

FACT SHEET

APPLICATION FOR APPROVAL FOR RELEASE OF PRODUCTS OF BT11 MAIZE FOR SUPPLY OR OFFER TO SUPPLY

NBB REF NO: JBK(S) 602-1/1/6

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 the Syngenta Crop Protection Sdn. Bhd.

1. What is this application for?

To import and release products of Bt11 maize/corn (insect-resistant and herbicide-tolerant maize)

2. What is the purpose of the import and release?

The aim of the import and release is to supply or offer to supply for sale/placing on the market - for direct use as food, feed and for processing (FFP).

3. How has the Bt11 maize been modified?

Bt11 corn has been genetically modified to be protected against feeding damage caused by the larvae of certain insect pest species, mainly European corn borer (*Ostrinia nubilalis*). Protection is achieved through the expression in the plant of an insecticidal protein derived from *Bacillus thuringiensis*, a common soil bacterium. Bt11 corn also shows tolerance to glufosinate ammonium herbicides through expression of the *pat* gene.

Bt11 maize/corn contains two novel genes. The first, *cry1Ab*, derived from *Bacillus thuringiensis*, encodes the insecticidal protein Cry1Ab. The second, *pat*, is present as a selectable marker and encodes the enzyme phosphinotrichin acetyl transferase (PAT) and is capable of detoxifying glufosinate ammonium herbicides.

4. Characteristics of the Bt11 maize

(a) Details of the parent organism

The recipient or parental plant is *Zea mays* L. spp *mays* (field or sweet maize). The maize plant has been genetically modified to protect itself from attacks of insect corn borers, mainly European corn borer (*Ostrinia nubilalis*).

Maize (or corn) is one of the world's leading cereal crops, behind wheat and rice, and is grown in over 25 countries. Maize covers about 140 million ha in the world; this plant has no detrimental effect on the environment. Moreover, maize has no wild relatives in Asia; therefore, it cannot hybridize with any other species in the Asia.

Foodstuffs derived from corn or maize kernel based ingredients such as oil, high fructose corn syrup, and starch products may include canned or frozen corn, flour, breakfast cereals, snack foods, bakery products, confectionery and food coatings.

Bt11 may enter Malaysia as food ingredients for processing or packaging or as finished products ready for distribution, or as feed meal or pellets for animals.

(b) Donor organism

Bacillus thuringiensis var *kurstaki*, source of *cry1Ab* gene which produces crystal protein effective as insecticide against specific group of insects and *Streptomyces viridochromogenes* which produces the *pat* gene encoding an enzyme, the phosphinotricin-N-acetyl transferase that detoxifies glufosinate ammonium

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

Bt 11 maize/corn and all corn lines/hybrids derived from this event contain the *cry1ab* coding sequence derived from *Bacillus thuringiensis* var *kurstaki* which is a common soil bacterium. The *cry1ab* gene encodes for the production of Cry1Ab (Btk) protein. This crystal protein protects the plant from insect damage. When eaten by the insects and corn pests, the *Btk* protein is broken down by digestive enzymes in the larva's alkaline intestine, generating a shorter protein that binds to the wall of the intestine. This damages the cell membrane, making it leaky, and stops the larva in its tracks. This corn event also contains the marker gene *pat* derived from the soil bacterium *Streptomyces viridochromogenes*. The *pat* coding sequence encodes for the production of phosphinotricin acetyl-transferase (PAT) protein. This protein gives the plant tolerance to glufosinate ammonium, an active ingredient in herbicide. The glufosinate ammonium inhibits the glutamine synthetase in plants, resulting in an accumulation of ammonia in plant tissues leading to its death.

(d) Safety of the Expressed Proteins

Mammalian toxicity studies conducted using Btk and PAT test material did not reveal any harmful effects. The amino acid sequence of the truncated Btk protein expressed in Bt11 maize/corn is closely related to the sequence of the same proteins that are present in strains of *B. thuringiensis* that have been used as commercial organic microbial insecticides. An analysis of the amino acid sequences of the inserted Btk and PAT proteins did not show homologies with known mammalian protein toxins and they are not assessed to have any risk for human toxicity. The truncated *Btk* and PAT proteins expressed in Bt11 maize/corn do not possess characteristics typical of known protein allergens. There were no regions of homology when the sequences of these introduced proteins were compared to the amino acid sequences of known protein allergens. Unlike known protein allergens, both of these proteins are rapidly degraded by acid and/or enzymatic hydrolysis when exposed to simulated gastric fluids. The Btk and PAT proteins are extremely unlikely to be allergenic.

(e) Assessment of Risks to Human Health

No significant health hazards are currently associated with this product. Potential health effects associated with the product or exposure to its dusts include those described below.

Toxicological Information

There are 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. In addition, there are no amino acid sequence similarities to known mammalian toxins.

Carcinogenicity

To the best of our knowledge, this product does not contain any substances that are considered by the US Occupational Safety and Health Administration (OSHA), National Toxicology Program (NTP), or the International Agency for Research on Cancer (IARC) to be probable or suspected human carcinogens. To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

Pathogenicity

Bacillus thuringiensis var kurstaki has no known pathogenicity and allergenicity to humans, animals and non-target organisms.

Streptomyces viridochromogenes has no known pathogenicity and allergenicity to humans, animals and non-target organisms.

(f) Assessment of Risks to the Environment

Environmental Assessment

The application does not cover an environmental release. The release is intended only to cover the import of the Bt11 maize/corn products from countries where the corn is already approved and commercially grown, and that may enter Malaysia as foodstuffs or as feed or for further food processing.

Nutritional Composition (Compositional Analysis)

The grain analysis, protein, oil, starch and fiber content of the ECB resistant maize lines were shown to be substantially equivalent to the untransformed maize. The proximate analysis (protein, fat, fiber and starch.) of the ECB resistant maize hybrids gave values well within the published range for traditional maize cultivars. Under the same agronomic condition, the analysis of nutrients (the levels of protein, calcium, magnesium, phosphorus and potassium) from Bt11 maize/corn and its conventional counterpart did not reveal any significant differences.

Anti-Nutritional Factors

Few anti-nutrients have been reported to occur in corn which has no relevance for its food use. Regarding the feed use of corn, phytic acid reduces the availability of phosphorus, especially in mono-gastric animals. There are no toxic or anti-nutritional factors present in corn which would need to be controlled by a specification. Though trypsin inhibitor, phytic acid, and secondary metabolites such as raffinose, ferulic acid and p-coumaric acid have been established as anti-nutrients in corn, they are present in very low amount and are below the thresholds considered to raise a food safety concern. The amount of anti-nutrients present in Bt11 maize/corn fell within the range found in non-transgenic corn. Results of animal feeding studies demonstrated similar performance between animals fed with Bt11 maize/corn and conventional maize. Feeding studies done with cattle showed that there was no effect on dry matter intake, milk production, milk composition or a number of rumen parameters relating to feed utilization. Similarly, there were no significant differences observed for feed intake, bodyweight, egg production and egg weight in laying hens.

5. What is the Emergency Response Plan?

Bt11 maize/corn and food and feed products derived from it have been assessed as being safe as its conventional non-GM counterparts and there are no reports of adverse effects since its commercialization in 1996. Should adverse effects be reported and verified, appropriate follow up action would be taken to investigate these and if verified appropriate action taken.

First Aid Measures

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

Accidental Release Measure

No special measures are required in response to an accidental release. Spilled seed should be swept, scooped or vacuumed in a manner that avoids dust generation and dust-related hazards.

Handling and Storage

No special handling procedures are required for this product. Handle as any corn seed product. No special storage procedures are required for this product. Store as any corn seed product.

Disposal Considerations

There are no constraints to the disposal of this product. Empty containers should be discarded. Empty containers should not be used for other purposes. No materials used in this study should enter the food and feed chain, including unused corn material or derived feed, animal parts or carcasses. Disposal should be via incineration, autoclave or in the case of unused starting material return to the company in secure, clearly labeled double walled containers. Disposal should be managed in accordance with local, state or federal regulations.

6. 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 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 **12 January 2012** and written submissions are required by that date. Submissions must be addressed to: Director General, Department of Biosafety, Ministry of Natural Resources and Environment, Level 1, Podium 2, Wisma Sumber Asli, No. 25, Persiaran Perdana, Precinct 4, 62574 Putrajaya, MALAYSIA. E-mail: biosafety@nre.gov.my. Fax: 03-88904935.

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

