FACT SHEET

APPLICATION FOR APPROVAL FOR RELEASE OF PRODUCTS OF J163 ALFALFA FOR SUPPLY OR OFFER TO SUPPLY FOR SALE OR PLACING IN THE MARKET

NBB REF NO: JBK(S) 600-2/1/17

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 genetically modified J163 alfalfa 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 genetically modified J163 alfalfa. J163 alfalfa may enter Malaysia as hay to be used as feed meal for animals. The J163 alfalfa is not intended for cultivation in Malaysia.

3. How has J163 alfalfa been modified?

Genetically modified J163 alfalfa was produced by insertion of the *cp4 epsps* gene from *Agrobacterium sp*. strain CP4 into the genome of conventional alfalfa using an *Agrobacterium*-mediated transformation method. J163 alfalfa produces the protein 5-enolpyruvylshikimate-3-phosphate synthase (CP4 EPSPS) which confers tolerance to the herbicide glyphosate.

4. Characteristics of J163 alfalfa

a. Details of the parent organism

The recipient or parental plant is *Medicago sativa* L.*,* also known as alfalfa. Alfalfa (including both cultivated alfalfa and closely related subspecies) originated in Asia Minor, Transcaucasia, Turkmenistan, and Iran. Also known as lucerne, it has the longest history of any plant grown solely for forage. Due to its importance as an animal feed, it has spread globally and become acclimatized in Australia, New Zealand, North America, South America, and South Africa. Alfalfa is an important forage crop and as a legume, it is also desired for rotational use to improve soil characteristics such as nitrogen content.

b. Donor organism

Characteristics of *Agrobacterium sp.*

Agrobacterium sp. 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 (FAO-WHO, 1991).

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

J163 alfalfa 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 have 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 alfalfa

Throughout history, the primary use of alfalfa has been as animal feed source for ruminant animals, including dairy cows, beef cattle, sheep, and goats, as well as for some non-ruminant animals, particularly horses. Greater than 95% of alfalfa used on farms is hay, silage, or haylage which is field dried or dehydrated hay. Other forms include greenchop or dehydrated pellets. Dairy producers are the largest purchasers of alfalfa hay in supreme and premium grades.

Minor food uses include the consumption as dietary supplements, herbal remedies and sprouts in many countries. J163 alfalfa may enter Malaysia as hay, or as feed meal for animals.

5. Assessment of Risks to Human Health

a. Nutritional Data

The compositional analyses of J163 forage showed that for 35 components statistically evaluated, statistically significant differences were observed for the level of some of the analytes in comparison to the control. Where values were different, the means were within the 99% tolerance interval developed from the existing alfalfa varieties. Hence, these differences are unlikely to be biologically meaningful. The applicant concludes from these results that forage produced by alfalfa plants containing J163 is comparable to forage produced by control or conventional alfalfa varieties.

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 the CP4 EPSPS protein to known toxins.

c. Pathogenicity

Agrobacterium sp. strain CP4 is ubiquitous in the environment and not known to be associated with any 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 J163 alfalfa products from countries where alfalfa is already approved and commercially grown, and that may enter Malaysia as hay or as feed for further processing. There are no viable alfalfa materials associated with the J163 alfalfa products imported into Malaysia. Alfalfa hay does not contain viable plant materials.

7. What is the Emergency Response Plan?

J163 alfalfa 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. Nonetheless, spilled import forms such as hay or feed meals for further processing 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. J163 alfalfa and its products may be handled and stored as any conventional alfalfa product.

d. Disposal Consideration

The same measures for waste disposal and treatment as for conventional alfalfa are valid for J163 alfalfa.

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 25 March 2021 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.