Water
Level 1, Podium 2, Wisma Sumber Asli
No. 25, Persiaran Perdana, Presint 4, 62574
Putrajaya, MALAYSIA.
Email: biosafety@kats.gov.my.
Fax: 03-88904935.

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