ASSESSORS' CONSOLIDATED REPORT ON MONSANTO PHILIPPINES INC'S SOYBEAN MON87708 APPLICATION FOR DIRECT USE AS FOOD, FEED OR FOR PROCESSING

EXECUTIVE SUMMARY

On June 20, 2018 Monsanto Philippines Inc. filed for application of soybean MON87708 for direct use as food and feed, or for processing, 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 Monsanto Philippines Inc., the assessors namely: Scientific and Technical Review Panel (STRP), BPI Plant Products Safety Services Division (BPI-PPSSD) and Bureau of Animal Industry-Biotech Team (BAI-BT), concurred that soybean MON87708 is as safe for human food and animal feed as its conventional counterpart.

The Department of Environment and Natural Resources – Biosafety Committee (DENR-BC), after a thorough scientific review and evaluation of the documents related to Environmental Risk along with the submitted sworn statement and accountability of the proponent, recommended the issuance of a biosafety permit for this regulated soybean MON87708, provided that the conditions set by DENR are complied. Also, the Department of Health – Biosafety Committee (DOH-BC), after a thorough scientific review and evaluation of documents related to Environmental Health Impact, concluded that soybean MON87708 will not pose any significant risk to the health and environment and that any hazards could be managed by the measures set by the department. DOH-BC also recommended for the issuance of biosafety permit for the transformation soybean MON87708.

Furthermore, the Socio-economic, Ethical and Cultural (SEC) Considerations expert also recommended for the issuance of biosafety permit for this regulated article after assessing the socio-economic, social and ethical indicators for the adoption of Genetically Modified Organisms.

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 the complete dossier submitted by Monsanto Philippines Inc. The SEC expert, on the other hand, was provided with a questionnaire on socio-economic, ethical and cultural considerations that have been addressed by soybean MON87708 in relation to their application. These assessors were given thirty (30) days to submit their independent assessment to BPI Biotech Secretariat.

INFORMATION ON THE APPLIED EVENT

MON 87708 contains a gene from Stenotrophomonas maltophilia strain DI-6 that expresses DMO protein to confer tolerance to dicamba (3,6-dichloro-2-methoxybenzoic acid) herbicide. Tolerance of MON 87708 to dicamba will facilitate both preemergence and postemergence in-crop dicamba applications through the early reproductive (R1) growth stage. MON 87708 was produced by *Agrobacterium tumefaciens*-mediated transformation of conventional soybean using the plasmid vector PV-GMHT4355

Countries Where Approvals Have Been Granted (for FFP; for Commercial Propagation)

Country	Food direct use or processing	Feed direct use or processing	Cultivation domestic or non-domestic use
Australia	2012		
Brazil	2016	2016	2016
Canada	2012	2012	2012
China	2016	2016	
European Union	2015	2015	
Indonesia	2015		
Japan	2013	2013	2013
Mexico	2012		
New Zealand	2012		
Nigeria	2019	2019	
Philippines	2014	2014	
Russia	2019	2019	
South Korea		2012	
Taiwan	2013		
Turkey		2017	
United States	2011	2011	2015
Vietnam	2015	2015	

Source: https://www.isaaa.org/gmapprovaldatabase/event/default.asp?EventID=253
last updated: June 29, 2020

STRP's Assessment

1. Host Organism

a. Soybean is one of the main sources of plant protein consumed by humans and animals, and is a leading source of vegetable oil. Humans also consume processed soybean in the form of tofu, soy sauce, and many more [1][2].

b. Soybean is a source of anti-nutritional factors namely phytic acid, saponins, protease/trypsin inhibitor (Kurnitz type and Bowman-Birke type), isoflavones, lectins (haemagglutinins), tannins, and antivitamins [3][4].

c. There are no reported toxins from soybeans for humans and livestock, although the anti-nutritional factors present such as lectins and trypsin inhibitors can have toxic effects to human and monogastric animals [5][6][7][8][9].

d. Soybean is a source of six (6) allergenic proteins: Gly m 3, Gly m 4, Gly m 5, Gly m 6, Gly m 7, and Gly m 8 [10][11][12][13][14][15].

2. Donor Organism

a. MON 87708 contains a gene derived from *Stenotrophomonas maltophilia* that expresses DMO, a mono-oxygenase enzyme that rapidly demethylates dicamba rendering it inactive, thereby conferring tolerance to dicamba [1][16][17][18].

b. *S. maltophilia* is an aerobic, non-fermentative, Gram-negative bacterium present in the environment and in humans. Bioinformatics analysis confirmed that MON 87708 DMO protein lacks structural similarity to known allergens and toxins that may have adverse effects on mammals [1][19][20].

c. The DMO protein is classified as an oxygenase. Extensive exposure of humans and animals to homologous oxygenase proteins confirmed that oxygenase proteins have history of safe use. In addition, there are no reports of any adverse effects due to the DMO protein [1][21][22][23].

3. Transformation System

a. PV-GMHT4355 was used for the transformation of conventional soybean to produce MON 87708 through the *Agrobacterium*-mediated transformation method. It is approximately 11.4 kb and contains two T-DNAs, each delineated by Left and Right Border sequences to facilitate transformation. The first T-DNA, designated as T-DNA I, contains the *dmo* coding sequence while the second T-DNA, designated as T-DNA II, contains the *cp4 epsps* coding sequence. During transformation, both T-DNAs were inserted into the soybean genome [24].

b. Molecular characterization by Southern blot analyses determined that MON 87708 contains one copy of the T-DNA I at a single integration locus and all expression elements are present. These data also demonstrated that MON 87708 does not contain detectable backbone sequences from the plasmid vector or T-DNA II sequences [25].

c. The order of the genetic elements within the insert of MON 87708 was confirmed by DNA sequence analyses. The complete DNA sequence of the insert and adjacent genomic DNA sequence confirmed the integrity of the inserted *dmo* expression cassette within the inserted sequences and identified the 5′ and 3′ insert-to-genomic DNA junctions [1][25].

d. Southern blot analysis demonstrated that the insert in MON 87708 has been maintained through at least five generations of breeding, thereby confirming the stability of the insert over multiple generations [1][25].

e. PCR and sequence analyses revealed that there was an 899 bp deletion (and a 128 bp insertion just 5′ of T-DNA I, and a 35 bp insertion just 3′ of T-DNA I) of soybean genomic DNA sequence at the site of cassette insertion in MON 87708. Further analyses revealed that there is no known function associated with this deleted region [25][26].

f. Bioinformatics analyses showed that no short polypeptide matches were shared between any of the putative polypeptides and proteins in the allergen database. These putative polypeptides are unlikely to be allergens, toxins, or display any adverse biological activity [1].

4. Food and Feed Safety

a. SDS-PAGE and western blot methods were used to assess the digestibility of MON 87708 DMO in simulated gastric/intestinal fluid. Using SDS-PAGE, no fragments were observed in 30-second digestion sample, which is the estimated T50 result for simulated gastric fluid. Using western blot analysis, no fragments were also observed and the estimated T50 result for SIF is below 5 minutes. These results confirmed that MON 87708 DMO was readily digestible in SGF and SIF [1][27].

b. Functional activity assay and SDS-PAGE were used to evaluate the effect of heat treatment on the activity of MON 87708 DMO. Results showed that functional activity of the protein was lost at temperatures equal and greater than 55°C [1].

c. Bioinformatic analyses were done to determine the potential for toxicity of the DMO protein sequence. No structurally relevant similarity exists between MON 87708 DMO protein and any known toxin according to TOX_2010 database and FASTA sequence alignment program [1][20].

d. An acute oral toxicology study was conducted with MON 87708 DMO. Results indicate that it did not cause any adverse effects in mice, with a No Observable Adverse Effect Level (NOEL) of 140 mg/kg body weight (BW), the highest dose level tested [1][28].

e. Bioinformatic analyses were done to determine the potential for allergenicity of the DMO protein sequence. No structurally relevant similarity exists between MON 87708 DMO protein and any known toxin according to TOX_2010 database and FASTA sequence alignment program [1].

f. Results of the study demonstrated that soybean-specific IgE binding to endogenous allergens in MON 87708 and control are comparable with the IgE binding to conventional reference soybean varieties, thus confirming that MON 87708 and its derived products do not pose an increased endogenous allergenicity concern to humans over currently consumed soybean products [1][29].

g. Results of proximate analysis show that for seed nutrients: ash, carbohydrates, and protein were observed to be not significantly different with the conventional counterpart at 99% level of confidence and moisture and total fat were at 95% level of confidence. For forage nutrients, all the proximate properties were not significantly different with the conventional control at 95% level of confidence [1][7].

h. In comparison to commercial varieties, results showed that the data for proximate properties for seed and forage nutrients were within the 99% tolerance level and these values still fall within the commercial range and International Life Science Institute (ILSI) range [1][7][30].

i. In comparison of the key nutrients, all observations in the differences between the MON 87708 and the conventional counterpart are acceptable and the values are within the range of published literature [1][7].

j. The anti-nutrients were not significantly different compared with the conventional control at 99% level of confidence and the data for anti-nutrients were within literature and/or ILSI database ranges. Hence it is also expected that there is no difference in the levels of anti-nutrients in the processed products of MON 87708 and the conventional control [1][7].

STRP'S Conclusion

After a thorough review and evaluation of the documents provided by the proponent Monsanto Philippines, Inc., through the Bureau of Plant Industry (BPI), in support of their application for approval for direct use as food, feed or for processing (FFP) of soybean MON 87708, , the STRPs find scientific evidence that the regulated article applied for human food and animal feed use is as safe as its conventional counterpart and shall not pose any significant risk to human and animal health

BAI's Assessment

1. Toxicological Assessment

a. Results of SDS-PAGE and Western blot analysis demonstrated that no fragments correspond to MON 87708 DMMO upon digestion to simulated gastric fluid with pepsin. Meanwhile, Western blot analysis results confirmed that most of DMO was readily digested in simulated intestinal fluid with pancreatin [1][27].

b. Functional activity assay and SDS-PAGE determined that as the temperature increases, the activity of MON 87708 DMO decreases since it is denatured at elevated temperature. Thus, DMO protein will not be consumed since processing of soybean involves high temperature or heat treatment [1][20].

c. Results of FASTA sequence alignment showed that MON 87708 DMO protein does not share any sequence similarity with any known toxins, thus, it is unlikely to be toxic. [1][20].

d. Results of acute oral gavage showed no treatment-related effects when DMO was administered to a group of five male and five female CD-1 mice at a dose level of 140 m g/kg body weight. Thus, NOEL is considered to be 140 mg/kg bw [1][28].

2. Allergenicity Assessment

a. Using FASTA sequence alignment program and ALLERGENSEARCH program, it was found that the DMO protein sequence has no relevant similar toxins sequences that may pose harm based from food and feed safety perspective [1][31].

b. The amount of DMO protein in a soybean MON 87708 seed is 0.011% of its total protein [1].

c. The results of serum screening showed that the transformation events did not alter the naturally-occurring allergens in soybean [1][29].

3. Nutritional Data

a. The differences in terms of proximate analysis between MON 87708 and control samples were small, while those values that are statistically different are still acceptable because they are within the 99% tolerance interval based from literature values [1][7].

b. All test values of proximates were within the 99% tolerance interval when compared with a range of commercial varieties. These values are within the literature and/or ILSI database ranges and are not considered to be biologically relevant and meaningful from a food and feed safety perspective [1][7].

c. Through combined-site analysis, the measured difference of the values for key nutrients were relatively small. As for the acid detergent fiber (ADF), statistically significant difference was found, however, the difference is within the 99% tolerance interval based from literature values [1][7].

d. All test values of key nutrients were within the 99% tolerance interval when compared with a range of commercial varieties. These values are within the literature and/or ILSI database ranges and are not considered to be biologically relevant and meaningful from a food and feed safety perspective [1][7].

e. Four (phytic acid, raffinose, stachyose, and daidzein) out of the eight anti-nutrient components were found to have statistically significant difference, however, these differences are within the 99% tolerance interval based from literature values [1][7].

f. The level of MON 87708 antinutrients are compositionally equivalent to that of conventional soybean and processing soybean MON 87708 has no expected adverse effects [1][7].

g. The measured levels of antinutrients were within the 99% tolerance interval based from literature values and all the statistically significant differences are found not to be biologically relevant [1][7].

BAI's Conclusion

Upon evaluation of the documents provided by the proponent and scientific literature search conducted for the food safety risk assessment of soybean MON 87708, the following assessments were made:

History of safe use is attributed on the host organism (*Glycine max*) as well as the donor organism, *Stenotrophomonas maltophilia* which are not known to be toxic or allergenic to humans and animals.

Safety of the novel protein, DMO, in MON 87708 soybean was assessed based on the digestibility, heat inactivation, amino acid sequence comparison and oral toxicity studies and other related scientific literatures provided by the developer. Results of the analyses indicated that the novel proteins are being digested rapidly in mammalian gastric fluid, a characteristics of dietary proteins, are being inactivated by induction of heat which is normally occurring during processing and cooking, and do not cause toxicity on mice via acute oral gavage. Amino acid sequence analysis indicated that DMO have no significant homology to any known toxins or allergens.

Safety assessment based on the nutritional data indicates that there is no significant difference between the proximate, fiber, amino acid, fatty acid, vitamin and anti-nutrient levels of MON 87708 soybean and conventional soybean that can be considered biologically relevant.

For MON 87708 soybean, weight of evidences approach indicates the substantial equivalence of the single event in terms of nutritional composition and food safety, with the conventional soybean other than the tolerance to dicamba-containing herbicides. After reviewing the provided material of Monsanto Philippines, Inc. and other literatures, it is therefore concluded that soybean MON 87708 is as safe as its conventional counterpart.

BPI PPSSD's Assessment

1. **Toxicological Assessment**

   a. The digestibility study indicated that DMO is rapidly degraded in simulated gastric fluid (SGF) within 30 seconds of incubation. The estimated T50 result for SGF is below 0.5 minutes [1][27].

   b. Based on the bioassay data, DMO protein was deactivated after exposure to 55OC and above for 30 min [1][20].

   c. Bioinformatics analyses using FASTA sequence alignment program and TOX-2010 database provided by the developer indicated that DMO has no significant homology to any known toxin [1][20].

   d. Acute oral toxicity study indicated no treatment related adverse effects on survival, clinical observations, body weight gain, food consumption or gross pathology of mice administered with DMO protein [1][28].

2. **Allergenicity Assessment**

   a. The results of bioinformatics analysis provided by the developer using FASTA sequence alignment tool and ALLERGENSEARCH program showed that DMO protein has no homology to any known toxins in the FARPP sequence AD_2010 database [1][32].

   b. Based on the concentration of DMO protein in grain and percent dry weight of total protein in MON 87708, the percent of DMO protein in one gram of MON 87708 grain the DMO protein is 0.011% which represents a very small portion of total protein in MON 87708 harvested grain [1].

   c. The results of assessment of the binding potential of human serum IgE antibodies and soybean-specific IgE binding to endogenous allergens provided showed comparable results with the IgE binding and conventional reference soybean varieties which do not pose any increased allergenicity concern [1][29].

3. Nutritional Data

a. Compositional analysis indicated significant differences between all proximate levels of MON 87708 and the non-transgenic soybean. It indicated significantly higher levels of ash, carbohydrates and fiber and significantly lower levels of protein in MON 87708 compared to non-transgenic soybean [1][7].

b. Results of the proximate analysis showed that the differences between the mean values obtained from MON 87708 and its conventional counterpart were not biologically relevant since all proximate levels of MON 87708 were still within the range of commercial reference varieties and literature values [7].

c. Compositional analysis indicated significant differences between all amino acid, fatty acid and vitamin E levels of MON 87708 and the non-transgenic soybean [7].

d. Combined-site analysis showed that majority of the parameters in MON 87708 were significantly lower than the non-transgenic soybean except for cystine, palmitic acid, linoleic acid, linolenic acid and vitamin E [1][7].

e. Statistical differences observed between MON 87708 and non-transgenic soybean were not biologically relevant since all key nutrient levels of MON 87708 were still within the range of commercial reference varieties and literature values [7].

f. Compositional analysis indicated significant differences between all antinutrient and isoflavone levels of MON 87708 and the non-transgenic soybean. Combined-site analysis showed that the levels of phytic acid, raffinose and stachyose in MON 87708 were significantly lower than the non-transgenic soybean while the level of daidzein was significantly higher [7].

g. Based on the compositional analysis, soybean MON 87708 is conventionally equivalent to that of conventional soybean. Hence, any effect of processing on the level of anti-nutrient in MON 87708 would be similar to that of the conventional soybean [33][34].

h. Statistical differences observed between MON 87708 and non-transgenic soybean were not biologically relevant since all antinutrient and isoflavone levels of MON 87708 were still within the range of commercial reference varieties and literature values. [7].

BPI PPSSD's Conclusion

After a thorough review and evaluation of the documents provided by the proponent Monsanto Philippines, Inc., through the Bureau of Plant Industry (BPI), in support of their application for approval for direct use as food, feed or for processing (FFP) of soybean

MON 87708, the BPI PPSSD find scientific evidence that the regulated article applied for animal feed use is as safe as its conventional counterpart and shall not pose any significant risk to human and animal health.

DENR-BC'S Assessment

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 Soybean (MON877O8), hereunder are the observations arid appropriate actions:

1. The direct use of the regulated article whether for food, feed or for processing will not cause arty significant adverse effect on the environment (land, and water) and biodiversity. The transgenic crop will riot increase its weediness potential in case the seeds spill out into the environment because the dicamba monooxygenase (dmo) protein produced by the transgenic crop will degrade upon exposure to the natural environment arid general condition that is high temperature, 55°C and above, varying pH, enzyme digestion, etc [35].

2. Based or the bioinformatics assessment through Basic Local Alignment Search Tool (BLAST) ax.d Fast Alignment (FASTA) algorithm, dmo protein sequence shows no structural nor functional similarities with known toxin sequences. Also, the proteins readily become non- functional in the presence of mammalian digestive enzymes [35].

3. The project description report (PDR) discusses the specified environmental management plan indicating the possible risk and harm to the environment and biodiversity 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, soybeans generally are very highly domesticated and do not survive well without human intervention [36].

DENR BC's Conclusion

Based on the evaluation and review of literatures cited, the DENR-BC considered the regulated article safe to the environment and biodiversity, and hereby submits the technical report relative to the application of Monsanto Philippines, Inc. for Biosafety Permit for direct use as food, feed, or for processing of Soybean MON877O8.

DOH-BC's Assessment

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 soybean or the conventional soybean varieties.

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.

DOH-BC's Conclusion

After a thorough review and evaluation of the documents provided by the proponent Monsanto Philippines, Inc., through the Bureau of Plant Industry (BPI), in support of their application for approval for direct use as food, feed or for processing (FFP) of soybean MON 87708, the DOH-BC find that the regulated article is safe as its conventional counterpart and shall not pose any significant risk to human and animal health and environment.

SEC Expert's Assessment

a. Local production of soybean is minimal and is primarily alloted to the food industry. With this, the Philippines feed industry became highly dependent on imported soybean meal.

b. Soybean meal is used as a filler and protein source in animal feeds. There is no known substitute to the protein content of soybean meal unlike corn that can be substituted by wheat feed. Currently, Philippines is the largest market for US soybean meal and imports are forecast to reach 2.5 MMT in MY 16/17 [37].

c. Soybean oil is mainly used for mayonnaise and salad dressings. The Philippines soybean oil production is supported almost exclusively by imported beans and the imports are expected to marginally increase through MY 16/17 due to increasing food demand [38].

d. Approval of Soybean MON 87708 application will not drastically change current patterns of production and consumption/utilization but it is necessary to maintain global trade of soybean products that are imported into the country. Importation of soybean which includes MON 87708 is expected to contribute to the local feeds industry's growing demand for soybean [36][37].

SEC Expert's Recommendation

After a thorough review and evaluation of the documents provided by the proponent Monsanto Philippines, Inc., through the Bureau of Plant Industry (BPI), in support of their application for approval for direct use as food, feed or for processing (FFP) of soybean MON 87708, the SEC Expert recommends for the approval and issuance of biosafety permit of the said GM product.

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