

Decision for the Safety Assessment of  
**MONSANTO's** Cotton 531 x 1445  
For Renewal for Direct Use as food and feed or for processing

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Monsanto Philippines, Inc. submitted an application to renew Cotton 531 x 1445 for direct use as food and feed or for processing to the Bureau of Plant Industry on November 06, 2009. Monsanto Philippines, 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 Cotton 531 x 1445 were provided to the Scientific Technical Review Panel (STRP) who reviewed all the documents submissions to determine the safety of the regulated article on human and animal health.

Section 7 of DA Memorandum Circular No 6 requires that any petition for a renewal for food and feed or for processing (FFP) should be submitted to the BPI not later than three (3) months prior to expiration of existing permit. The assessment for stacked product is not different from single event. The review of new information took two steps: wherein assessment will start with the single transformation event (TE) and there should be no new information on adverse effect of single TE. Additionally, on the evaluation of possible interaction based on new information, there is no observed interaction reported in the scientific literature. During the preliminary conduct of research of new literatures on the safety of the product, Cotton 531 x 1445, the Biotech Core Team found that there is no new information which has come to shed light on any adverse effect of the single TE and no or possible interaction between single TEs has been reported.

The scientific data and information relevant to the application of Monsanto Philippines, Inc. were reviewed by the Scientific Technical Review Panel who concluded that Cotton 531 x 1445 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. Monsanto Philippines Inc. has published the Public Information sheet in two newspapers: Malaya and the Daily Tribune on November 10, 2009 pursuant to Memorandum Circular No. 6, Series of 2007. The Bureau of Plant Industry (BPI) has not received any comments during the comment period for the renewal of Cotton 531 x 1445 for direct use as food and feed or for processing.

Monsanto Philippines Inc. has satisfactorily complied with all requirements for the renewal of a previous biosafety notification. The BPI Biotechnology Core Team reviewed the results of the assessment of the STRP. The results of the final review concluded the safety of Cotton 531 x 1445 for direct use as food and feed or for processing, which was therefore recommended for the renewal of its Biosafety notification for direct use as food and feed or for processing.

A biosafety notification renewal for Cotton 531 x 1445 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 was issued to Monsanto Philippines, Inc. on January 8, 2010. The biosafety notification indicated that no interactions were found between the stacked traits, hence Cotton 531 x 1445 is as safe for human food and livestock feed or for processing as its conventional counterpart.

Cotton 531 x 1445 will be included in the Approval Registry for direct use as food and feed or for processing being prepared by the Department of Agriculture-Bureau of Plant Industry.