**CONSOLIDATED RISK ASSESSMENT REPORT OF BASF PHILIPPINES, INC.'S SOYBEAN FG72 APPLICATION FOR DIRECT USE AS FOOD, FEED OR FOR PROCESSING (FFP)**

## EXECUTIVE SUMMARY

On December 5, 2019, BASF Philippines Inc. submitted soybean FG72 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 applicant, 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 FG72 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, considered that the regulated article poses no significant adverse effect to the environment.

Furthermore, the Department of Health – Biosafety Committee (DOH-BC), after a thorough scientific review and evaluation of documents related to Environmental Health Impact, find scientific evidence that the regulated article will not cause significant adverse health effects to human and animal health.

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 BASF 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 BASF Philippines Inc. 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 EVENTS

FG72 soybean possesses the *hppdPfW336* and *2mepsps* genes from *Pseudomonas fluorescens* and *Zea mays*, respectively. The h*ppdPfW336* gene codes for the 4-hydroxyphenylpyruvate (HPPD W336) which confers tolerance to HPPD inhibitors such as isoxaflutole herbicide. The *2mepsps* gene codes for the L 5-enolpyruvylshikimate 3-phosphate synthase (2mEPSPS) protein which confers tolerance to glyphosate herbicides.

### 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 |
|---|---|---|---|
| Argentina | 2018 | | 2018 |
| Australia | 2012 | | |
| Brazil | 2015 | 2015 | 2015 |
| Canada | 2012 | 2012 | 2012 |
| China | 2018 | 2018 | |
| Colombia | 2016 | | |
| European Union | 2016 | 2016 | |
| Iran | 2018 | | |
| Japan | 2016 | 2016 | 2016 |
| Malaysia | 2014 | 2014 | |
| Mexico | 2014 | | |
| New Zealand | 2012 | | |
| Nigeria | 2018 | 2018 | |
| Philippines | 2015 | 2015 | |
| Russia | 2015 | 2014 | |
| Singapore | 2018 | | |
| South Korea | 2014 | 2013 | |
| Taiwan | 2013 | | |
| United States | 2012 | 2012 | 2013 |

*Source: http://www.isaaa.org/gmapprovaldatabase/event/default.asp?Event ID=251*

**STRP'S ASSESSMENT**

## *1. Host Organism*

a. Soybean is a source of key nutrients mainly as oil and soybean products. It is the major source of protein ingredient of farm animals like pigs and poultry (about 30% of feed composition). Humans also consume processed soybean in the form of tofu, soy sauce, etc. as a component of food preparation, in a limited amount. [1][2]
b. Soybean is not a common source of toxicants. Allergic reactions reported is between 0.3% and 0.7% of the general population. [1]

## *2. Transgenic Plant*

a. Soybean FG72 has been reviewed and approved for food and/or feed use in many countries.
b. The introduction of FG72 soybean in the market will not affect the consumption pattern of the Filipinos. [3]

## *3. Donor Organism*

a. FG72 soybean possesses the *hppdPf W336* gene from *Pseudomonas fluorescens* and *2mepsps* gene from Z*ea mays. Pseudomonas fluorescens* and *Zea mays* have a long history of safe use and not known to be toxic or allergenic. [4][5]
b. The *hppdPf W336* gene encodes for the HPPD W336 protein conferring tolerance of FG72 soybean to 4-Hydroxyphenylpyruvate dioxygenase inhibitors, such as isoxaflutole, herbicide. The *2mepsps* gene encodes for the 2mEPSPS protein conferring tolerance of FG72 soybean to glyphosate herbicides. [4][5]
c. All potentially inserted regulatory sequences have been fully described. [6]

## *4. Transformation System*

a. FG72 soybean was developed through direct gene transfer using the transformation vector pSF10 containing the *hppdPf W336* and *2mepsps* expression cassettes. [6]
b. An embryogenic Glycine max cell line of variety Jack was genetically modified with a purified Sal1 fragment from plasmid pSF10. Transformed cells were selected using isoxaflutole, and after a round of multiplication cycles in the presence of the selection agent, were regenerated into embryos and shoots in the absence of the selective agent. The regenerated plantlets were then transferred to the greenhouse and glyphosate was used as a selection agent and for herbicide tolerance evaluation. [31]
c. The target of genetic modification was the nucleus to render the recipient organism and its progenies tolerant to HPPD inhibitors and glyphosate herbicides. [31]

## *5. Inserted DNA*

a. A single insertion site was demonstrated through Southern blot analysis. [7][8]
b. Digested genomic FG72 DNA was probed with both the Ph4a748B probe and the complete T-DNA probe. The complete T-DNA probe revealed the FG72 internal fragments and the 5' and the 3' integration fragments. The 158 bases of Ph4a748 promoter sequences located next to the translocated sequence could not always be visualized using the T-DNA probe. The stability of this region was demonstrated using the Ph4a748B probe. The obtained Southern blot profile was identical for all samples, which demonstrates the stability of transformation event FG72 at the genomic level in different generations, different environments and different backgrounds. [8]
c. There was a genomic region that translocated to a new position, which was joined by 158 bases of the Ph4a748 promoter sequence at the 3' junction upon transformation, as the applicant described it. However, the bioinformatics analysis performed by the applicant was valid and exhaustive and its results clearly show no indication of the presence of genes or regulatory elements in the analyzed genomic soybean sequences as well as the unlikely interruption or alteration of the transcriptional or translational activity of known endogenous soybean genes by the insertion of T-DNA sequences in the FG72 locus. [8][30]

## *6. Genetic Stability*

a. Stability of transformation event FG72 at the genomic level in different generations, different environments and different backgrounds was demonstrated. [30]
b. Chi square analysis of segregation data demonstrated the expected Mendelian inheritance pattern for a single insertion**.** [3**1**]

## *7. Expressed Material*

a. The expression of novel protein 2mepsps and HPPD W336 were determined using ELISA/EIA (Enzyme linked Immunosorbent Assay).
    i. The expression of 2mepsps in FG72 soybean matrices expressed as µg/g dry weight (DW) ranged from 73.05 µg/g DW (observed in root) to 1283.19 µg/g DW (observed in leaf at V5 to V6 growth stage). The expression of 2mepsps in flowers from treated and untreated FG72 soybean ranged from 24.99 – 48.03 µg/g FW. [10]
    ii. The expression of HPPD W336 in FG72 soybean matrices expressed as µg/g DW ranged from 0.82 µg/g DW (observed in grain) to 49.23 µg/g DW (observed in leaf at R3 growth stage). The expression of HPPD W336 in flowers from treated and untreated FG72 soybean ranged from 1.88 – 3.81 µg/g FW. [10]
    iii. The highest protein expression levels of 2mepsps were observed in leaf at the V5 to V6 growth stage, and the lowest expression levels of 2mepsps were observed in root. The highest expression levels of HPPD W336 were observed in leaf and forage at the R3 growth stage, and the lowest expression levels of HPPD W336 were observed in grain. The expression levels of 2mepsps and HPPD W336 in all matrices were similar between

FG72 soybean treated with trait-specific herbicide and untreated FG72 soybean. [10]

b. Both *2mepsps* and HPPD W336 proteins have no metabolic role. [17]

### *8. Toxicological Assessment*

a. It was concluded that oral exposure to the HPPD W336 and *2mepsps* proteins is unlikely to produce any toxic effects. In addition, HPPD W336 and *2mepsps* proteins do not possess characteristics associated with food toxins, i.e., they have no sequence homology with any known toxins, are rapidly degraded in gastric and intestinal fluids, and are devoid of adverse effects in mice after oral administration. [11][12][13] [14][15][17][18][19][20][21][22]

b. HPPD W336 and 2mEPSPS proteins in FG72 are expressed independently of each other. These proteins do not act on the same metabolic pathway. [10]

### *9. Allergenicity Assessment*

HPPD W336 and *2mepsps* proteins do not possess characteristics associated with food allergens, i.e., they have no sequence homology with any known allergens, have no N-glycosylation sites, and are rapidly degraded in gastric and intestinal fluids. There is reasonable certainty of no harm to humans and animals resulting from HPPD W336 and *2mepsps* proteins. FG72 soybean is as safe as its non-genetically modified counterpart hence, no potential effect on human or animal health and the environment is envisaged. [11][12][13][14][15][17][18][19][20][21][22]

### *10. Nutritional Data*

a. There are no biologically significant differences in the levels of key components of soybean FG72 when compared with the non-GM control or with the range of levels found in non-GM commercial soybean cultivars. Furthermore, any statistical differences observed in amino acids, fatty acids, minerals, and vitamins, and antinutrients are not biologically relevant. [3]
b. The extensive compositional analyses of soybean FG72 indicate that it is equivalent in composition to conventional soybean. [3][7]

**STRP'S RECOMMENDATION**

The three journal article attachments, which were sound and conducted using the scientific method, further point to the safety of BASF's soybean FG72. FG72 has been shown to have no potential effects on human and animal health and the environment. In addition, the safety of the expressed protein (HPPD W336) in FG72 has been shown based on its lack of homology with other toxins or allergens and on its easy digestion in gastric juice. [35][36][37]

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. Host Organism*

a. Soybeans are used as feed. Soybean meal, which is a by-product of oil extraction, is used in diets for poultry, swine, dairy cattle, beef cattle and pets. Unprocessed soybeans, however, contain anti-nutritional factors, thus adequate heat processing must be done. [1]
b. Soybean is not a source of toxicants. Furthermore, there are a number of proteins in the soybean that are considered potential allergens due to their IgE binding ability. [1]
c. Soybean and soybean products are consumed by all population subgroups. The main product derived from soybeans seeds for human consumption is soybean oil, while soy sprouts, baked soybeans, roasted soybeans, full fat soy flour and the traditional soy foods are derived from whole soybeans. [1]

### *2. Transgenic Plant*

a. FG72 had been granted food/feed approvals in 19 countries namely: Argentina, Australia/New Zealand, Brazil, Canada, China, Colombia, European Union, India, Japan, Korea, Malaysia, Mexico, Philippines, Russian Federation, Singapore, South Africa, Taiwan, United States. [27]
b. Since FG72 is compositionally and nutritionally equivalent to its non-transgenic counterpart and to current commercial soybean varieties, the consumption pattern for soybean will not be changed. [3]

### *3. Donor Organism*

a. Donor organisms, *Pseudomonas fluorescens* and *Zea mays,* are not known to be toxic or allergenic and have a good history of safe use. [4][5]
b. All protein-encoding sequences found in the original gene have been described with respect to source and potential pathogenic or allergenic properties. [4][5]
c. Results of molecular characterization using Southern Blot analysis showed the absence of vector backbone in the soybean transformation event FG72. [5]

### *4. Transformation System*

a. Biolistic transformation was the method used by the applicant. [29]
b. Nucleus was the target for genetic modification. [29]
c. The applicant used plasmid pSF10 to produce Soybean FG72. They sufficiently provided the description and components of the plasmid which includes the size, orientation, and location of all genetic elements, oligonucleotide primers used for PCR analysis, and the sites of any restriction endonucleases used in the analysis of the inserted DNA. [8]

### *5. Inserted DNA*

Integrity and organization of genetic elements within each insertion site was confirmed using Southern Blot analysis. Results of the analysis determined that the hybridization

fragments obtained with genomic DNA of FG72, digested with different restriction enzymes and probed with the different probes showed that the insert consists of two partial 3'histonAt sequences in a head to head orientation, followed by 2 complete T-DNA copies arranged in a head to tail orientation. Upon transformation, a genomic region translocated to a new position, which is joined by 158 bases of Ph4a748 promoter sequence at the 3' junction. [8]

### *6. Genetic Stability*

a. The stability of the introduced traits was assessed using Southern Blot analysis which demonstrates the stability of transformation event FG72 at the genomic level in different generations, different environments and different backgrounds. [33]
b. Two generations of backcrosses were tested. Chi square analysis of segregation data for rows (fully or partially tolerant) and of individual plants within rows (tolerant or sensitive) demonstrated the expected Mendelian inheritance pattern for a single insertion. Results from the segregation analysis were consistent with reported copy number. [34]

### *7. Expressed Material*

a. The expression of HPPD W336 in FG72 soybean matrices expressed as µg/g DW ranged from 1.96 µg/g DW (observed in root) to 49.23 µg/g DW (observed in leaf at R3 growth stage).
b. The expression of *2mepsps* in FG72 soybean matrices expressed as µg/g dry weight (DW) ranged from 73.05 µg/g DW (observed in root) to 1283.19 µg/g DW (observed in leaf at V5 to V6 growth stage). [10]

### *8. Toxicological and Allergenicity Assessment*

a. Both Coomassie blue stained SDS-PAGE and Western blots showed no HPPD W336 protein band or any smaller bands after incubation at $37^0$C for at least 30 sec in human SGF (in the presence of pepsin) and in less than 30 sec in SIF (with pancreatin) indicating complete digestion. [6][11].
b. *2mepsps* protein was completely digested within less than 30 sec of incubation at $37^0$C. [21][22].
c. SDS-PAGE and Western blot analyses both showed one major band corresponding to the molecular weight of the HPPD W336 protein. The protein is heat stable. [35].
d. Solubilized *2mepsps* samples were incubated at $4^0$, $25^0$, $37^0$, $55^0$ and $95^0$C for 30 minutes and subjected to SDS-PAGE and Western blot. Analyses showed that the protein remained soluble up to $37^0$C. [36].
e. Complete query sequence comparisons using the NCBI non-redundant protein database and the 2018 internal toxin database indicated that HPPD W336 has no relevant similarities with any toxic protein.
f. For *2mepsps*, several *in silico* approaches failed to demonstrate any amino acid sequence similarity with known toxins and allergens. [13][18].
g. Oral gavage for HPPD W336 and 2mepsps proteins indicated no signs of systemic toxicity in mice. [12][20].
h. The latest additional study submitted by the applicant showed the latest characterization and safety assessment of HPPD W336. The results were:

i. The levels of the newly expressed proteins present in soybean FG72 were obtained and reported adequately.
ii. They used *E. coli*-produced HPPD W336 protein which was structurally and functionally equivalent to Soybean FG72 -purified HPPD W336.
iii. HPPD W336 has no relevant sequence homologies with known allergens or toxins which was consistent with the result of their previous characterization.
iv. *In vitro* test confirmed the absence of hemolytic activity of HPPD W336.
v. As expected, the HPPD W336 protein was completely degraded within 30 seconds of incubation in SGF with pepsin as well as in SIF with pancreatin which imply that the protein will be likely rapidly degraded in gastric/intestinal condition and is therefore unlikely to pose a human and animal health concern.
vi. HPPD W336 protein was also shown to lose its activity very rapidly when heated at 60 °C or more. Therefore, the protein loses its functional activity when subjected to high temperature indicating that processing the soybean for feed use loses the activity of the protein which further supports the safety of soybean FG72.
vii. No mortality or clinical signs were observed in any animals in the acute oral toxicity study in mouse. The body weight of the HPPD W336-treated animals were comparable to the control animals. The study concluded that at 2000 mg/kg body weight acute oral treatment with HPPD W336, there is no evidence of systemic toxicity.
[36][37]

## 9. *Nutritional Data*

a. For the proximate analysis, majority of the nutrients showed no significant differences between treatments when site-by-site analysis was done. There were significant differences observed but this will not affect the safety of FG72. [3]
b. Significant differences were also observed in the amino acid, fatty acid, and vitamins, and anti-nutrients but the differences cited are not biologically relevant to affect the safety of FG72. [3]
c. The study was performed to compare the effects upon exposure of ROSS variety chickens (Gallus gallus domesticus) to feed containing either transgenic FG72 toasted soybean meal or non-transgenic, non-GM counterpart meal over a 42-day period. Results of the study shows that there were no adverse effects detected in feed consumption, feed conversion ratio, survival, body weight gain, or in weight of chilled carcass, legs, thighs, wings or breasts between broiler chicken fed the diet containing the genetically modified FG72 toasted soybean meal and the two control groups, which were fed a diet either incorporating meal from a non-transgenic commercial variety or the non-transgenic non-GM counterpart. Thus, the result implies that there are no effects on the nutrient intake or normal growth of the poultry when fed a diet containing FG72 soybean meal. Moreover. the growth and health of chickens being fed a diet containing FG72 toasted soybean meal were comparable to the growth and health of chickens consuming either of the two control diets. [38]
d. According to the scientific opinion of EFSA (2015) the performance data from Stafford (2009) feeding study, suggests that the meal derived from GM soybean

FG72 is as nutritious as those derived from the conventional counterpart and the single commercial non-GM soybean tested. [35][38]

**BAI'S RECOMMENDATION**

Find scientific evidence that the regulated article applied for animal feed use is as safe as its conventional counterpart and shall not pose greater risk to human and animal health.

**BPI-PPSSD'S ASSESSMENT**

### *1. Host Organism*

a. Soybean is a source of carbohydrates, fiber, amino acids, fatty acids, minerals and vitamins. It also contains anti-nutritional factors such as oligosaccharides, trypsin inhibitors, lectins, phytic acid and other compounds such as isoflavones, phospholipids, sterols and saponins. [1]
b. It is a common source of allergens, but toxicants are not commonly found in soybean. [1]
c. The consumption pattern in the overall population or any population sub-groups will not be changed, as FG72 will be used in the same ways as the other conventional soybean. [3]

### *2. Transgenic Plant*

The consumption pattern in the overall population or any population sub-groups will not be changed, as FG72 will be used in the same ways as the other conventional soybean. [14]

### *3. Donor Organism*

a. The *2mepsps* gene encoding *2mepsps* protein was derived from *Zea mays L.* and the *hppdPf W336* gene encoding modified p-hydroxyphenylpyruvate dioxygenase (HPPD) enzyme was derived from *Pseudomonas fluorescens* strain A32. [16][18]
b. History of safe use is attributed to corn (*Zea mays* L.) as it is normally consumed as staple food worldwide. [16][18]
c. *Pseudomonas fluorescens* is a common soil bacterium which is generally non-pathogenic to humans or animals. [16][18]

### *4. Transformation System*

a. Direct gene transfer was the method used in the transformation of soybean FG72 [29]
b. Nuclear DNA was the target for genetic modification. [29]

### *5. The Inserted DNA*

a. Southern blot analysis using different probes 10 restriction enzymes indicated that there is a single insertion site in FG 72 soybean. [8]
b. The integrity and order of genetic elements were demonstrated through Southern blot analysis of the test DNA using different probes and 10 restriction enzymes. The resulting fragments were identical to the expected fragments from the FG72 insert organization model. The insert consists of two (2) partial 3'histonAt sequences in a head to head orientation followed by 2 T-DNA copies in a head to tail orientation. [8]

## *6. Genetic Stability*

a. Multigenerational stability showed that the DNA insert has been stably inherited from one generation to the other. [22]

b. Segregation was assessed through Chi square analysis of segregation data from T2 progenies. Results showed no significant differences between the observed segregation ratios and the expected segregation ratios. The insert segregates following Mendelian law. [32]

c. The study also demonstrated the substrate specificity of HPPD W336 protein which indicates that the genetic modification of HPPD W336 has negligible effect on its substrate specificity and that its substrate spectrum is narrower than the native soybean HPPD protein. This implies that HPPD W336 protein acts more specifically on its target substrate. [36][37]

## *7. Expressed Material*

a. ELISA demonstrated that HPPD W336 and *2mepsps* protein are both present in leaves, root, flower and seed. The concentration of HPPD W336 protein in seed, which is the edible portion, is approximately 0.93 – 0.99 µg/g fresh weight and 1.05 – 1.10 µg/g dry weight. [10]
b. The concentration of *2mepsps* protein in seed is approximately 198.75 – 216.51 µg/g fresh weight and 222.79 – 240.60 µg/g dry weight. [10]

## *8. Toxicological and Allergenicity Assessment*

a. HPPD W336 protein has no significant homology to any known toxin or allergen. Digestibility study in simulated gastric fluid (SGF) demonstrated that >90% HPPD W336 is rapidly digested within 30 seconds. Acute oral toxicity study recorded no treatment-related macroscopic observations upon administration of 2000mg/kg body weight of the protein. [6][16]
b. Digestibility study through SDS PAGE and Western blot analysis demonstrated that 2mEPSPS protein was rapidly digested upon incubation with simulated gastric fluid (SGF) with pepsin and SIF with pancreatin within 30 seconds. 2mEPSPS has no homology to any known toxin or allergens. Toxicological and allergenicity studies demonstrated that 2mEPSPS protein is not likely to cause toxicity or allergenicity to humans or animals. Acute oral gavage demonstrated that administration of 2000 mg/kg bw 2mEPSPS protein in mice did not yield any significant effects on survival, clinical observations, body weight gain, food consumption or gross pathology. [6][16][19][20][21]
c. HPPD W336 and 2mEPSPS are not known to interact. The two proteins have different mode of actions and are not involved in the same metabolic pathways. [16][23][24]
d. The studies by Dreesen et al. (2018a and 2018b) supports our assessment with regards to the HPPD W336 digestibility, response to high temperature, protein composition, homology to known toxins or allergens, acute oral toxicity equivalence of test protein to FG72-produced protein. [36][37]

e. The study demonstrated that HPPD W336 protein has no hemolytic potential. This was confirmed through in vitro assessment of the effect of HPPD W336 protein in the blood plasma from male and female human donors. [36][37]

**9. *Nutritional Data***

a. Based on the statistical analyses, there were no statistical differences between the proximate analysis of FG 72 soybean and non-transgenic soybean that can be considered biologically relevant. [3]
b. Any statistical differences between the fatty acid, amino acid, vitamin and mineral levels of FG 72 soybean and non-transgenic soybean are not biologically relevant. All values are within the range of commercial varieties and/or literature values. [3]
c. There were no biologically relevant differences in the levels of anti-nutrients between FG72 soybean and the conventional counterpart. Hence, the effect of the level of anti-nutrients in processed products of FG72 soybean is expected to be similar with the conventional counterpart. Processing may reduce the anti-nutrient content of the product. [3][25]
d. As for the compositional analysis, the study also covers the tocochromanol and homogentisate content of FG72 soybean which indicates that the over-expression of HPPD W336 protein do not have biologically relevant effect on the composition of soybean in comparison with conventional soybean. [36][37]

**BPI-PPSSD'S RECOMMENDATION**

Find scientific evidence that the regulated article applied for human food 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 and scientific evidence from literature submitted by BASF Philippines, Inc. concerning its application for Direct Use for food, feed, or for processing of Soybean FG72, the DENR-BC considered that the regulated article poses no significant adverse effect to the environment on the following bases:

1. The regulated article is considered substantially equivalent to its conventional counterpart for its history of safe use as food in nineteen (19) countries and as feed in eleven (11) countries. It has also been approved for cultivation in five (5) countries. FG72 soybean has also been previously approved for direct use in the Philippines. [26]
2. Safety evaluation of the HPPD W336 protein indicate that it is as safe as other food proteins and unlikely to pose a threat of being toxic or allergenic based on differences in the DNA sequence. A safety assessment of the 2mEPSPS protein considered it safe without any property associated with toxins and allergens and is easily digested in the gastrointestinal tract indicating that it is less likely to cause harm to local wildlife. [4][16]; and
3. The project description report (PDR) discusses the specified environmental management plan indicating the possible risk and harm to the environment particularly on biodiversity, as well as the mitigating measures and contingency plan. However, there is low possibility that the regulated article will grow in non-cultivated land. It cannot survive a nonagricultural environment and any unintended release is less likely to cause the crop to persist or become invasive in unmanaged habitats. [27]

**DENR BC'S RECOMMENDATION**

Based on the evaluation and review of literatures cited, the DENR-BC considered the regulated article safe to the environment, particularly on biodiversity and non-target organisms.

**DOH BC'S ASSESSMENT**

Find that the regulated article applied for Direct Use as Food, Feed or for Processing (FFP) is 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 soybean varieties.
4. The regulated article is not materially different in nutritional composition from that of the non-transgenic soybean.

[3][17]

**DOH BC'S RECOMMENDATION**

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 agreed that indeed, domestic production of soybeans is low relative to its demand. It was also noted that the applicant has submitted recent available supply and demand data for soybean. GM soybean for direct use is favorable, economically to the Philippines. Hence, the SEC Expert recommended for the approval of FG72. [28]

**SEC EXPERT'S RECOMMENDATION**

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

## REFERENCES


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