

Decision for the Safety Assessment of
Monsanto's Potato Bt-6 (RBBT02-06 & SPBT02-05)
For Renewal for Direct use as Food and Feed, or for Processing

Monsanto Philippines, Inc. submitted an application to renew Potato Bt-6 (RBBT02-06 & SPBT02-05) for Direct Use as Food and Feed, or for Processing to the Bureau of Plant Industry on November 7, 2008.

Potato Bt-6 (RBBT02-06 & SPBT02-05) is a discontinued product of Monsanto. As such, Monsanto is not developing new regulatory data of the discontinued product and no new additional information were generated after the said product discontinuance. However, Monsanto still applied for renewal of its permit for direct use as food and feed or for processing to address low level presence issues that may arise in the future. Monsanto Phils., Inc. has provided the renewal report for Potato Bt-6 (RBBT02-06 & SPBT02-05) in support to renew the biosafety permit for direct use as food and feed or for processing. The Scientific Technical Review Panel (STRP) reviewed the previous risk assessment documents of Potato Bt-6 (RBBT02-06 & SPBT02-05) which was previously confirmed by members of STRP to be as safe as conventional corn counterpart to determine the safety of the regulated article on human and animal health. The STRP was requested to provide list of available scientific studies/papers/literatures reviewed related to this transformation event including its highlights relevant to the said application

The petitioner/applicant published the petition notice of the application on two nationally circulated newspapers: Malaya and The Daily Tribune both on November 19, 2008. The publication was made to solicit public comments. The Bureau of Plant Industry received no comment on the petition during the 15 day comment period.

After reviewing the scientific data and information relevant to the application of Monsanto Phils., Inc., the Scientific Technical Review Panel concluded that Potato Bt-6 (RBBT02-06 & SPBT02-05) and all progenies derived from crosses of the product with any conventionally-bred potato, and potato containing approved-biotech events for direct use as food and feed or for processing is as safe and substantially equivalent to its unmodified counterpart, and was therefore recommended for approval for the renewal of its Biosafety permit for direct use as food and feed or for processing. The BPI Biotechnology Core Team in consultation with the Department of Agriculture-Biotechnology Advisory Team reviewed the results of the assessment of the STRP. The results of the final review concluded the safety of Potato Bt-6 (RBBT02-06 & SPBT02-05) for direct use as food and feed, or for processing.

A biosafety permit renewal for Potato Bt-6 (RBBT02-06 & SPBT02-05) and all progenies derived from crosses of the product with any conventionally-bred potato and potato containing approved-biotech events for direct use as food and feed or for processing was issued to Monsanto Phils., Inc. on December 22, 2008. The biosafety permit provides that "Potato Bt-6 (RBBT02-06 & SPBT02-05) is as safe for human food, animal feed and for processing as its conventional counterparts". The approval, however does not include cultivation of Potato Bt-6 (RBBT02-06 & SPBT02-05) in the Philippines. Potato Bt-6 (RBBT02-06 & SPBT02-05) will be included in the Approval Registry being prepared by the Department of Agriculture.

Monsanto Phils., Inc. informed the public of this approval by way of publishing in Manila Bulletin on March 6, 2009 that imports of this product is covered by conditions for approval as provided in Department of Agriculture Memorandum Circular No. 8, Series of 2003.