

Regulatory Decision on the Application of Eggplant EE-1 for Commercial Propagation

I. Brief Identification of the Genetically Modified Organism

Designation: EE-1 Eggplant

Applicant: University of the Philippines Los Baños

Host Plant: *Solanum melongena* L.

Trait Description: Event EE-1 eggplant expresses a Cry1Ac protein that confers protection against the target insect pest, eggplant fruit and shoot borer (EFSB) (*Leucinodes orbonalis* Guenee). The plants also express an NPTII enzyme that acts as a selectable marker that enables the identification of transformed cells during the genetic modification, but with no function in the grown plant.

Trait Introduction Method: *Agrobacterium tumefaciens*-mediated transformation

Donor Organism(s): The donor organism for *cry1Ac* gene is *Bacillus thuringiensis* subsp. *kurstaki*, which is a spore-forming bacterium known for producing insecticidal proteins known as δ -endotoxins, while *nptII* gene encoding NPTII protein was derived from *Escherichia coli* strain K12, a ubiquitous facultative anaerobic species of bacteria commonly found in the human digestive tract.

Proposed Use: For commercial propagation

II. History of Safe Use of the Host Plant

Eggplant fruits have a long history of safe use as food, typically consumed cooked and have been part of the human diet. Some species of eggplant were used as purgative and treatment to ease urination problems, about 77 medicinal properties were recorded demonstrating the importance of eggplant in local medicine. There are few reports of allergic reactions, mainly from India and Asia, although severe cases are rare. Some of the reported allergens are polyphenol oxidase and Sola m 1 (abundant mainly in seeds).

III. Characteristics of Host Plant

Eggplant belongs to the nightshade family (Solanaceae) subgenus *Leptostemonum*, also called the “spiny” solanums. Eggplant has many common names that vary by region. For example, it is known as brinjal in India, talong in the Philippines, and aubergine in European countries. Eggplant is cultivated worldwide throughout the tropical and subtropical regions in Africa, Asia, America, Europe and Oceania. In temperate zones, eggplant is cultivated during the summer or in glasshouses. In most Asian countries, eggplant can be cultivated all year round. The greatest

diversity of landraces and cultivars is found in Asia (India, China and southeast Asia), with secondary centers in the Middle East and around the Mediterranean.

IV. Characteristic and safety assessment of the GM product

Apart from the intended genetic modification resulting in FSB resistance in Event EE-1 eggplant, there is no change in the agronomic and phenotypic characteristics of these plants compared with conventional eggplants. The integrity and order of the genetic elements are demonstrated through a series of Southern blot analyses, molecular, and sequence analyses of EE-1 eggplant. Multi-generational stability test using Southern blot analyses, shows that a single copy of *cry1ac* gene was stably inherited from one generation to the other. Moreover, Mendelian inheritance of *cry1Ac* and *nptII* transgenes across multiple generations of event EE-1-UPLB derived eggplants were assessed using gene-specific PCR analyses and results showed that the transgenes were stably inherited. Furthermore, Cry1Ac and NPTII proteins are found to be present in leaves, flowers, fruit flesh, fruit skin, stem and roots of EE-1 eggplant. It was determined that the highest concentration of Cry1Ac was found in the terminal leaves and flowers.

Bioinformatics analyses showed that the amino acid sequence of the Cry1Ac and NPTII proteins have no significant homology to any known toxins and Cry1Ac is only toxic to known target insects. The observed differences among the nutritional parameters (crude protein, crude fiber, ash content, potassium, iron, magnesium, and flavonoids) were within the 99% tolerance interval of the concurrently grown conventional varieties and/or within the range of published literature values. Therefore, these differences are unlikely to be of biological significance or cause adverse effects in humans or animals. It is noted that the EE-1 eggplant does not have weediness potential. Moreover, EE-1 eggplant has no significant adverse impact on the canopy and ground-dwelling non-target arthropod communities; species richness, diversity, and evenness of non-target arthropods do not differ between Bt and non-Bt eggplant.

Last 2013, Bangladesh approved the propagation and food use of EE-1 eggplant and is now being produced commercially in Bangladesh. EE-1 eggplant was also approved in the Philippines for direct use as food and feed, or for processing last 2021. EE-1 eggplant is found to be as safe as its counterpart based on the data presented and assessments.

V. Regulatory Decision

After reviewing the scientific data and information relevant to the application of the University of the Philippines Los Baños (UPLB), the Bureau of Plant Industry (BPI) has approved the commercial propagation for EE-1 eggplant. The BPI issued Biosafety Permit for Commercial Propagation of EE-1 eggplant with conditions that need to be complied with by UPLB. Copy of the Biosafety Permit issued may be accessed through the BPI Biotechnology website.