FACT SHEET

APPLICATION FOR APPROVAL FOR RELEASE OF PRODUCTS OF BPS-CV127-9 SOYBEAN FOR SUPPLY OR OFFER TO SUPPLY FOR SALE OR PLACING IN THE MARKET

NBB REF NO: JBK (S) 602-1/1/13

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 BASF (Malaysia) Sdn. Bhd.

1. What is the application for?

The scope of this application covers food and feed uses, import and processing of BPS-CV127-9 soybean.

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

The aim of the import is to supply or offer to supply for sale/placing on the market – for direct use as food, feed and processing (FFP). The said soybean event is not intended for cultivation in Malaysia.

3. How has the BPS-CV127-9 soybean been modified

CV127 soybean plants are tolerant to the imidazolinone class of agricultural herbicides. The BPS-CV127-9 event was produced by introduction of the acetohydroxyacid synthase large subunit (AHASL) gene (*csr1-2),* including its native promoter, from *Arabidopsis thaliana* into the soybean plant genome. The *csr1-2* gene is tolerant to imidazolinone herbicides due to a point mutation that results in a single amino acid substitution in which the serine residue at position 653 is replaced by asparagine (S653N). The herbicide tolerance in CV127 soybean will allow growers to treat the soybean crop with imidazolinone herbicides for weed control without causing injury to the soybean plant at normal field application rates.

4. Characteristics of BPS-CV127-9 soybean

(a) Details of the parent organism

The recipient or parental plant is the cultivated soybean [*Glycine max* (L.) Merr.]. Soybean is commonly considered one of the oldest cultivated crops used for food and feed purposes. Therefore, soybean can be regarded as a crop with a long history of safe use in the environment as well as use in food and feed products. The cultivated soybean is a highly

domesticated annual crop that does not persist outside of cultivated areas in unmanaged habitats.

Today soybean is grown as a commercial crop in more than 35 countries throughout the world. The major world producers of soybeans are the USA, Brazil, Argentina and China. The majority of soybeans are processed for soybean meal used in animal feed, and soybean oil for human food uses.

(b) Details of the donor organism

The genes integrated into the genome of BPS-CV127-9 soybean are derived from *A. thaliana*, a small flowering plant that is widely used as a model organism in plant biology. *A. thaliana* is not known to be pathogenic to humans or animals, nor is it known to be allergenic or the source of toxins. It is a member of the mustard family, which includes cultivated species such as cabbage and radish. Arabidopsis has been handled for many years in research with no known toxicity or allergenicity issues.

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

The transformation fragment contained a genomic fragment from *Arabidopsis thaliana*. This DNA fragment contains the *csr1-2* gene cassette which consists of the *csr1-2* gene from *A. thaliana* with its native promoter and 3' untranslated region that contains the polyadenylation signal. The *csr1-2* gene encodes the *A. thaliana* AHASL (AtAHASL) protein, which is responsible for the imidazolinone herbicide tolerance-trait in BPS-CV127-9 soybeans. In addition to the *csr1-2* gene, the transformation fragment also includes the majority of the *A. thaliana* gene encoding the SEC61γ subunit (AtSEC61γ). The At*SEC61γ* gene is only weakly transcribed in BPS-CV127-9 soybean leaf tissue and no detectable amounts of the AtSEC61γ protein are produced in either leaf tissues or grain of BPS-CV127-9 soybean.

(d) Safety of the expressed proteins

AHAS enzymes are ubiquitous in nature and AHAS protein has a history of safe consumption in food crops. The AtAHAS protein is highly homologous to, and has the same biological activity and mode of action as, the AHAS proteins that are present in all plants. AHAS with the respective S653N mutation as in BPS-CV127-9 soybean has been part of the human diet for many years in conventionally bred mutants that are commercialized under the Clearfield® brand name (Clearfield® is a registered trademark of BASF). In addition, the AHAS protein is expressed at extremely low levels in BPS-CV127-9 tissues. Highest levels of AHAS protein

were detected in young leaves (maximum value measured: 714 ng/g dry weight), whereas AHAS protein levels in all grain samples were at or below the limit of quantification in BPS-CV127-9 soybean. In processed fractions of BPS-CV127-9 soybean grain that are used in human foods as well as animal feeds the AHAS protein is present at detectable but not quantifiable levels.

5. Assessment of Risks to Human Health

(a) Toxicological Information

Absence of toxicity associated with the AtAHAS protein expressed in CV127 soybean was demonstrated by the following: *Arabidopsis thaliana*, the source organism of the *csr1-2* gene, is not known to produce toxic substances and is not a known human or animal pathogen. There is a long history of safe human consumption of AHAS proteins in plants. The AtAHASL protein encoded by the *csr1-2* gene is highly similar to the native soybean AHASL enzyme and is structurally and biologically closely related to the AHASL proteins in all plants. Several imidazolinone-tolerant crops that produce AHASL enzymes with the same serine to asparagine substitution at residue 653 that is present in CV127 soybeans have been commercialized and cultivated under the Clearfield® brand name for many years without any adverse environmental or health effects. The AtAHAS protein does not share any amino acid sequence homology with known toxins. The AtAHAS protein is rapidly inactivated by temperatures above 60℃ and is rapidly degraded in simulated digestive fluids. An acute oral toxicity study was conducted with purified AtAHAS protein and the results demonstrated no adverse effects in mice, which confirmed the non-toxic nature of the AtAHAS protein in mammals.

(b) Allergenicity

CV127 soybean is not likely to be more allergenic than its commercial comparator for the following reasons: The source organism of the *csr1-2* gene that encodes the AtAHAS protein in CV127 soybean, *Arabidopsis thaliana*, is not known to cause allergic reactions in humans. AtAHAS expressed in CV127 soybean has amino acid sequence homologous to other AHAS proteins with a history of safe use in food and feed products. Neither AtAHAS protein nor AtSEC61γ protein share any amino acid sequence homology to known protein food allergens. Both AtAHAS protein and AtSEC61γ protein are rapidly degraded in simulated digestive fluids and AtAHAS is rapidly inactivated by temperatures above 60°C.

(c) Nutritional composition

Compositional analyses conducted with grain from BPS-CV127-9 soybean and commercial soybean varieties demonstrate that the introduction of the *csr1-2* gene into the soybean genome does not impact the nutritional composition of grain produced by BPS-CV127-9

soybean. Components analyzed for grain included proximates (protein, fat, ash, carbohydrates, calories, and moisture), fiber, amino acids, fatty acids, minerals, vitamins, isoflavones, phospholipids, and antinutrients, such as phytate, raffinose, stachyose, lectin, urease and trypsin inhibitor. The levels of the analyzed components were comparable to the ranges in the conventional standard soybean varieties cultivated in the same trials, and/or were within the normal published ranges of values reported for soybeans. Also, imidazolinone herbicide application to BPS-CV127-9 soybean did not have a significant effect on grain nutrient and antinutrient composition. The results demonstrate that BPS-CV127-9 soybean is compositionally and nutritionally equivalent to currently grown conventional commercial soybean varieties.

7. Assessment of Risks to the Environment

The application does not cover cultivation in Malaysia. The application is intended only to cover the import of BPS-CV127-9 soybean products from countries where the soybean is commercially grown, and that may enter Malaysia as food, feed or for further processing.

8. What is the Emergency Response Plan?

The grain derived from BPS-CV127-9 soybean is intended to be imported for processing; there is no intention to plant the soybean in Malaysia. Specific detection methods are available to identify grain derived from BPS-CV127-9 soybean. The identified plants could be easily destroyed by herbicides other than imidazolinone herbicides or by mechanical means.

Grain and forage derived from BPS-CV127-9 soybean is compositionally equivalent to conventional soybean. The plants are agronomically and phenotypically equivalent to conventional soybeans, except for the intended resistance towards imidazolinone herbicides. However, in case information becomes available that indicates the possibility of an unanticipated adverse effect, BASF Plant Science will immediately investigate to determine and confirm whether a correlation between the observed effect and BPS-CV127-9 can be established. If the investigation confirms that BPS-CV127-9 is the cause of the adverse effect, appropriate action will be taken.

(a) First Aid Measures

No special first aid measures are required for exposure to BPS-CV127-9 soybean and derived products.

(b) Accidental Release Measures

No special measures are required in response to an accidental release. Spilled seed should be cleaned up according to common practice in conventional soybean handling. In the unlikely event that BPS-CV127-9 soybean plants resulting from unintended grain spillage would establish locally, these could be controlled as other commercial soybean following conventional practices, e.g. mechanically or by selective use of herbicides with the exception of imidazolinone herbicides.

(c) Handling and Storage

No specific management strategies for storage and handling of BPS-CV127-9 grain and derived products are required. Since the intended use of BPS-CV127-9 is the same as that of any other commercial soybean, the procedures for the import, handling and processing of BPS-CV127-9 will be the same.

(d) Disposal Considerations

Waste generated from the production of processed foods originating from BPS-CV127-9 soybean will be handled in the same way as waste produced from other commercial soybean. The same practices for waste disposal and treatment that are currently in place for other soybeans will also apply to BPS-CV127-9 soybeans.

9. How can I comment on this application?

Any member of the public may submit their comment or queries on publicly notified information about the application. Before submission of comments 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 25 June 2013 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 indicate your full name, address, and contact details in your submission.