This is to inform the public that the National Biosafety Board (NBB) is currently assessing two applications for approval submitted by Bayer Co. (Malaysia) Sdn. Bhd. (7563M) to release the following genetically modified products for the purpose of supply or offer to supply for sale/placing in the market:

1. MON 94100 canola (*Brassica napus*)
   NBB Reference no.: **JBK(S) 600-2/1/26**
2. MON 95379 maize (*Zea mays* L.)
   NBB Reference no.: **JBK(S) 600-2/1/25**

NBB welcomes written submissions of opinions/comments from the public regarding these applications. More information on these applications can be obtained from **www.biosafety.gov.my** under Public Consultation. Please quote NBB Reference number for correspondence.

Submissions must be addressed to:
The Director General, Department of Biosafety, Level 4, Block F11, Compleks F, Lebuh Perdana Timur, Precinct 1, Pusat Pentadbiran Kerajaan Persekutuan, 62000 Putrajaya, MALAYSIA.
E-mail: dob@biosafety.gov.my / Fax: 03-80917371

The closing date for submissions is **3 May 2022**.

FACT SHEET
APPLICATION FOR APPROVAL FOR RELEASE OF PRODUCTS OF MON 94100 CANOLA FOR SUPPLY OR OFFER TO SUPPLY FOR SALE OR PLACING IN THE MARKET

NBB REF NO: JBK(S) 600-2/1/26

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 products of MON 94100 canola 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 94100 canola. MON 94100 canola may enter Malaysia as oil, feedmeal, or food ingredients for processing or packaging or as finished products ready for distribution, or as feed meal for animals. The MON 94100 canola is not intended for cultivation in Malaysia.

3. How has MON 94100 canola been modified?

Genetically modified MON 94100 canola was produced by insertion of *dmo* gene from *Stenotrophomonas maltophilia* strain DI-6 into the genome of conventional canola using *Agrobacterium tumefaciens* mediated transformation method. MON 94100 canola produces a dicamba mono-oxygenase (DMO) protein to confer tolerance to dicamba (3,6-dichloro-2-methoxybenzoic acid) herbicide.

4. Characteristics of MON 94100 canola

a. Details of the parent organism

The recipient or parental plant is *Brassica napus* L., also known as canola.

Brassica napus (*B. napus*) or oilseed rape is thought to have originated in the Mediterranean and was cultivated by ancient civilizations in Asia and the Mediterranean and its oil was used for lighting. In the 1960s, through intensive breeding programmes, Canadian scientists made two important genetic modifications to oilseed rape which led to the first double-low (low-erucic acid and low glucosinolate) variety. In 1978, to distinguish this new edible variety of *B. napus* oil from industrial *B. napus* oil, the Canola Council of Canada chose the word “canola”

(Canadian oil, low acid) to become the registered trademark for edible *B. napus* oil with less than 2% erucic acid in the oil (Brown *et al,* 2009; CCC, 2020[1]; Codex Alimentarius, 2005).

b. Donor organism

Characteristics of *Stenotrophomonas maltophilia*

Stenotrophomonas maltophilia is the source of the *dmo* gene. It 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 (Heller *et al.*, 2016; *Lira et al.*, 2017). *S. maltophilia* has not been reported to be a source of allergens.

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

MON 94100 canola contains a *dmo* gene from *Stenotrophomonas maltophilia* strain DI-6 that expresses DMO protein to confer tolerance to the dicamba herbicide (3,6-dichloro-2-methoxybenzoic acid).

d. Safety of the expressed protein

Information and data from studies demonstrate that the DMO protein is unlikely to be an allergen or toxin. This is based on the assessment of the donor organism of which no reports of allergies have been reported associated with the organism (An and Berg, 2018; Heller *et al.*, 2016; Lira et al., 2017; Mukherjee and Roy, 2016; Okuno *et al.,* 2018; Todaro *et al.,* 2011). Examination of the DMO amino acid sequence against bioinformatics databases showed a lack of significant structural similarity between the DMO protein and known allergens or toxins (Gu and Silvanovich, 2021). In addition, studies using the DMO protein have demonstrated that the protein was digested rapidly in simulated gastrointestinal fluids (Burge *et al.,* 2010), and ingestion of the protein did not cause acute toxicity in mice (Smedley, 2010). These data support the safety for DMO protein. Detailed safety of the expressed proteins information can be obtained from the Department of Biosafety.

e. Utilization of canola

Today, canola is grown principally for its oil which is extracted from the seed, and has both food and industrial applications. Canola oil is high quality oil that is used in a variety of foods including frying and baking oils, salad oils, margarines and shortenings, and is the most valuable component of canola seed. It is the world's third largest source of vegetable oil with

[1] https://www.canolacouncil.org/canola-encyclopedia/history-of-canola-seed-development/

14% of world vegetable oil consumption after soybean oil at 28% and palm oil at 36% (ASA, 2019; USDA-FAS, 2019).

MON 94100 may enter Malaysia as oil, feedmeal, or food ingredients for processing or packaging or as finished products ready for distribution.

5. Assessment of risks to human health

a. Nutritional data

The compositional analyses of MON 94100 showed no statistically significant differences ($p<0.05$) for 44 of the 45 components analyzed from MON 94100 grain. There was one component (sinapine) that showed a statistically significant difference between MON 94100 and the conventional control. However, the mean difference between MON 94100 and the conventional control was less than the conventional control range and the MON 94100 mean component value was also within the range of values observed in the ILSI-CCDB values (Taylor *et al.*, 2020). Hence, this difference was not biologically meaningful. This data supports the statement that MON 94100 canola is compositionally equivalent to conventional canola. Detailed MON 94100 canola composition analysis information can be obtained from the Department of Biosafety.

b. Toxicological information

There is no known health hazards associated with the product. Studies conducted using the DMO protein have shown no toxicity toward mammals (Burge *et al.,* 2010; Smedley, 2010). Additionally, there are no amino acid sequences similarities to known toxins (Gu and Silvanovich, 2021). Detailed MON 94100 canola toxicology information can be obtained from the Department of Biosafety.

c. Pathogenicity

Stenotrophomonas maltophilia is ubiquitous in the environment (Mukherjee and Roy, 2016; An and Berg, 2018; Todaro et al., 2011). 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).

d. Allergenicity

The Codex 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 DMO protein sequence was

used as a query for a FASTA search of the AD_2020 database. Furthermore, no short (eight amino acid) polypeptide matches were shared between the DMO protein sequence and proteins in the allergen database. These data show that DMO protein sequence lacks both structurally and immunologically relevant similarities to known allergens, gliadins, and glutenins. Detailed MON 94100 canola allergenicity information can 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 94100 canola products from countries where canola is already approved and commercially grown, and that may enter Malaysia as oil, feedmeal, or food ingredients for processing or packaging or as finished products ready for distribution. 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, canola is not an indigenous species (OECD, 2000), and is not a major economic crop in Malaysia.

Therefore, MON 94100 canola is unlikely to germinate and establish upon accidental spillage in Malaysia.

7. What is the emergency response plan?

MON 94100 canola 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 action 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 94100 canola and its products may be handled and stored as any conventional canola products.

d. Disposal consideration

The same measures for waste disposal and treatment as for conventional canola are valid for MON 94100 canola.

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 in this Fact Sheet. 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 3 May 2022 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
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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