FACT SHEET

APPLICATION FOR APPROVAL FOR RELEASE OF PRODUCTS OF MON 87429 MAIZE FOR SUPPLY OR OFFER TO SUPPLY FOR SALE OR PLACING IN THE MARKET

NBB REF NO: JBK(S) 600-2/1/24

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 genetically modified herbicide resistant MON 87429 maize and its products. The application does not cover deliberate environmental release (i.e. cultivation) in Malaysia.

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 87429 maize. This means that MON 87429 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 87429 maize is not intended for cultivation in Malaysia.

3. How has MON 87429 maize been modified?

Genetically modified MON 87429 maize was produced by insertion of *dmo*, *pat*, *ft_t*, and *cp4 epsps* genes into the maize genome using *Agrobacterium*-mediated transformation method to confer tolerance to the herbicides dicamba, glufosinate, aryloxyphenoxypropionate (AOPP) acetyl coenzyme A carboxylase (ACCase) inhibitors ("FOPs" herbicides such as quizalofop) and 2,4-dichlorophenoxyacetic acid (2,4-D). Information on the inserted genes are as follows:

	Gene	Donor organism	Trait
1	dmo	Stenotrophomonas maltophilia	Tolerance to dicamba herbicide
2	pat	Streptomyces viridochromogenes	Tolerance to glufosinate herbicide
3	<i>ft_t</i> (a modified version of the R-2,4-dichlorophenoxypropionate dioxygenase (<i>Rdpa</i>) gene)	Sphingobium herbicidovorans	Tolerance to FOPs and 2,4-D herbicides

4	cp4 epsps	Agrobacterium sp. strain CP4	Tolerance to glyphosate

4. Characteristics of MON 87429 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, 2020¹). 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 an aerobic, gram-negative bacterium ubiquitously present in the environment, including in water and dairy products (An and Berg, 2018; Mukherjee and Roy, 2016; Okuno *et al.*, 2018; Todaro *et al.*, 2011). These bacteria have been used as effective biocontrol agents in plant and animal pathogenesis (Mukherjee and Roy, 2016), and have antibacterial activity against both gram-positive and gram-negative bacteria (Dong *et al.*, 2015). These bacteria can form biofilms that become resistant to antibiotics (Berg and Martinez, 2015; Brooke *et al.*, 2017). *S. maltophilia* has been found in healthy individuals without any hazard to human health. Other than the potential to become an opportunist pathogen in immunocompromised hosts, *S. maltophilia* is not known for human or animal pathogenicity (Heller *et al.*, 2016; Lira *et al.*, 2017).

Characteristics of Streptomyces viridochromogenes

Streptomyces viridochromogenes is a saprophytic, soil-borne bacterium with no known safety issues. *Streptomyces* species are widespread in the environment and present no known allergenic or toxicity issues (Kämpfer, 2006; Kutzner, 1981), though human exposure is quite common (Goodfellow and Williams, 1983). *S. viridochromogenes* is widespread in the environment and the history of safe use is discussed in Hérouet *et al.* (2005).

Characteristics of Sphingobium herbicidovorans

Sphingobium herbicidovorans is a common gram-negative, rod-shaped, non-motile, nonspore-forming soil bacterium (Takeuchi *et al.*, 2001; Zipper *et al.*, 1996), which is strictly aerobic and chemo-organotrophic, and not known to be associated with human disease. Members of the genus *Sphingobium* have been isolated from a wide variety of habitats

¹ FAOSTAT. 2020. Food and Agricultural Organization statistical database. Food and Agricultural Organization of the United Nations, Rome, Italy. <u>http://www.fao.org/faostat/en/#data/QC</u> [Accessed June 03, 2020].

including soil and freshwater (Chaudhary *et al.*, 2017). *Sphingobium* species have also been isolated from food products such as maize (Rijavec *et al.*, 2007), papaya (Thomas *et al.*, 2007) and tomato (Enya *et al.*, 2007). The biosysthesis and biodegrading properties of this genus have been exploited in the food industry (Fialho *et al.*, 2008; Pozo *et al.*, 2007), bioremediation (Alarcón *et al.*, 2008; Jin *et al.*, 2013), and biofuel industry (Varman *et al.*, 2016).

Characteristics of Agrobacterium tumefaciens strain CP4

Agrobacterium tumefaciens strain CP4 is the source of the *cp4 epsps* gene. Agrobacterium *sp*. is a gram-negative, motile, soil-dwelling plant pathogen. Agrobacterium species are not known for human or animal pathogenicity and are not commonly allergenic (FAO-WHO, 2001).

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

MON 87429 maize contains *dmo*, *pat*, *ft_t*, and *cp4 epsps* genes that expresses DMO, PAT, FT_T and CP4 EPSPS proteins, respectively that confer tolerance to the herbicides dicamba, glufosinate, FOPs, 2,4-D and glyphosate.

d. Safety of the expressed proteins

Information and data from studies demonstrate that the DMO, PAT, FT T and CP4 EPSPS proteins are unlikely to be allergens or toxins or other biologically active proteins. This is based on the assessment of the donor organisms, Stenotrophomonas maltophilia strain DI-6, Streptomyces viridochromogenes, Sphingobium herbicidovorans and Agrobacterium tumefaciens strain CP4 which are not known for human or animal toxicity, and are not commonly allergenic (Heller et al., 2016; Lira et al., 2017; Kämpfer, 2006; Takeuchi et al., 2001; Chaudhary et al., 2017; FAO-WHO, 2001). Bioinformatics analysis was used to compare the DMO, PAT, FT T and CP4 EPSPS amino acid sequences against known allergens and toxins and other biologically active proteins and the results showed a lack of significant structural similarity between the DMO, PAT, FT_T and CP4 EPSPS proteins and known allergens or toxins or other biologically active proteins (Gu et al., 2018; Vest and Silvanovich, 2018; Skottke and Silvanovich, 2018). In addition, studies using the DMO, PAT, FT T and CP4 EPSPS proteins have demonstrated that the proteins were digested rapidly in simulated digestive fluids (Gu, 2018; Chen and Wang, 2019; Calcaterra, 2018; Leach et al., 2002), and ingestion of the proteins did not cause acute toxicity in mice (Smedley, 2012a; Smedley, 2012b; Good, 2018; Naylor, 1993). These data support the safety for DMO, PAT, FT_T and CP4 EPSPS proteins.

e. Utilization of maize

Maize has been a staple of the human diet for centuries, and its processed fractions are consumed in a multitude of food and animal feed products. Food uses of maize include processed products from field maize and direct consumption of sweet maize and popcorn. Food products derived from the wet milling process include starch and sweetener products (e.g., high fructose maize syrup) (May, 1987). Food products derived from the dry milling

process include maize grits, maize meal, and maize flour (Watson, 1988). Maize oil may be derived from either milling process (Watson, 1988).

Maize is used extensively as a livestock feed for reasons that include its palatability, digestibility, and metabolizable energy (Loy and Lundy, 2019). Animal feed products include maize gluten feed, maize gluten meal, and hominy feed (Loy and Lundy, 2019). Ethanol production from dry milled maize provides distillers grains, another source of animal feed (Loy and Lundy, 2019). Maize can also be fed as a whole plant silage.

MON 87429 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 87429 maize showed that there were no statistically significant differences in 50 of the 61 comparisons made between MON 87429 and conventional control. A statistically significant difference between MON 87429 and the conventional control does not necessarily imply biological relevance from a food and feed safety perspective. Therefore the 11 components that showed statistically significant difference were evaluated further (assessments related to comparisons to natural variations) to determine whether the detected difference indicated a biologically relevant compositional change. The mean values for the 11 components were found to be within the natural variability of these components as published in scientific literature and the ILSI Crop Composition Database (ILSI-CCDB)(Klusmeyer *et al.*, 2018) and could be due to normal biological variability that exist in corn. Therefore, these statistically significant differences are not considered biologically relevant. This data supports the statement that MON 87429 maize is compositionally equivalent to conventional maize.

Detailed information on the composition analysis may be obtained from the Department of Biosafety.

b. Toxicology

There are no known health hazards associated with the product. Studies conducted using the DMO, PAT, FT_T and CP4 EPSPS proteins produced in MON 87429 have shown no toxicity toward mammals (Smedley, 2012a; Smedley, 2012b; Good, 2018; Naylor, 1993). Additionally, there are no amino acid sequences similarities of MON 87429 maize to known toxins or other biologically active proteins that would raise a safety concern for human (Gu *et al.*, 2018; Vest and Silvanovich, 2018; Skottke and Silvanovich, 2018).

Detailed information on the toxicology studies may be obtained from the Department of Biosafety.

c. Allergenicity

Stenotrophomonas maltophilia, Streptomyces viridochromogenes, Sphingobium herbicidovorans and Agrobacterium tumefaciens strain CP4 are ubiquitous in the environment and have lack of reports of allergies derived from the organisms (Mukherjee and Roy, 2016; An and Berg, 2018; Todaro et al., 2011; Kämpfer, 2006; Kutzner, 1981; FAO-WHO, 2001). The opportunistic pathogenicity of S. maltophilia is mainly associated with individuals with compromised immune systems rather than with any specific virulence genes of these bacteria. Thus, documented occurrences of S. maltophilia infections have been limited to immunocompromised individuals in hospital settings (Lira et al., 2017). S. viridochromogenes is widespread in the environment and the history of safe use is discussed in Hérouet et al. (2005). The ubiquitous presence of Sphingobium species in the environment has resulted in widespread human and animal exposure without any known adverse safety or allergenicity reports. The Agrobacterium tumefaciens strain CP4 has a demonstrated history of safe use with the first product commercialized in 1996 (ILSI-CERA, 2010).

Detailed information on the allergenicity studies may be obtained from the Department of Biosafety.

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 87429 maize products from countries where MON 87429 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. Thus, the potential exposure to the environment is limited to 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, maize is not an indigenous species (OECD, 2000), and is not a major economic crop in Malaysia.

Therefore, MON 87429 maize is unlikely to germinate and establish upon accidental spillage in Malaysia.

7. What is the emergency response plan?

MON 87429 maize and food and feed products derived from it have been assessed as being as safe as its conventional non GE counterparts. Should adverse effects be reported and verified, appropriate follow up actions would be 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 87429 maize and its products may be handled and stored as any conventional maize products.

d. Disposal considerations

The same measures for waste disposal and treatment as for conventional maize are valid for MON 87429 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 <u>15 March 2022</u> and written submissions are required 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 Federal Government Administrative Centre 62000 Putrajaya, MALAYSIA E-mail: dob@biosafety.gov.my

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

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