ASSESSORS' CONSOLIDATED REPORT ON MONSANTO PHILIPPINES INC.'s APPLICATION FOR DIRECT USE AS FOOD AND FEED, OR FOR PROCESSING OF CORN MON 87427 × MON 89034 × TC1507 × MON 88017 × DAS-59122-7

EXECUTIVE SUMMARY

On July 10, 2018, Monsanto Philippines Inc. submitted corn MON 87427 × MON 89034 × TC1507 × MON 88017 × DAS-59122-7 for direct use as original application under the DOST-DA-DENR-DOH-DILG Joint Department Circular (JDC) No. 1 Series of 2016.

After reviewing the Risk Assessment Report and attachments submitted by the applicant, the STRP, BAI, and BPI-PPSSD found scientific evidence that corn MON 87427 × MON 89034 × TC1507 × MON 88017 × DAS-59122-7 is as safe for human food and animal as its conventional counterpart and that there is no evidence of gene interaction on the resulting gene products.

The Department of Environment and Natural Resources – Biosafety Committee (DENR-BC), after a thorough scientific review and evaluation of the accomplished Project Description Report (PDR) and Environmental Risk Assessment (ERA) form along with the submitted sworn statement and accountability of the proponent, considered corn MON 87427 × MON 89034 × TC1507 × MON 88017 × DAS-59122-7 safe to the environment and biodiversity, particularly to non-target organisms and is less likely to pose any significant adverse effect to the environment.

The DOH-BC, after a thorough scientific review and evaluation of documents related to Environmental Health Impact, found scientific evidence that the GM application will not cause significant adverse effects to human and animal health, is unlikely to result in allergenic reaction, and is as safe as food or feed derived from conventional varieties.

Furthermore, the Socio-economic, Ethical and Cultural (SEC) expert, after reviewing thoroughly the accomplished SEC questionnaire, also recommended for the issuance of biosafety permit.

BACKGROUND

In accordance with Article VII. Section 20 of the JDC, no regulated article, whether imported or developed domestically, shall be permitted for direct use as food and feed, or for processing, unless: (1) the Biosafety Permit for Direct Use has been issued by the BPI; (2) in the case of imported regulated article, the regulated article has been authorized for commercial distribution as food and feed in the country of origin; and (3) regardless of the intended use, the regulated article does not pose greater risks to biodiversity, human and animal health than its conventional counterpart.

The BPI Biotech Office provided the assessors with the complete dossier submitted by Monsanto Philippines. The SEC expert, on the other hand, was provided with accomplished questionnaire on socio-economic, ethical and cultural considerations that have been addressed by the applicant.

Upon receipt of the individual reports from the assessors, the BPI Biotech staff prepared this consolidated risk assessment report for the information of the public.

STRP, BPI-PPSSD, BAI SAFETY ASSESSMENT AND RECOMMENDATIONS

Based on the documents submitted by the applicant:

A. Gene Interaction

The differences in the modes of action of the CP4 EPSPS, Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34/35Ab1 and PAT proteins, and the localizations of these proteins in the plant cells indicates no likelihood of interaction with one another which could lead to production of a new allergen or toxin. In addition to these, there is no known mechanism of interaction among these proteins that could lead to adverse effects in humans or animals (Monsanto, 2018).

The gene products CP4 EPSPS, Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34/35Ab1 and PAT, have different modes of action and sites of biological activity hence accumulation will not be in the same compartment of the plant parts.

B. Metabolic Pathways

Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34/35Ab1 proteins are insect control proteins and acts through a toxic action in the midgut of target insects.

CP4 EPSPS protein belongs to the EPSPS synthase family which is involved in the penultimate step of the biochemical shikimate pathway that leads to production of aromatic amino acids in the chloroplasts of plants. PAT protein acetylates phosphinotricin, inactivating the compound, and confers tolerance to chemically synthesized phosphinotricin compounds such as the herbicide glufosinate ammonium. The inclusion of the PAT gene enables plant selection of the Bt lines and provides tolerance to glufosinate ammonium herbicides.

There is no known mechanism of interaction among CP4 EPSPS, Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34/35Ab1 and PAT proteins that could lead to adverse effects in humans or animals (Monsanto, 2018; Alibhai and Stallings, 2001; Betz et al., 2000; English and Slatin, 1992; Höfte and Whiteley, 1989; OECD, 2007; Rupar et al., 1991; U.S. EPA, 2005).

C. Gene Expression

Results of testing conducted on the product showed that the expression levels of the individual protein products did not differ as that of the individually approved transformation events.

The proteins CP4 EPSPS, Cry1A.10, Cry2Ab2, Cry1F, PAT, Cry3Bb1, Cry34Ab1, and Cry35Ab1 in stacked MON 87427 × MON 89034 × TC1507 × MON 88017 × DAS-59122-7 are expressed properly (within the literature range) and similarly than those of the corresponding single events (Monsanto, 2018). There is no possible interaction that could affect the stability and expression level of either one of the genes.

D. Recommendation
STRP, BPI-PPSSD, and BAI found scientific evidence that the regulated article applied for direct use has no evidence of interaction on the resulting gene products

DENR'S ASSESSMENT AND RECOMMENDATION

After a comprehensive review and evaluation of the documents including the scientific evidence from references and literature submitted by Monsanto Philippines, Inc., on its application for Direct Use as FFP of Corn MON87427 X MON89034 X TC1507 X MON88017 X DAS59122-7, hereunder are the observations and appropriate actions:

1. The individual events of the gene stacked corn have biosafety permits for direct use, which were previously issued. Therefore, each event has undergone rigorous safety assessment, and is considered safe to the environment and biodiversity, particularly non-target organisms. Similarly, it is less likely to pose any significant adverse effect on the environment.
2. The incorporation of gene stacked event is through conventional breeding, which is regarded as innocuous for its long history of safe use. Furthermore, the method of crossing individual genetically modified parents is similar with that of non-genetically modified parents. This method does not introduce any greater variation in the genome beyond what is obtained (Weber, et al., 2012).
3. The project description report (PDR) discusses the specified environmental management plan indicating the possible risk and harm to the environment and non-target organisms as well as the mitigating measures and contingency plan. Furthermore, the chances of unintended release or planting of the regulated article is very minimal and will not cause any damaging and lasting effects because the receiving environment (areas near the port, roads, railways, etc.) is not conducive for plant growth. Also, corn is a highly domesticated plant that requires human intervention for it to persist in the environment (OECD O. f., 2003) and (Raybould, et al., 2012).

DOH'S ASSESSMENT AND RECOMMENDATION

After a thorough review and evaluation of the documents provided by the proponent, Monsanto Philippines, the DOH-BC found that the regulated article applied for Direct Use as Food, Feed or for Processing (FFP) is as safe as its conventional counterpart and shall not pose any significant risk to human and animal health and environment.

The following are the observations and recommendations:

1. Scientific pieces of evidence from Toxicity studies and references, find that the regulated article will not cause significant adverse health effects to human and animal health.
2. Dietary exposure to the regulated article is unlikely to result in allergic reaction.
3. The regulated article is as safe as food or feed derived from conventional corn varieties.
4. The regulated article is not materially different in nutritional composition from that of the non-transgenic corn or the conventional corn,

5. It is suggested that the Bureau of Plant Industry (BPI) ensure that there shall be clear instructions that the product is only for the purpose of direct use for FFP and is not to be used as planting materials.

SEC EXPERT'S ASSESSMENT

The SEC expert reported that based on the data, the trend of corn production has been going down while the production of livestock has been increasing to meet the local demand. The deficit in supply has been made up for by importation. This is shown by the import dependency ration that has been increasing and the self-sufficiency ratio that has been declining.

Given the decline in the production of corn and the increase in demand from the livestock industry due to the increase in population and income, there will be an increase in demand for imported corn. The importation will be filling in the requirements of a growing livestock industry. Thus, there should be no drastic change in the current patterns of production, consumption/utilization and trade of corn.

SEC EXPERT'S RECOMMENDATION

The SEC expert has recommended for the approval and issuance of the biosafety permit of the GM product.