FACT SHEET

APPLICATION FOR APPROVAL FOR RELEASE OF PRODUCTS OF MON 88701 COTTON FOR SUPPLY OR OFFER TO SUPPLY FOR SALE OR PLACING IN THE MARKET

NBB REF NO: JBK(S) 600-2/1/12

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 88701 cotton 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 88701 cotton. This means that MON 88701 cotton 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 88701 cotton is not intended for cultivation in Malaysia.

3. How has MON 88701 cotton been modified?

The MON 88701 cotton has been genetically modified to be tolerant to dicamba and glufosinate herbicides. MON 88701 contains a demethylase (*dmo*) gene that expresses a dicamba mono-oxygenase (DMO) protein to confer tolerance to dicamba herbicide and a bialaphos resistance (*bar*) gene that expresses phosphinothricin N-acetyltransferase (PAT) protein to confer tolerance to glufosinate herbicide. The genes were transferred into the genome of cotton using *Agrobacterium*-mediated transformation method.

4. Characteristics of MON 88701 cotton

a. Details of the parent organism

The recipient or parental plant is *Gossypium hirsutum* L., also known as cotton. Cotton is a perennial plant that is harvested and planted annually. Cotton is grown worldwide and is grown primarily for the value of the fiber with cottonseed being a by-product. Cotton is the leading plant fiber crop produced in the world. Cotton is primarily a self-pollinated species and is propagated by seed. Outcrossing levels in cotton are low and there are no identified non-cotton plants that are sexually compatible with cultivated cotton.

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. *Stenotrophomonas maltophilia* has not been reported to be a source of allergens.

Characteristics of *Streptomyces hygroscopicus*

Streptomyces hygroscopicus is the source of the *bar* gene. It is a saprophytic, common soil-borne bacterium ubiquitously present in the environment with widespread human exposure without any adverse safety or allergencity reports.

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

MON 88701 cotton contains a *dmo* gene from *Stenotrophomonas maltophilia* that expresses DMO protein to confer tolerance to dicamba herbicide and *bar* gene from *Streptomyces hygroscopicus* 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 hygroscopicus,* which are ubiquitous in the environment and have lack of reports of allergies derived from the organisms. Bioinformatics was 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 DMO and PAT proteins.

e. Utilization of cotton

The primary product of cotton production is lint for textile use. However, cottonseed has a number of industrially important uses including livestock feed in the form of whole or crushed cottonseed and cottonseed meal, as well as human food use in the form of oil and linters. The presence of the anti-nutrients gossypol and cyclopropenoid fatty acids in cottonseed has limited the human and animal consumption of cottonseed. Cottonseed is processed into four major by-products: oil, meal, hulls, and linters. The primary human foods from cottonseed are the highly processed refined, bleached, and deodorized (RBD) oil and linters. Cottonseed oil is used in a variety of food uses, including frying, salad, and cooking oil, mayonnaise, salad dressing, shortening, margarine, and packing oil. Linters, which are nearly pure cellulose, are used as a fiber supplement, casings for processed meats, binder for solids in the

pharmaceutical industry, and to improve viscosity in products such as toothpaste, ice cream, and salad dressing.

Cottonseed meal is primarily sold as feed for livestock, of which the major value is as a protein concentrate. Due to the presence of gossypol and cyclopropenoid fatty acids in cottonseed, most monogastric farm animals are not fed cottonseed meal to any appreciable level, while ruminants are able to incorporate only limited amounts of cottonseed into their diets as a protein supplement.

Hulls are used as feed for livestock and can be an economical roughage that provides fiber as well as a good carrier for cottonseed meal and grain.

Gin by-products, the dried plant material cleaned from the fiber during ginning (process of removing the seeds and debris from cotton), is also used as a source of roughage for livestock feeds.

MON 88701 cotton 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 cottonseed of MON 88701 concluded that MON 88701 cottonseed is compositionally equivalent to conventional cotton (not genetically modified).

b. Toxicological Information

There are no known health hazards associated with the product. Studies have shown no toxicity toward mammals. Additionally, there are no amino acid sequences similarities of MON 88701 cottonseed to known toxins.

c. Pathogenicity

Stenotrophomonas maltophilia and *Streptomyces hygroscopicus* are ubiquitous in the environment and lacks reports of allergies derived from these 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 88701 cotton products from countries where cotton 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 88701 cotton 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 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 88701 cotton and its products may be handled and stored as any conventional cotton product.

d. Disposal Consideration

The same measures for waste disposal and treatment as for conventional cotton are valid for MON 88701 cotton.

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.