FACT SHEET

APPLICATION FOR APPROVAL FOR RELEASE OF PRODUCTS OF J101 ALFALFA FOR SUPPLY OR OFFER TO SUPPLY FOR SALE OR PLACING IN THE MARKET

NBB REF NO: JBK(S) 600-2/1/16

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 J101 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 J101 alfalfa. J101 alfalfa may enter Malaysia as hay, or as feed meal for animals. The J101 alfalfa is not intended for cultivation in Malaysia.

3. How has J101 alfalfa been modified?

Genetically modified J101 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. J101 alfalfa produces the protein 5-enolpyruvylshikimate-3-phosphate synthase (CP4 EPSPS) which confers tolerance to the herbicide glyphosate.

4. Characteristics of J101 alfalfa

a. Details of the parent organism

The recipient or parental plant is *Medicago sativa* L.*,* also known as alfalfa. Including both cultivated alfalfa and closely related subspecies, alfalfa 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. Forage is harvested from two to eleven times a season depending on the region and the system of management. Alfalfa is among the most important forage crops in the United States and ranks as the fourth most widely grown crop by acreage, after corn, soybean, and wheat. 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 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

J101 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 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 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. Alfalfa forage is harvested and fed as hay, silage, haylage, greenchop, or dehydrated pellets. Greater than 95% of alfalfa used on farms is hay, silage, or haylage. The vast majority of alfalfa purchased as feed is sold as field dried or dehydrated hay. Dairy producers are the largest purchasers of alfalfa hay and the largest consumers of high-quality hay in supreme and premium grades.

Minor food uses include the consumption as dietary supplements, herbal remedies and sprouts in many countries. Although it is possible for J101 alfalfa to be present through adventitious presence in alfalfa minor food uses, J101 alfalfa is not sold for direct food consumption in the U.S. or globally and farmers are not allowed to plant J101 alfalfa for food uses. J101 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 J101 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. These data are consistent with the conclusion that forage produced by alfalfa plants containing J101 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 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 J101 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 J101 alfalfa products imported into Malaysia. Alfalfa hay does not contain viable plant materials.

7. What is the Emergency Response Plan?

J101 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. J101 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 J101 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 December 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.