

Decision for the Safety Assessment of
MONSANTO'S Cotton 15985 (Insect resistant cotton)
For Renewal for Direct use as Food and Feed, or for Processing

Monsanto Philippines, Inc. submitted an application to renew Cotton 15985 for Direct Use as Food and Feed, or for Processing to the Bureau of Plant Industry on October 15, 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 Cotton 1445 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- Malaya and Daily Tribune both on November 1, 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 Cotton 15985 and all progenies derived from crosses of the product with any conventionally-bred cotton, and cotton 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 Cotton 15985 for direct use as food and feed, or for processing.

A biosafety permit renewal for Cotton 15985 and all progenies derived from crosses of the product with any conventionally-bred cotton and cotton containing approved-biotech events for direct use as food, feed or for processing was issued to Monsanto Phils., Inc. on December 5, 2008. The biosafety permit provides that "Insect resistant Cotton 15985 is as safe for human food, animal feed and for processing as its conventional counterparts". The approval, however does not include cultivation of Insect resistant Cotton 15985 in the Philippines. Cotton 15985 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 December 31, 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.