FACT SHEET
APPLICATION FOR APPROVAL FOR RELEASE OF PRODUCTS OF MON 89788 SOYBEAN FOR SUPPLY OF OFFER TO SUPPLY FOR SALE OR PLACING IN THE MARKET

NBB REF NO: JBK(S) 602-1/1/9

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 Monsanto Singapore (Pte) Ltd.

1. What is the application for?

This application is to import and release products of MON 89788 glyphosate tolerant (Roundup Ready 2 Yield™) soybean.

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 for direct use as food, feed and for processing (FFP).

3. How has MON 89788 Roundup Ready 2 Yield soybean been modified?

MON 89788 Roundup Ready 2 Yield soybean has been genetically modified to be tolerant to glyphosate herbicides. MON 89788 was produced by incorporation of the *cp4 epsps* coding sequence derived from the common soil bacterium *Agrobacterium sp*. strain CP4. The *cp4 epsps* coding sequence directs the production of the 5-enolpyruvyl shikimate-3-phosphate synthase (termed CP4 EPSPS) that is less sensitive to inhibition by glyphosate compared to plant endogenous EPSPS. The CP4 EPSPS renders Roundup Ready 2 Yield soybean tolerant to glyphosate, which is the active ingredient in Roundup® agricultural herbicides.

4. Characteristics of MON 89788 Roundup Ready 2 Yield soybean

(a) Details of the parent organism

The recipient or parental plant is *Glycine max* (soybean). The soybean has been genetically modified to be tolerant to glyphosate, the active ingredient in Roundup® agricultural herbicides.

Soybean is the most commonly grown oilseed in the world. In 2008/09, approximately 211 MMT (millions metric tons) of harvested seed were

produced, representing 56% of the world's oilseed production. Soybean is grown as a commercial crop in over 35 countries. This plant has no detrimental effect on the environment. Soybean is a largely self-pollinated species, although low levels of natural cross-pollination can occur. In studies with cultivated soybean where conditions have been optimized to ensure close proximity and flowering synchrony, natural cross-pollination generally has been found to be very low.

Soybeans are used in various food products, including tofu, soy sauce, soymilk, energy bars, and meat products. Soybean meal is used as a supplement in feed rations for livestock. Soybean meal is the most valuable component obtained from processing the soybean, accounting for roughly 50-75% of its overall value. By far, soybean meal is the world's most important protein feed, accounting for nearly 65% of world supplies.

MON 89788 may enter Malaysia as grain, food ingredients for processing or packaging or as finished products ready for distribution, or as feed meal for animals.

(b) Details of the donor organism

Agrobacterium sp. strain CP4 is the source of the *cp4 epsps* gene. The *cp4 epsps* coding sequence directs the production of the 5-enolpyruvyl shikimate-3-phosphate synthase (termed CP4 EPSPS) that is less sensitive to inhibition by glyphosate compared to plant endogenous EPSPS. The CP4 EPSPS renders Roundup Ready 2 Yield soybean tolerant to glyphosate.

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

Roundup Ready 2 Yield soybean (MON 89788) and all soybean lines/ varieties derived from this event contain the *cp4 epsps* coding sequence derived from *Agrobacterium* sp. strain CP4 which is a common soil bacterium. The *cp4 epsps* coding sequence directs the production of the 5-enolpyruvyl shikimate-3-phosphate synthase (termed CP4 EPSPS) that is less sensitive to inhibition by glyphosate compared to plant endogenous EPSPS. The CP4 EPSPS renders Roundup Ready 2 Yield soybean tolerant to glyphosate.

(d) Safety of the Expressed Proteins

Information and data from studies also support the safety of the CP4 EPSPS protein and demonstrate that this protein is unlikely to be an allergen or toxin. This is based on the assessment of the donor organism, *Agrobacterium sp.* strain CP4, which is not a known human or animal pathogen and there are no reports of allergies derived from the organism. Examination of the CP4 EPSPS amino acid sequence against a bioinformatics database showed a lack of significant structural similarity between the CP4 EPSPS protein and known allergens or pharmacologically active proteins. In addition, studies using the purified CP4 EPSPS protein have demonstrated that the protein was digested rapidly in simulated gastric fluid, and ingestion of the protein did not cause acute toxicity in mice. These data are consistent with the conclusion of safety for CP4 EPSPS protein. This conclusion is further supported by the lack of any documented reports of adverse effects from the consumption of other Roundup Ready crops since 1996, all of which contain the same CP4 EPSPS protein as in MON 89788.

5. Assessment of Risks to Human Health

No significant health hazards are currently associated with this product. MON 89788 is substantially equivalent to conventional soybean, which have no specific detrimental health effects.

(a) 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. Additionally, there are no amino acid sequences similarities to known toxins.

(b) Carcinogenicity

The United States Environmental Protection Agency (EPA) considers glyphosate to be relatively low in toxicity, and without carcinogenic or teratagenic effects. The EPA considered a "worst case" dietary risk model of an individual eating a lifetime of food entirely from glyphosate-sprayed fields, and with residue levels remaining at their maximum levels, and concluded no adverse effects would exist under these conditions.

(c) Pathogenicity

Agrobacterium sp. strain CP4 has no known pathogenicity and allergenicity to humans, animals and non-target organisms.

6. Assessment of Risks to the Environment

(a) Environmental Assessment

The application does not cover an environmental release. The application is intended only to cover the import of Roundup Ready2Yield (MON 89788) soybean products from countries where soybean is already approved and commercially grown, and that may enter Malaysia as foodstuffs or as feed or grain for further processing.

(b) Nutritional Composition (Compositional Analysis)

Soybean grain and forage derived from MON 89788 are compositionally and nutritionally equivalent to those of the conventional soybeans.

(c) Anti-Nutritional Factors

Soybean grain contains several well-described anti-nutritional factors, which include: trypsin inhibitors, lections, isoflavones (daidzein, genistein and glycitein), stachyose, raffinose, and phytic acid. Both trypsin inhibitor and lectins are inactivated during processing of soybean protein products or soybean meal, and if processed appropriately, the final edible soybean fractions should contain minimal levels of these anti-nutrients. It is not universally accepted that the isoflavones are anti-nutrients as they have also been reported to have beneficial anti-carcinogenic effects (OECD, 2001).

7. What is the Emergency Response Plan?

MON 89788 soybean and food and feed products derived from it have been assessed as being as safe as its conventional non-GM counterparts and there are no reports of adverse effects since its commercialization. Should adverse effects be reported and verified, appropriate follow up action would be taken to investigate these, and if verified, appropriate action taken.

(a) First Aid Measures

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

(b) 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.

(c) Handling and Storage

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

(d) Disposal Consideration

MON 89788 is equivalent to conventional soybean with the exception of glyphosate tolerance. Waste from MON 89788 can be treated similar to conventional soybean waste.

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. 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 to 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 15 August 2012 and written submissions are required by that date. Submissions must be addressed to:

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