**FACT SHEET**

**APPLICATION FOR APPROVAL FOR RELEASE OF PRODUCTS OF RT73 CANOLA FOR SUPPLY OR OFFER TO SUPPLY FOR SALE OR PLACING IN THE MARKET**

**NBB REF NO: JBK(S) 600-2/1/4**

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 RT73 canola 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 RT73 canola. This means that RT73 canola 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 RT73 canola is not intended for cultivation in Malaysia.

## 3. How has RT73 canola been modified?

RT73 canola has been genetically modified to be glyphosate-tolerant. RT73 canola produces the 5-enolpyruvylshikimate-3-phosphate synthase protein from *Agrobacterium* sp. strain CP4 (CP4 EPSPS) and the modified Glyphosate oxidoreductase (GOXv247) protein from the bacterium *Ochrobactrum anthropi* strain LBAA. Both these proteins (CP4 EPSPS and GOXv247) confer tolerance to glyphosate, which is the active ingredient in Roundup® agricultural herbicides.

## 4. Characteristics of RT73 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 belongs to the Brassicaceae family, also known as the mustard family. Biology documents on the unmodified plant species, canola (Brassica napus L.), have been published by the Australia Office of the Gene Technology Regulator , Canadian Food Inspection Agency and by the Organisation for Economic Co-Operation and Development. 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 (formerly known as the Rapeseed Association 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.

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 15% of world vegetable oil consumption after soybean oil at 28% and palm oil at 32%.

RT73 may enter Malaysia as oil, feedmeal, or food ingredients for processing or packaging or as finished products ready for distribution.

**b. Donor organism**

*Agrobacterium* sp. strain CP4 is the source of the *cp4 epsps* gene and *Ochrobactrum anthropic* strain LBAA is the source of the *goxv247* gene.

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

RT73 canola and all canola lines/ varieties derived from this event contain the *cp4 epsps* and *goxv247* coding sequences derived from *Agrobacterium* sp. strain CP4 and *Ochrobactrum anthropic* strain LBAA, which are ubiquitous in the environment. The CP4 EPSPS and GOX v247 proteins provide tolerance to glyphosate application.

**d. Safety of the Expressed Proteins**

Information and data from studies support the safety of the CP4 EPSPS and GOX v247 proteins and demonstrate that these proteins are unlikely to be an allergen or toxin. This is based on the assessments of the donor organisms, *Agrobacterium* sp. strain CP4 and *Ochrobactrum anthropic* strain LBAA, which are not known to be human or animal pathogens and there are no reports of allergies derived from these organisms. Examination of the CP4 EPSPS and GOX v247 amino acid sequences against a bioinformatics database showed a lack of significant structural similarity between the CP4 EPSPS, GOX v247 proteins and known allergens or pharmacologically active proteins. In addition, studies using CP4 EPSPS and GOX v247 proteins have respectively demonstrated that the proteins were digested rapidly in simulated digestive fluid, and ingestion of the proteins did not cause acute toxicity in mice. These data are consistent with the conclusion of safety for CP4 EPSPS and GOX v247 proteins.

**5. Assessment of Risks to Human Health**

No significant health hazards are currently associated with this product. RT73 canola is substantially equivalent to conventional canola, which has no specific detrimental health effects.

**a. Nutritional Data**

Canola seeds derived from RT73 canola are compositionally and nutritionally equivalent to those of the conventional canola. Canola seeds contains several anti-nutritional factors, which

include: erucic acid, sinapine and glucosinolates. Compositional analyses of the canola seeds indicated that erucic acid, sinapine and glucosinolates were present at similar levels in RT73 canola and control canola, and no statistical differences were observed for all comparisons.

### b. Toxicological Information

There is no known health hazards associated with the product. It is not known to be capable of causing allergic sensitization. Studies have shown no toxicity toward mammals. Additionally, there are no amino acid sequences similarities to known toxins.

### c. Pathogenicity

*Agrobacterium* sp. strain CP4 and *Ochrobactrum anthropic* strain LBAA have no known pathogenicity and allergenicity to humans, animals and non-target 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 RT73 canola products from countries where canola is already approved and commercially grown, and that may enter Malaysia as oil, foodstuffs or as feedmeal for further processing.

## 7. What is the Emergency Response Plan?

RT73 canola and food and feed products derived from it have been assessed as being as safe as its conventional 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 and subsequently 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 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 procedures are required for this product. Handle as any canola products. No special storage procedures are required for this product. Store as any canola products.

### d. Disposal Consideration

RT73 is equivalent to conventional canola with the exception of glyphosate tolerance. Waste from RT73 can be treated similar to conventional canola waste.

## 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 and 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 to 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 6 February 2020 and written submissions are required by that date. Submissions must be addressed to:

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Ministry of Water, Land and Natural Resources
Level 1, Podium 2, Wisma Sumber Asli
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**Please include your full name, address and contact details in your submission.**