

Decision for the Safety Assessment of
MONSANTO'S Soybean 40-3-2 (Herbicide tolerant soybean)
For Renewal for Direct use as Food and Feed, or for Processing

Monsanto Philippines, Inc. submitted an application to renew Soybean 40-3-2 for Direct Use as Food and Feed, or for Processing to the Bureau of Plant Industry on May 12, 2008. Monsanto Phils., Inc. has provided latest scientific studies in support of the safety claims to renew the biosafety permit for direct use as food and feed or for processing. A dossier of relevant scientific studies on the regulated article of Soybean 40-3-2 and other related information was required to be submitted. The Scientific Technical Review Panel (STRP) reviewed all the document submissions to determine the safety of the regulated article on human and animal health.

The petitioner/applicant published the petition notice of the application on two nationally circulated newspapers- Manila Standard and Manila Times on June 23, 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 soybean 40-3-2 and all progenies derived from crosses of the product with any conventionally-bred soybean, and soybean 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 Soybean 40-3-2 for direct use as food and feed, or for processing.

A biosafety permit renewal for Soybean 40-3-2 and all progenies derived from crosses of the product with any conventionally-bred soybean and soybean containing approved-biotech events for direct use as food, feed or for processing was issued to Monsanto Phils., Inc. on July 22, 2008. The biosafety permit provides that "Herbicide tolerant Soybean 40-3-2 is as safe for human food, animal feed and for processing as its conventional counterparts". The approval, however does not include cultivation of Herbicide tolerant Soybean 40-3-2 in the Philippines. Soybean 40-3-2 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 November 26, 2008 that imports of this product is covered by conditions for approval as provided in Department of Agriculture Memorandum Circular No. 8, Series of 2003.