FACT SHEET

APPLICATION FOR APPROVAL FOR RELEASE OF PRODUCTS OF GA21 CORN FOR SUPPLY OR OFFER TO SUPPLY FOR SALE OR PLACING IN THE MARKET

NBB REF NO: JBK(S) 602-1/1/24

The objective of the Biosafety Act is to protect human, plant and animal health, the environment and biological diversity. Under the Biosafety Act, the National Biosafety Board (NBB) is currently assessing an application for approval submitted by Syngenta Crop Protection Sdn. Bhd.

1. What is the application for?

This application is to import and release GA21 corn (*Zea mays* L.) 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 GA21 corn for direct use as food and feed and for processing (FFP).

3. How has the GA21 corn been modified?

Corn derived from insertion event GA21 is genetically modified (GM) to produce a protein that provides tolerance to glyphosate herbicides. This protein, a modified 5-enolpyruvylshikimate-3-phosphate synthase (mEPSPS), is expressed from the gene *mepsps*, a variant of the native *epsps* from corn. GA21 corn was produced via microprojectile bombardment of corn cells in suspension culture. This is described in the International Patent PCT/US98/06640. Expression of the gene *mepsps* encoding the modified mEPSPS enzyme is controlled in part by the rice actin promoter intron sequences and the NOS 3' termination sequence derived from the Ti plasmid of the plant pathogen *Agrobacterium tumefaciens*.

4. Characteristics of GA21 maize

(a) Details of the parent organism

The recipient or parental plant is *Zea mays* L. (corn), also known as maize. Corn is one of the world's leading cereal crops, ranked after wheat and rice, and is grown in over 25 countries. Corn has a long history of safe use as food for consumption by humans and other animals. No significant native toxins are reported to be associated with the genus *Zea.* Corn is cultivated worldwide and represents a staple food for a significant proportion of the world's population. A major proportion of grain and forage derived from corn is used in animal feed. Corn-derived products are also routinely used in a large number and diverse range of foods for human consumption. Such products include flour, breakfast cereals, high fructose corn syrup and starch products. Corn grain is also used to produce industrial products, such as ethanol by fermentation.

(b) Details of the donor organism

The donor organism is also *Zea mays* (maize; corn).

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

GA21 corn expresses a modified version of the *epsps* gene that occurs naturally in corn. The native 5-enolpyruvylshikimate-3-phosphate synthase (EPSPS) in corn is an enzyme in the shikimate pathway, involved in the synthesis of aromatic amino acids in plants and microbes. (The shikimate pathway does not occur in animals.) The native EPSPS is inhibited by glyphosate. The mEPSPS produced by GA21 corn has lower affinity for glyphosate, thus conferring tolerance to glyphosate in herbicide products. When corn plants producing mEPSPS are treated with glyphosate, the plants are unaffected because the continued action of the tolerant mEPSPS enzyme meets the plant's needs for aromatic amino acids.

(d) Safety of the expressed protein

Both the native corn EPSPS and mEPSPS have a long history of safe use, as they are widely consumed in corn crop commodities. Because of the ubiquitous occurrence of EPSPS proteins in microorganisms and plants it is likely that small amounts of EPSPS from various sources have always been present in the food and feed supply. Humans have a long history of dietary exposure to EPSPS proteins from the endogenous proteomes of microorganisms and certain plant species and their presence in many commercially available transgenic crop plants, including corn and soybean. No adverse effects associated with intake of mEPSPS or other EPSPS proteins have been reported.

5. Assessment of Risks to Human Health

Food and feed products derived from GA21 corn are not materially different from food and feed products derived from conventional corn.

(a) Nutritional Data

GA21 corn grain is compositionally equivalent to nontransgenic corn grain in terms of proximate composition, key nutrients, vitamins, minerals, and anti-nutrients. There are no biologically significant differences between GA21 corn and nontransgenic corn, with the exception of the intended expression of the mEPSPS protein, which has been demonstrated to be safe for food and feed uses.

(b) Toxicology

Both the native EPSPS and the modified corn EPSPS (mEPSPS) proteins have a long history of safe use, as they are widely consumed in corn crop commodities. The mEPSPS protein in GA21 corn is greater than 99% identical in amino acid sequence to the native corn EPSPS protein, and has been demonstrated to be nontoxic in acute toxicity tests in mammals. The mEPSPS enzyme retains the native function of corn EPSPS, which is to enable the synthesis of aromatic amino acids via the shikimate pathway; this pathway does not occur in animals. The mEPSPS protein is readily digested in simulated mammalian gastric and intestinal fluids and lacks biologically relevant amino acid sequence similarity to known or putative toxins.

(c) Allergenicity

Both the native corn EPSPS and mEPSPS proteins in GA21 corn have a long history of safe use, as they are widely consumed in corn crop commodities. The mEPSPS protein is not likely to allergenic. The source organism (corn) from which mEPSPS was derived

is a common food source globally. The mEPSPS protein has no biologically relevant amino acid sequence similarity to allergens, and does not share biochemical properties in common with known or putative food allergens; mEPSPS is rapidy digested by simulated gastric and intestinal fluids, is not heat stable, and is not glycosylated.

6. Assessment of Risks to the Environment

There are no intentions to cultivate GA21 corn in Malaysia. The release is intended only to cover the import of the GA21 corn products from countries where the corn is approved for commercial cultivation purposes. GA21 corn may enter Malaysia as food ingredients for processing or packaging, as finished products ready for distribution, or as animal feed meal or pellets.

7. What is the Emergency Response Plan?

(a) First Aid Measures

No special first aid measures are required for exposure to this product.

(b) Accidental Release Measures

It is possible for seed to be accidentally released during transport however corn is not weedy in character. Corn has lost the ability to survive without cultivation and is very uncompetitive against perennial vegetation. The agronomic and phenotypic characteristics of GA21 corn were compared to those of conventional corn. No differences indicative of increased weediness potential were observed in plant growth habit, vegetative vigor, flowering characteristics or yield.

(c) Handling and Storage

There are no specific instructions or recommendations for use, storage and handling of GA21 corn. The characteristics of GA21 corn and products derived from it are not different from those of conventional corn, apart from the introduced mEPSPS trait. The same measures for handling and storage for conventional corn are valid for GA21 corn.

(d) Disposal Considerations

GA21 corn has been assessed as being as safe as its conventional non-GM corn counterpart. Waste grain and processed products from GA21 corn may be disposed of and treated in the same way as grain and processed products of non-GM corn.

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. 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 of 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 or 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 **30th October 2015** and written submissions are required by that date. Submissions must be addressed to:

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Please include your full name, address and contact details in your submission.