RISK ASSESSMENT GENERATED BY A REGULATORY PROCESS (RA) BCH-RA-PH-258567-1

LAST UPDATED: 06 JAN 2022

General information

Country

Philippines **PARTY TO THE CARTAGENA PROTOCOL ON BIOSAFETY** **ENTRY INTO FORCE: 03 JAN 2007**

Title of the risk assessment

Determination for the Safety Assessment of Soybean MON87708 x MON89788 x A5547- 127 for Direct Use as Food, Feed and for Processing EN

Date of the risk assessment

Date not available

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

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Risk assessment details

Living modified organism(s)

BCH-LMO-SCBD-111951-1 | MON-87751-7 x MON-877Ø1-2 x MON-877Ø8-9 x MON-89788-1 - Herbicide tolerant insect resistant soybean | Resistance to diseases and pests - Insects - Lepidoptera (butterflies and moths) Resistance to herbicides - Glyphosate
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

? http://biotech.da.gov.ph/ *(English)*

Glyphosate herbicide tolerance **-** decreases binding affinity for glyphosate, thereby conferring increased tolerance to glyphosate herbicide; Glufosinate herbicide tolerance - eliminates herbicidal activity of glufosinate (phosphinothricin) herbicides by acetylation Dicamba herbicide tolerance – confers tolerance to the herbicide dicamba (2-methoxy-3,6-dichlorobenzoic acid) by using dicamba as substrate in an enzymatic reaction	EN

Methodology and points to consider

Potential adverse effects identified in the risk assessment

DMO, CP4 EPSPS and PAT are structurally and functionally different and they are independent from each other. Thus, even if they are bred together in a single hybrid, it is highly likely that they will function independently as in single events.	EN

Likelihood that the potential adverse effects will be realized

Genetic and molecular analyses showed that all three genes are inherited, expressed and functioning properly in MON 87708 x MON 89788 x A5547-127, as they did similarly in single events. The possibility of occurrence of an unexpected effect of the stacked genes on the metabolism of the hybrid in highly unlikely.	EN

Possible consequences

DMO, CP4 EPSPS and PAT are all expressed at low levels in MON 87708 x MON 89788 x A5547-127. In addition, protein expression level analysis did not show any indication that the marker genes were transferred and expressed in plants containing the combined genes.	EN

Estimation of the overall risk

The likelihood of interaction among the three (3) proteins (DMO, PAT, and CP4 EPSPS) is unlikely because their modes of action are different. In addition, allergen and toxicity analyses of the three proteins have shown that these proteins show no homology to any known mammalian allergen or toxin.	EN

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

There is scientific evidence that **soybean MON87708 x MON 89788 x A5547-127** applied for direct use has no evidence of interaction on the resulting gene products.	EN

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

Scientific pieces of evidence from toxicity studies and references find that **Soybean**	EN

MON87708 x MON89788x A5547-127 will not cause significant adverse health effects to human and animal health. Dietary exposure to the regulated article is unlikely to result allergic reaction	

Receiving environment(s) considered

The application of **Soybean MON87708 x MON89788x A5547-127** is not for propagation. This LMO will be directly used for food, feed and for processing.	EN

LMO detection and identification methods proposed

Diagnostic lateral flow strips, ELISA and PCR for routine qualitative and semi-quantitative detection of transgenes. For higher sensitivity, real-time PCR methods may be used.	EN

Information sharing with other databases

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

No

Additional Information

Soybean MON87708 x MON89788 x A5547-127 is intended for direct use as food, feed and for processing. The effect of **Soybean MON87708 x MON89788x A5547-127** on the environment depends largely on the viability of the product to be utilized for direct use. If the article is transported in a non-viable form, there is no danger to the environment.	EN

Other relevant website addresses and/or attached documents

? http://biotech.da.gov.ph/ *(English)*

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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.

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