

**FACT SHEET**  
**APPLICATION FOR APPROVAL FOR RELEASE OF PRODUCTS OF**  
**5307 CORN**  
**FOR SUPPLY OR OFFER TO SUPPLY FOR SALE OR PLACING IN THE MARKET**

**NBB REF NO: JBK(S) 602-1/1/21**

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 of 5307 corn (maize; *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 5307 corn for direct use as food and feed and for processing (FFP). The said corn event is not intended for cultivation in Malaysia

**3. How has the 5307 corn been modified?**

Corn event 5307 (marketed under the brand name Syngenta Agrisure Duracade™) is genetically modified (GM) to produce a protein, that controls corn rootworm (*Diabrotica spp.* [Coleoptera]). This protein, eCry3.1Ab, is a chimeric protein engineered by combining portions of two *cry* genes modified *cry3A* (*mcry3A*) and *cry1Ab* each of which is derived from a native gene of *Bacillus thuringiensis*, a ubiquitous soil bacteria . Additionally, a marker transgene, *pmi*, has been added to allow the selection of transformed plants during development. The *pmi* gene was isolated from the common bacteria, *Escherichia coli*. The protein vector pSYN12274. produced by this gene is the enzyme phosphomannose isomerase (PMI). 5307 corn was produced by *Agrobacterium tumefaciens*–mediated transformation by using plasmid.

**4. Characteristics of 5307 corn**

**(a) Details of the parent organism**

The recipient or parental plant is *Zea mays* L. , also known as corn. 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*. 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 transgene *ecry3.1Ab* in 5307 corn expresses a chimeric protein engineered by combining portions of two *cry* genes modified *cry3A* (*mcry3A*) and *cry1Ab*. The native *cry3A* gene is derived from *B. thuringiensis* subsp. *tenebrionis* whereas the native *cry1Ab* gene is derived from *B. thuringiensis* subsp. *kurstaki*. Cry proteins from *B. thuringiensis*, have a long history of safe use in food crops and pesticide products.

The gene *pmi*, also known as *manA*, was derived from *E. coli* strain K-12, a non-pathogenic strain. *E. coli* is a normal inhabitant of the intestinal flora of humans and other animals, where it doesn't normally cause disease.

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

5307 corn contains the transgenes *ecry3.1Ab* and *pmi*. 5307 corn is tolerant against certain Coleoptera, including western corn rootworm (*Diabrotica virgifera virgifera*), northern corn rootworm (*D. longicornis barberi*), and Mexican corn rootworm (*D. virgifera zea*), which are significant pests of corn in the United States. Protection against coleopteran pests is provided through expression of eCry3.1Ab protein.

The amino acid sequence of the encoded mCry3A protein corresponds to that of the native Cry3A protein, except that its N-terminus corresponds to methionine 48 of the native protein and a cathepsin G protease recognition site has been introduced, beginning at amino acid residue 155 of the native protein. This modification increases the toxicity to target pests, particularly *D. virgifera virgifera* and *D. longicornis barberi*.

The *pmi* transgene, also known as *manA*, which encodes the enzyme phosphomannose isomerase. It was utilized as a plant selectable marker during development of 5307 corn. The PMI enzyme catalyzes the isomerization of mannose-6-phosphate to fructose-6-phosphate. It allows transformed corn cells to utilize mannose as a primary carbon source in culture media, whereas cells that lack *pmi* expression will fail to proliferate.

**(d) Safety of the expressed protein**

Cry proteins have been used in agriculture for many years and their safety has been well-established. Human safety has previously been established for a range of Bt crystal (Cry) proteins, and supports the prediction that no adverse health effects will result from exposure to the protein mCry3A present in 5307 corn.

The safety of PMI has been established previously and it is exempt from food and feed tolerances in all crops in the USA (US Code of Federal Regulations 40 CFR §174.527). Small amounts of PMI proteins have always been present in the food and feed supply as a result of the ubiquitous occurrence of PMI proteins in nature, including in food plants and animals. PMI proteins have been found in

such diverse plant species as tobacco, walnut and *Brassica* species as well as in seeds of soybeans and other legumes.

## **5. Assessment of Risks to Human Health**

Food and feed products derived from 5307 corn are not materially different from food and feed products derived from conventional corn. The mode of action of eCry3.1Ab, like that of most other Cry proteins, is highly specific to insects and is not operable in mammalian or other vertebrate species.

### **(a) Nutritional Data**

5307 corn grain is compositionally equivalent to non-transgenic corn grain in terms of proximate composition and concentrations of key nutrients, vitamins, minerals, and anti-nutrients. There are no biologically significant differences (including nutritional differences) between 5307 corn and non-transgenic corn, with the exception of the intended traits conferred by expression of the eCry3.1Ab and PMI proteins, which have been demonstrated to be safe for food and feed uses.

### **(b) Toxicology**

Both eCry3.1Ab and PMI proteins were demonstrated to be non-toxic at high doses in acute oral toxicity tests in mammals. PMI protein is a non-toxic enzyme involved in sugar metabolism, and eCry3.1Ab protein is toxic only to the larvae of certain Coleopteran insect species. Mammals, and other insects, lack the specific receptors necessary for eCry3.1Ab protein to exert its toxic action. Exposure to eCry3.1Ab and PMI proteins is expected to be minimal, because both proteins are rapidly digested in simulated mammalian gastric and intestinal fluids. 5307 corn grain is not toxic in feeding studies, and is compositionally equivalent to conventional maize grain.

### **(c) Allergenicity**

Neither eCry3.1Ab nor PMI proteins is likely to be allergenic, based on their derivation from nonallergenic source organisms (bacteria), a lack of biologically relevant sequence similarity to known allergens, minimal exposure following rapid digestion, and lack of glycosylation (a characteristic observed in some allergens). Exposure to eCry3.1Ab and PMI proteins is expected to be negligible, since each is rapidly digested in simulated gastric and intestinal fluids.

## **6. Assessment of Risks to the Environment**

The application does not cover an environmental release. The release is intended only to cover the import of the 5307 corn and its products from countries where the corn is already approved and commercially grown, and that may enter Malaysia as food, feed and for further processing (FFP).

## **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 (*Zea mays*) 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 characteristic of 5307 corn was compared to that of conventional maize. No differences indicative of increased weediness potential were observed in plant growth habit, vegetative vigor, flowering characteristics or yield.

Further, exposure in laboratory studies of nontarget invertebrates and/or mammals to eCry3.1Ab and PMI proteins at concentrations equal to or greater than estimated environmental concentrations via cultivation of 5307 corn showed no adverse effects.

### **(c) Handling and Storage**

There are no specific instructions or recommendations for use, storage and handling of 5307 corn. The characteristics of 5307 corn and products derived from it are not different from those of its conventional counterpart, apart from the introduced trait. The same measures for handling and storage for conventional corn are valid for 5307 corn.

### **(d) Disposal Considerations**

5307 corn has been assessed as being as safe as its conventional non-GM counterparts. Waste grain and processed products from 5307 corn may be disposed of and treated in the same way as grain and processed products on 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 **30<sup>th</sup> October 2015** 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, Periaran Perdana, Presinct 4, 62574  
Putrajaya, MALAYSIA.  
E-mail: [biosafety@nre.gov.my](mailto:biosafety@nre.gov.my).  
Fax: 03-88904935.**

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

**Reference**

US Code of Federal Regulations 40 CFR §174.527