





Biosafety Clearing-House (BCH)

RISK ASSESSMENT GENERATED BY A REGULATORY PROCESS (RA) BCH-RA-PH-109747-1 LAST UPDATED: 03 MAR 2016 **General information** Country **Philippines** PARTY TO THE CARTAGENA PROTOCOL ON BIOSAFETY ENTRY INTO FORCE: 03 JAN 2007 Title of the risk assessment Determination of the Safety of Monsanto's Herbicide (Dicamba) Tolerant Soybean MON EN 87708 For Direct Use as Food and Feed and for Processing Date of the risk assessment 05 May 2014 Competent National Authority(ies) responsible for the risk assessment - COMPETENT NATIONAL AUTHORITY: BCH-CNA-PH-46524-5 | BCH-CNA-PH-46524-5 **COMPETENT NATIONAL AUTHORITY** Department of Agriculture Elliptical Road, Diliman Quezon City 1100, Philippines Phone: +632 920-3986, +632 924-1278 local 2802 Fax: +632 920-3986 Email: osec.da@gmail.com Website: http://www.da.gov.ph

Contact details of the main responsible risk assessor

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PERSON

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RELATED ORGANIZATION

Risk assessment details

Living modified organism(s)

BCH-LMO-SCBD-104665-6 MON-877Ø8-9 - Dicamba Tolerant Soybean | Resistance to herbicides Show detection method(s)

Scope of the risk assessment

LMOs for direct use as food LMOs for direct use as feed LMOs for processing

Risk assessment report / summary

? DA-BPI Biotech Website (English)

Methodology and points to consider

Likelihood that the potential adverse effects will be realized

Data confirmed that MON 87708 is unlikely to be a toxin or allergen based on extensive information collected. MON 87708 was readily digestible in simulated gastric and simulated intestinal fluids, inactivated when exposed to heat and showed no oral toxicity or cause any adverse effects on mice.

Possible consequences

MON 87708 was compared to conventional soybean in eight anti-nutrient components. Statistically significant differences were observed in four namely, phytic acid, raffinose, stachyose, and daidzein. The levels of these antinutrients in seed of MON 87708 were within the range of natural variability of conventional commercial reference soybean varieties. The results further showed no health risk concern with the consumption of MON 87708 soybean.

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Soybean meal produced from MON 87708 compared to meal produced from conventional soybean through a broiler study showed no biologically meaningful differences in broiler performance, carcass yield or meat composition between the two groups. There was a comparable nutritional wholesomeness of the two diets.

Estimation of the overall risk

Soybean MON87708 is found substantially equivalent to conventional counterpart and does not pose any significant risk to animal and human health.

Recommendation(s) on whether the risks are acceptable/manageable and any management strategies

A biosafety permit for Herbicide (Dicamba) Tolerant MON 87708 and all progenies derived from crosses of the product with any conventional soybean containing approved-biotech events for direct use was issued to Monsanto Philippines Inc. Soybean MON87708 is found substantially equivalent to conventional counterpart and does not pose any significant risk to animal and human health.

Need(s) for further information on specific issues of concern

Soybean MON87708 is found substantially equivalent to conventional counterpart and does not pose any significant risk to animal and human health.

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Receiving environment(s) considered

This application is not for propagation of the Soybean MON87708. This LMO will be directly used for food, feed and for processing.

LMO detection and identification methods proposed

Quantitative diagnostic lateral flow strips, ELISA and PCR for routine quantitative and semiquantitative detection of transgenes. For higher sensitivity, real-time PCR may be used.

Information sharing with other databases

Is this risk assessment related to an LMO for commercial use?

No

Should this risk assessment be forwarded to the OECD Secretariat for possible inclusion in the BioTrack Product Database?

No

Is this risk assessment related to food safety?

No

Was it conducted in accordance with the Codex Alimentarius *Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants*?

No

Should this information be forwarded to the Secretariat of the FAO GM Foods Platform?

No

Additional Information

Soybean MON87708 is intended for direct use as food, feed and for processing.

All relevant references submitted by the technology developer in their application; other references requested by the Scientific and Technical Review Panel (STRP) members and DA Regulatory Agencies during the evaluation of this event.

Other relevant website addresses and/or attached documents

BCH-RA-PH-109747-1

Further Information

Questions about the Cartagena Protocol on Biosafety or the operation of the Biosafety Clearing-House may be directed to the Secretariat of the Convention on Biological Diversity. Secretariat of the Convention on Biological Diversity 413 rue Saint-Jacques, suite 800 Montreal, Québec, H2Y 1N9 Canada Fax: +1 514 288-6588 Email: secretariat@cbd.int