FACT SHEET

APPLICATION FOR APPROVAL FOR RELEASE OF PRODUCTS OF MON 87411 MAIZE FOR SUPPLY OR OFFER TO SUPPLY FOR SALE OR PLACING IN THE MARKET

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

The objective of the Biosafety Act is to protect human, plant and animal health, the environment and biological diversity. Under the Biosafety Act, 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 products of MON 87411 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 87411 maize.

3. How has MON 87411 maize been modified?

MON 87411 maize has been genetically modified to have protection against corn rootworm and tolerant to glyphosate herbicides. MON 87411 maize produces Cry3Bb1 protein from *Bacillus thuringiensis* (subspecies *kumamotoensis*) that selectively controls corn rootworm species. It also produces a 5-enolpyruvyl shikimate-3-phosphate synthase (termed CP4 EPSPS) from *Agrobacterium* sp. strain CP4, which confers tolerance to glyphosate, the active ingredient in Roundup® agricultural herbicides. More details of genetic elements that have been incorporated is available upon request.

4. Characteristics of MON 87411 maize

a. Details of the parent organism

The recipient of the gene or parental plant is *Zea mays* (maize) also known as corn. The maize has been genetically modified to have protection against corn rootworm insect pests and glyphosate tolerance.

Maize is grown in nearly all areas of the globe, and 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.

Today, the high yield of maize makes it one of the most economical sources of metabolizable energy for food, feed and industrial products. Little whole kernel maize is consumed by humans when compared to maize-based food ingredients, in spite of its great value as a source of energy. Therefore, indirect consumption is much greater than direct consumption by humans. 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 that warrant analytical or toxicological tests.

MON 87411 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.

b. Donor organism

Agrobacterium sp. strain CP4 is the source of the *cp4 epsps* gene, and *Bacillus thuringiensis* subsp. *kumamotoensis* is the source of the *cry3Bb1* gene.

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

MON 87411 maize and all maize lines/ varieties derived from this event contain the *cry3Bb1* gene derived from *Bacillus thuringiensis* (subspecies *kumamotoensis*) and the *cp4 epsps* gene from *Agrobacterium* sp. strain CP4 which is ubiquitous in the environment. MON 87411 maize produces a Cry3Bb1 protein that selectively controls corn rootworm species and a 5-enolpyruvyl shikimate-3-phosphate synthase (termed CP4 EPSPS) from *Agrobacterium* sp. strain CP4, which confers tolerance to glyphosate, the active ingredient in Roundup® agricultural herbicide.

d. Safety of the Expressed Proteins

Information and data from studies also support the safety of the Cry3Bb1 and CP4 EPSPS proteins and demonstrate that these proteins are unlikely to be an allergen or toxin. This is based on the assessment of the donor organisms, *Bacillus thuringiensis* subsp*. kumamotoensis* and *Agrobacterium* sp*.* strain CP4, which are not a known human or animal pathogen and there are no reports of allergies derived from the organism. Analysis of the Cry3Bb1 and CP4 EPSPS amino acid sequences against a bioinformatics database showed a lack of significant structural similarity between the Cry3Bb1 and CP4 EPSPS proteins and known allergens, toxins or biologically active proteins of concern. In addition, studies using the purified Cry3Bb1 and CP4 EPSPS proteins have demonstrated that the proteins were digested rapidly in simulated digestive fluids, and ingestion of the protein did not cause acute toxicity in mice. These data are consistent with the conclusion of safety for Cry3Bb1 and CP4 EPSPS proteins.

Furthermore, Cry proteins have been used as components of topical *B.t*. microbial pesticides for over 45 years. The Cry3Bb1 protein is 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.

5. Assessment of Risks to Human Health

No significant health hazards are currently associated with this product. MON 87411 is substantially equivalent to conventional maize, which have no specific adverse health effects.

a. Nutritional Composition (Compositional Analysis)

Maize grain and forage derived from MON 87411 are compositionally and nutritionally equivalent to those of the conventional maize.

b. Anti-Nutritional Factors

Conventional non-genetically modified maize grain contains several well-described anti-nutritional factors and secondary metabolites, which include: phytic acid, raffinose, furfural, ferulic acid and p-coumaric acid. Compositional analyses of the grain indicated that phytic acid, raffinose, and furfural, ferulic acid and p-coumaric acid were present at similar levels in MON 87411 maize and control maize, and no statistical significant differences were observed for all comparisons.

c. Toxicological Information

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

d. Pathogenicity

Bacillus thuringiensis subsp*. kumamotoensis* and *Agrobacterium* sp*.* strain CP4 have no known pathogenicity 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 MON 87411 maize products from countries where maize 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 87411 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 actions 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. It will be handled as any maize seed product. No special storage procedures are required for this product. It will be stored as any maize seed product

d. Disposal Consideration

MON 87411 is equivalent to conventional maize with the exception of insect protection and glyphosate tolerance. Waste from MON 87411 can be treated similar to conventional maize 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 October 2019 and written submissions are required by that date. Submissions must be addressed to:

Director General
Department of Biosafety
Ministry of Water, Land and Natural Resources
Level 1, Podium 2, Wisma Sumber Asli
No. 25, Persiaran Perdana, Precinct 4
62574 Putrajaya, MALAYSIA.
Email: biosafety@kats.gov.my
Fax: 03-8890 4935

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