FACT SHEET

APPLICATION FOR APPROVAL FOR RELEASE OF PRODUCTS OF MON 95275 MAIZE FOR SUPPLY OR OFFER TO SUPPLY FOR SALE OR PLACING IN THE MARKET

NBB REF NO: JBK(S) 600-2/1/31

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 of MON 95275 maize and its products for supply or offer to supply for sale or placing in the market. The application does not cover deliberate environmental release (i.e. cultivation) in Malaysia and does not cover any subsequent maize products that result from the use of MON 95275 maize for breeding purposes (stacked events).

2. What is the purpose of the import and release?

The purpose of the import and release is for direct use as food, feed and for processing (FFP) of MON 95275 maize and its products. This means that MON 95275 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 95275 maize is not intended for cultivation in Malaysia.

3. How has MON 95275 maize been modified?

MON 95275 maize was produced by insertion of *mpp75Aa1.1* gene derived from *Brevibacillus laterosporus* and the *vpb4Da2* gene derived from *Bacillus thuringiensis* (*Bt*) into the genome of conventional maize using *Agrobacterium tumefaciens* mediated transformation method. The MON 95275 maize also produces a double-stranded RNA transcript from an inverted repeat sequence designed to match the Western corn rootworm (WCR; *Diabrotica virgifera virgifera*) *Snf7* gene (DvSnf7.1). The RNA interference cassette specifically targets expression

of Snf7 which is an essential cellular component of endosomal sorting complex required for transport. The Mpp75Aa1.1 and Vpb4Da2 proteins combined with DvSnf7.1 RNA provide protection from feeding damage caused by targeted Coleopteran insect pests.

4. Characteristics of MON 95275 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 (FAOSTAT, 2022[1]). However, unlike wheat and rice, the majority of maize produced is consumed as animal feed in the form of grain, forage, or silage.

b. Details of donor organism

Characteristics of *Brevibacillus laterosporus*

The origin of the *mpp75Aa1.1 gene* is from *Brevibacillus laterosporus* which is derived from the full-length precursor form of the insecticidal protein Mpp75Aa1. *B. laterosporus*, formerly classified as *Bacillus laterosporus*, is an endospore-forming insecticidal bacilli and not known for pathogenicity or allergenicity in humans or other vertebrates with the only known report of *B. laterosporus* infection occurring in an immunocomprimised pediatric patient (Curtis *et al*., 2020; Laubach, 1916; Shida *et al*., 1996). However, *B. laterosporus* shares a similar habitat to *Bt*, and can be isolated from a wide range of environments including soil, rocks, dust, and both fresh and sea waters (Nivetha and Jayachandran, 2017; Panda *et al*., 2014; Ruiu, 2013). Furthermore, *B. laterosporus* is also found to be present in many food sources such as cheese (Román-Blanco *et al*., 1999), curd (Panda *et al*., 2014), beans (Sarkar *et al*., 2002), and honey (Iurlina and Fritz, 2005), as well as being listed as a probiotic for humans (Hong *et al*., 2005) and feed additive for birds (Ruiu, 2013; Ruiu *et al*., 2014). *B. laterosporus* isolates has a characterized broad-spectrum insecticidal activity and was registered for pest control in horticulture and agriculture in New Zealand (NZ EPA, 2022). Taken together, the widespread presence of *B. laterosporus* in the environment provides a documented history of safe exposure and consumption for human and other vertebrates.

[1] FAOSTAT. 2022. Food and Agricultural Organization statistical database. Food and Agricultural Organization of the United Nations, Rome, Italy. http://www.fao.org/faostat/en/#data/QC [Accessed February 25, 2022].

Characteristics of *Bacillus thuringiensis*

The origin of the *vpb4Da2* gene is from *Bacillus thuringiensis* (*Bt.)*, a Gram-positive common soil bacteria, has a long history of commercial use in the United States of America (USA) to produce microbially-derived products with insecticidal activity. It also occurs naturally in the gut of caterpillars of various types of moths and butterflies, as well as on the dark surfaces of plants. The use of of *Bt* has a documented history of safe use in agriculture, including in organic farming (Federici and Siegel, 2008; Koch *et al*., 2015).

Since the first *Bt* isolate was registered as a pesticide in 1961, over 180 microbial Bt products have been registered in the United States of America (USA) with more than 120 microbial products registered in the European Union (EU) (Hammond, 2004). Microbial pesticides containing *Bt* insecticidal proteins have been subjected to extensive toxicity testing showing no adverse effects to human health (Baum *et al.,* 1999; Betz *et al*., 2000; McClintock *et al.,* 1995; Mendelsohn *et al.,* 2003; U.S. EPA, 2001; 2005). There are no confirmed cases of allergic reactions to the insecticidal proteins in microbial-derived *Bt* products for more than 50 years of use (Koch *et al.,* 2015). *Bt* Cry proteins have been used by organic and conventional farmers and are effective when expressed in genetically modified (GM) plants (Sanahuja *et al.,* 2011).

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

MON 95275 maize contains Mpp75Aa1.1 insecticidal protein derived from *B. laterosporus*, the Vpb4Da2 insecticidal protein derived from *Bt,* and a double-stranded RNA transcript from an inverted repeat sequence designed to match the WCR *Snf7* gene (DvSnf7.1) that provides protection against the feeding damage caused by targeted Coleopteran insect pests and very specifically WCR.

5. Modification Method

MON 95275 maize was developed through *Agrobacterium*-mediated transformation by insertion of *mpp75Aa1.1* gene derived from *B. laterosporus* and the *vpb4Da2* gene derived from *Bt* into the genome of conventional maize*.* The MON 95275 maize also produces a double-stranded RNA transcript from an inverted repeat sequence. The *DvSnf7*^{p} sequence is the partial coding sequence of the *Snf7* gene and was designed to match the gene present in from WCR (Baum *et al.,* 2007a; Baum *et al*., 2007b) encoding the SNF7 subunit of the ESCRT-III complex (Babst *et al.,* 2002). The 240bp dsRNA sequence in MON 95275 utilized

to induce the RNAi mechanism in WCR is the same sequence present in MON 87411 maize [JBK (S) 600-2/1/2 that was approved on 10 November 2020). The only difference between the full length DvSnf7.1 RNA expressed in MON 95275 and the full length DvSnf7 RNA expressed in MON 87411 is 5' UTR, which was optimized to increase in planta expression.

a. Characterization of the modification

The expression of the broad insecticidal proteins (Mpp75Aa1.1 and Vpb4Da2 proteins) against Coleoptera has a pore-forming mode of action in the midgut of feeding larvae. The expression of the *DvSnf7.1* suppression cassette targets specifically WCR and results in the formation of a dsRNA transcript containing a 240 bp fragment of the WCR *Snf7* gene (DvSnf7). Upon consumption of MON 95275 maize by WCR, the DvSnf7 dsRNA triggers an RNAi response, which targets the mRNA for degradation, resulting in gene silencing and in turn death of the feeding WCR larvae (Bolognesi *et al*., 2012).

b. Safety of the expressed proteins

Mpp75Aa1.1 and Vpb4Da2 proteins

Information and data from studies demonstrate that the Mpp75Aa1.1 and Vpb4Da2 proteins are unlikely to be allergens or toxins. This is based on the assessment of the donor organism, *B. laterosporus* and *Bt which* is not a known human or animal pathogen and have lack of reports of allergies derived from the organism. Bioinformatics was used to compare the Mpp75Aa1.1 and Vpb4Da2 amino acid sequences against known allergens and toxins and the results showed a lack of significant structural similarity between the Mpp75Aa1.1 and Vpb4Da2 proteins and known allergens or toxins (Skottke, 2022).

In addition, studies using the Mpp75Aa1.1 and Vpb4Da2 proteins have demonstrated that the proteins were digested rapidly by pepsin or pancreatin and indicates that the proteins are highly unlikely to pose any safety concern to human or animal health (Bretsnyder and Wang, 2022; Chen and Wang, 2020), and ingestion of the proteins did not cause acute toxicity in mice (Good, 2019; Good, 2022). This data supports the safety for Mpp75Aa1.1 and Vpb4Da2 proteins. Detailed safety studies of the expressed proteins information can be obtained from the Department of Biosafety.

***DvSnf7.1* suppression cassette**

Based on the ubiquitous nature of RNAi suppression utilizing endogenous dsRNAs in a wide variety of plant species consumed by humans and animals and demonstration of the specificity of *Snf7* suppression in WCR (Bachman *et al.,* 2013; Bachman *et al.,* 2016), the *DvSnf7.1* RNAi suppression sequence used in MON 95275 poses no observed risks to humans or other vertebrates. In addition, there is long history of safe consumption of RNA from a range of sources (Rodrigues and Petrick, 2020) and there is lack of records to show toxicity or allergenicity of dietary RNA (Petrick *et al.,* 2016). Detailed safety studies of the expressed proteins information can be obtained from the Department of Biosafety.

6. Assessment of risks to human health

a. Nutritional data

Data obtained from compositional analyses conducted on the grain and forage of MON 95275 maize showed that there were no statistically significant differences in 54 of the 61 comparisons made between MON 95275 maize and conventional control. For the 7 components that showed statistically significant difference between MON 95275 maize and the conventional control, the mean difference between MON 95275 maize and the conventional control was less than the range value (maximum value minus the minimum value) of the conventional control (Taylor *et al.,* 2020).

In addition, the MON 95275 maize mean component values were found to be within the natural variability of these components as published in scientific literature and/or the AFSI Crop Composition Database (AFSI-CCDB) (Taylor *et al.,* 2020). Therefore, these statistically significant differences are not considered biologically relevant. This data supports the statement that MON 95275 maize is compositionally equivalent to conventional maize. Detailed MON 95275 maize composition analysis information can be obtained from the Department of Biosafety.

b. Toxicology

There are no known health hazards associated with MON 95275 maize. Studies conducted using the Mpp75Aa1.1 and Vpb4Da2 proteins produced in MON 95275 maize have shown no toxicity toward mammals (Good, 2019; Good, 2022). Additionally, there are no amino acid sequences similarities of MON 95275 maize to known toxins (Skottke,

2022). There is no evidence to suggest that dietary consumption of nucleic acids is associated with toxicity (Petrick *et al.,* 2013; U.S. FDA, 1992). Detailed MON 95275 maize toxicology information can be obtained from the Department of Biosafety.

c. Pathogenicity

B. laterosporus is not known for pathogenicity or allergenicity in humans or other vertebrates with the only known report of *B. laterosporus* infection occurring in an immunocompromised pediatric patient (Curtis *et al.,* 2020; Laubach, 1916; Shida *et al.,* 1996). *Bt* is not a known human or animal pathogen and there are no known reports of allergies derived from the organism (Hammond, 2004; OECD, 2010).

d. Allergenicity

The Codex Alimentarius guidelines for the evaluation of the allergenicity potential of introduced proteins (Codex Alimentarius, 2009) are based on the comparison of amino acid sequences between introduced proteins and allergens, where allergenic cross-reactivity may exist if the introduced protein is found to have at least 35% amino acid identity with an allergen over any segment of at least 80 amino acids. The bioinformatic results demonstrated there were no biologically relevant sequence similarities to allergens when the Mpp75Aa1.1 and Vpb4Da2 proteins sequences were used as a query for a FASTA search of the AD_2021 database (Skottke, 2022).

Furthermore, no short (eight amino acid) polypeptide matches were shared between the Mpp75Aa1.1 and Vpb4Da2 proteins sequences and proteins in the allergen database. These data show that Mpp75Aa1.1 and Vpb4Da2 proteins sequences lacks both structurally and immunologically relevant similarities to known allergens, gliadins, and glutenins (Skottke, 2022). There is a history of safe consumption of the RNA molecules mediating gene suppression in plants, including those with homology to genes in humans and other animals (Ivashuta *et al*., 2009; Jensen *et al.,* 2013). There is also no evidence of allergenicity of dietary RNA in the peer-reviewed scientific literature. Detailed MON 95275 maize allergenicity information can be obtained from the Department of Biosafety.

7. Assessment of risks to the environment

The application does not cover an environment release. The application is intended only to cover the import of the MON 95275 maize products from countries where the said maize event 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.

8. What is the emergency response plan?

MON 95275 maize and food and feed products derived from it have been assessed as being as safe as its conventional non-genetically modified counterparts. 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 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 and storage procedures are required for this product. MON 95275 maize and its products may be handled and stored as any conventional maize products.

d. Disposal

The same measures for waste disposal and treatment as for conventional maize are valid for MON 95275 maize.

9. 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 in this Fact Sheet. Detailed MON 95275 safety study can be obtained from the Department of Biosafety. 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 to express your concerns. 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. The submission of comments and clarifications of queries should contribute to the NBB's assessment. Your submission will be given the same scrutiny as the application by the NBB. Please note that the consultation period closes on 13 September 2023 and written submissions are required before/by that date. Submissions must be addressed to:

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

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