FACT SHEET

APPLICATION FOR APPROVAL FOR RELEASE OF PRODUCTS OF MON 88702 COTTON FOR SUPPLY OR OFFER TO SUPPLY FOR SALE OR PLACING IN THE MARKET

NBB REF NO: JBK(S) 600-2/1/23

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 Bayer Co. (Malaysia) Sdn. Bhd.

1. What is the application for?

This application is to import and release MON 88702 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 88702 cotton. MON 88702 cotton may enter Malaysia as cottonseed, food ingredients for processing or packaging or as finished products ready for distribution, or as feed meal for animals. MON 88702 cotton is not intended for cultivation in Malaysia.

3. How has MON 88702 cotton been modified?

Genetically modified MON 88702 cotton was produced by insertion of the modified *Cry51Aa2* gene from *Bacillus thuringiensis* (*B.t.*) into the genome of conventional cotton using *Agrobacterium*-mediated transformation method. MON 88702 cotton produces a modified Cry51Aa2 insecticidal crystal (Cry) protein (referred to as mCry51Aa2) that protects against feeding damage caused by targeted hemipteran and thysanopteran insect pests.

4. Characteristics of MON 88702 cotton

a. Details of the parent organism

The 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 *Bacillus thuringiensis*

Bacillus thuringiensis (*B.t.)*, a common soil bacteria, is the source of the *mCry51Aa2* gene. Applications of sporulated *B.t.* have a long history of safe use for pest control in agriculture, especially in organic farming. Microbial pesticides containing *B.t.* Cry proteins have been subjected to extensive toxicity testing showing no adverse effects to human or animal health (Koch et al., 2015; Moar et al., 2017; OECD, 2010a). There are no confirmed cases of allergic reactions to Cry proteins in microbial-derived *B.t.* products during more than 50 years of use (Hammond, 2004; OECD, 2010b).

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

MON 88702 cotton has been genetically modified to contain *mCry51Aa2* gene derived from *Bacillus thuringiensis* that expresses mCry51Aa2 protein which confers protection from feeding damage caused by targeted hemipteran and thysanopteran insect pests.

d. Safety of the expressed proteins

Information and data from studies demonstrate that the mCry51Aa2 protein is unlikely to be an allergen or toxin. This is based on the assessment of the donor organisms, *Bacillus thuringiensis* which is not a known human or animal pathogen and have lack of reports of allergies derived from the organism. Additionally, there are no confirmed cases of allergic reactions to Cry proteins in microbial-derived *B. thuringiensis* products during more than 50 years of use (U.S. EPA, 1988; Hammond, 2004; Koch et al., 2015; McClintock et al., 1995). Bioinformatics was used to compare the mCry51Aa2 amino acid sequences against known allergens, toxins and biologically active proteins and the results showed a lack of significant structural similarity between the mCry51Aa2 protein and known allergens, toxins or biologically active proteins (Silvanovich and Kessenich, 2017). In addition, studies using the mCry51Aa2 protein have demonstrated that the protein was digested rapidly in simulated digestive fluids (Wang, 2017), and ingestion of the protein did not cause acute toxicity in mice (Landin, 2017). These data support the safety for mCry51Aa2 protein.

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 (Cherry, 1983). 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 (NCPA, 2002).

Cottonseed meal is primarily sold as feed for livestock, of which the major value is as a protein concentrate (NCPA, 2002). 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 (NCPA, 2002).

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 88702 cotton may enter Malaysia as cottonseed, 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

The compositional analyses of MON 88702 cottonseed showed that out of the 47 components statistically evaluated, 9 components showed statistically significant differences between MON 88702 and the conventional control. Where values were different, the means were found to be within the natural variability of these components as published in scientific literature and/or the ILSI Crop Composition Database (ILSI-CCDB), except for lauric acid, a low abundance fatty acid for which literature and ILSI-CCDB values were unavailable. Therefore, these differences are unlikely to be biologically meaningful. From these results, it is concluded that MON 88702 cottonseed is comparable to conventional cottonseed.

b. Toxicological information

There are no known health hazards associated with the product. Studies conducted using the mCry51Aa2 protein produced in MON 88702 have shown no toxicity toward mammals (Landin, 2017; Wang, 2017). Additionally, there are no amino acid sequences similarities of MON 88702 cottonseed to known toxins or other biologically active proteins (Silvanovich and Kessenich, 2017).

c. Pathogenicity

Bacillus thuringiensis is not a known human or animal pathogen and has lack of reports of allergies derived from the organism (Hammond, 2004; OECD, 2010b).

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 88702 cotton products from countries where cotton is already approved and commercially grown, and that may enter Malaysia as cottonseed, food ingredients for processing or packaging or as finished products ready for distribution, or as feed meal for animals.

Thus, the potential exposure to the environment is limited to rare spillage events. On environmental risk assessment of genetically engineered (GE) plants under low-exposure conditions, the loss of imported seeds are most likely to occur near ports or along roads from ports to manufacturing sites (Roberts et al., 2014). Most of the spilled seeds are unlikely to survive for long outside intentional cultivation by the following limiting factors:

i) seeds not encountering conditions favorable for germination;
ii) the plants germinated in the areas which are often managed (e.g. mowing, cleaning);
iii) poor competitive ability with native vegetation, cotton is not an indigenous species (OECD, 2000), and is not a major economic crop in Malaysia. Therefore, MON 88702 cotton is unlikely to germinate and establish upon accidental spillage in Malaysia.

7. What is the emergency response plan?

There have been no reports of adverse effects of MON 88702 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 measures

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 88702 cotton and its products may be handled and stored as any conventional cotton products.

d. Disposal considerations

The same measures for waste disposal and treatment as for conventional cotton are valid for MON 88702 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 2 November 2021 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 4, Block F11, Complex F
Lebuh Perdana Timur, Precinct 1
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Please include your full name, address and contact details in your submission.

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