FACT SHEET

APPLICATION FOR APPROVAL FOR RELEASE OF PRODUCTS OF H7-1 SUGAR BEET FOR SUPPLY OR OFFER TO SUPPLY FOR SALE OR PLACING IN THE MARKET

NBB REF NO: JBK(S) 600-2/1/13

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 H7-1 sugar beet 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 H7-1 sugar beet. This means that H7-1 sugar beet may enter Malaysia as pure and raw sugar (sucrose) as food ingredients for processing or packaging or as finished products ready for distribution, or as dried pulp and molasses for use as feed meal for animals. The H7-1 sugar beet is not intended for cultivation in Malaysia.

3. How has H7-1 sugar beet been modified?

Genetically modified H7-1 sugar beet was produced by insertion of the *cp4 epsps* gene from *Agrobacterium* sp. strain CP4 into the genome of conventional sugar beet using *Agrobacterium*-mediated transformation method. H7-1 sugar beet produces the protein 5-enolpyruvylshikimate-3-phosphate synthase (CP4 EPSPS) which confers tolerance to the herbicide glyphosate

4. Characteristics of H7-1 sugar beet

a. Details of the parent organism

The recipient or parental plant is *Beta vulgaris,* also known as sugar beet. Sugar beet (*Beta vulgaris* L. ssp. *vulgaris* var. *altissima*) belongs to the family *Chenopodiaceae* and the genus *B. vulgaris* comprises several cultivated forms of *B. vulgaris* subsp. *vulgaris*. Cultivars include leaf beet (i.e., Swiss chard) and beetroot (i.e., red table beet). Sugar beet is cultivated worldwide, but primarily in warm and temperate climates with sufficient precipitation. Sugar beet root is seldom used directly for food or feed, but is processed into refined sugar for food and molasses and pulp for feed uses.

b. Donor organism

Characteristics of *Agrobacterium* sp*.*

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

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

H7-1 sugar beet contains a *cp4 epsps* gene derived from *Agrobacterium* sp. strain CP4 that expresses CP4 EPSPS protein to confer tolerance to glyphosate herbicide.

d. Safety of the expressed proteins

Information and data from studies demonstrate that the CP4 EPSPS protein is unlikely to be an allergen or toxin. This is based on the assessment of the donor organism, *Agrobacterium* sp. strain CP4, which is not a known human or animal pathogen and there are no reports of allergies derived from the organism. The CP4 EPSPS and native plant EPSPS enzymes are functionally equivalent except for their tolerance to glyphosate. Bioinformatics was used to compare the CP4 EPSPS amino acid sequence against known allergens and pharmacologically active proteins and the results showed a lack of significant structural similarity between the CP4 EPSPS protein and known allergens or pharmacologically active proteins. In addition, studies using the CP4 EPSPS protein has demonstrated that the protein was digested rapidly in simulated digestive fluid, and ingestion of the protein did not cause acute toxicity in mice. These data support the safety for CP4 EPSPS protein.

e. Utilization of sugar beet

Sugar beet is used for the production of sugar and sugar is mainly used as a food ingredient. By-products of sugar production as pulp and molasses are used as animal feed. When sugar beet is grown in areas of livestock production, leaves of the plant may also be used for fodder. Feed products from sugar beet are high in fibre and energy. Therefore, they are primarily used in feeding ruminants (dairy cows, beef cattle, sheep), but can also be fed to non-ruminants. Sugar beet tops are usually ploughed under. In rare cases tops are ensiled or directly used in ruminant feeding. Wet pulp is typically pressed and dried for feeding purposes. In some regions mixtures of pulp and molasses are used for animal feed. Molasses is mainly used in animal feed or as a fermentation substrate (yeast, citric acid, alcohol, etc.). To a minor extent molasses is used for various industrial purposes such as fuels, rubber, printing, chemical and construction industries.

H7-1 sugar beet may enter Malaysia as pure and raw sugar (sucrose) as food ingredients for processing or packaging or as finished food products ready for distribution, or as or dried pulp and molasses for use as feed meal for animals.

5. Assessment of Risks to Human Health

a. Nutritional Data

Data obtained from compositional analyses conducted on the H7-1 sugar beet showed that out of a total of 55 statistical comparisons made between H7-1 and non-genetically modified sugar beet, seven of these comparisons were found to be statistically different, however, the ranges for the statistically different components overlapped or fell within the range of values observed for conventional sugar beet varieties. These results demonstrate that the levels of

key nutrients and other important components of H7-1 are compositionally equivalent to conventional sugar beet (non-genetically modified).

b. Toxicological Information

There are no known health hazards associated with the product. Studies conducted using the CP4 EPSPS protein have shown no toxicity toward mammals. Additionally, there are no amino acid sequences similarities of H7-1 sugar beet to known toxins.

c. Pathogenicity

Agrobacterium sp. strain CP4 is ubiquitous in the environment and has lack of reports of allergies derived from the organism.

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 H7-1 sugar beet products from countries where sugar beet is already approved and commercially grown, and that may enter Malaysia as foodstuffs or as feed or raw commodities (i.e., sugar, pulp and molasses) for further processing.

7. What is the Emergency Response Plan?

H7-1 sugar beet and food and feed products derived from it have been assessed as being as safe as its conventional non-genetically modified 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 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 Measure

No special measures are required in response to an accidental release. Spilled sugar, pulp and molasses 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. H7-1 sugar beet and its products may be handled and stored as any conventional sugar beet product.

d. Disposal Consideration

The same measures for waste disposal and treatment as for conventional sugar beet are valid for H7-1 sugar beet.

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 24 September 2020 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.