

**PUBLIC INFORMATION SHEET FOR
DIRECT USE AS FOOD AND FEED, OR FOR PROCESSING**

**PROPOSAL FOR DIRECT USE AS FOOD
AND FEED, OR FOR PROCESSING
Soybean MON 94313**

1. Applicant's Name

Bayer CropScience, Inc.

2. Applicant's Address

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3. Telephone Number/ Facsimile Number, E-Mail Address of the Applicant

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4. Name of Responsible Officer/Authorized Representative

Ms. Nisha Sharma, Country Commercial Lead (Responsible Officer/RO)

Mr. Revlech V. Manset, Regulatory Affairs Manager, *Seeds and Traits* (Authorized Representative)

5. Description of the Regulated Article for Direct Use (mention the crop, transformation event, new trait conferred, name of the gene transferred, method of transformation, and advantages of the trait conferred).

MON 94313 soybean was created through an *Agrobacterium*-mediated transformation in A3555 soybean using the PV-GMHT529103 binary plasmid vector DNA which contains two separate T-DNAs. The first T-DNA, designated as T-DNA I, contains the *dmo*, *pat*, *ft_t.1*, and *TDO* expression cassettes for the herbicide tolerance traits. The second T-DNA, designated as T-DNA II, contains the *splA* and *aadA* expression cassettes for selection of transformed plants.

MON 94313 expresses the PAT protein to confer tolerance to glufosinate herbicide, a dicamba mono-oxygenase (DMO) protein to confer tolerance to dicamba herbicide, a FOPs and 2,4-D dioxygenase protein (FT_T.1) to confer tolerance to 2,4-D herbicide, and the triketone dioxygenase (TDO) protein to confer tolerance to mesotrione herbicide.

6. If to be imported, Country(ies) of Origin of the Regulated Article

United States of America (USA)

7. Brief Summary of Potential Effects on Human and Animal Health and the Environment (summarize human and animal health and environmental assessments done and studies implemented indicating potential effects on human and animal health and the environment).

Consumption of MON 94313 as food and feed will not result in harmful effects on humans and animals. Multiple, well-established lines of evidence confirm the food and feed safety and the lack of plant pest potential of MON 94313. It supports the conclusion that the food and feed derived from MON 94313 and its progeny are as safe and nutritious as food and feed derived from conventional soybean.

The characterization of the genetic modification in MON 94313 demonstrates that a single copy of the intended T-DNA I insert was stably integrated at a single locus of the soybean genome and that no plasmid backbone or T-DNA II sequences are present in MON 94313. The genetic elements are present in the expected order and are inherited following Mendelian principles.

Extensive evaluation of the DMO, PAT, FT_T.1 and TDO proteins demonstrates that they do not pose any meaningful risk to food or feed safety. A multistep approach to the safety assessment of the DMO, PAT, FT_T.1 and TDO proteins were conducted, includes: 1) documenting the history of safe consumption of the expressed protein or its structural and functional homology to proteins that lack adverse effects on human or animal health; 2) characterization of the physicochemical and functional properties of expressed protein; 3) quantification of the expressed protein's expression in plant tissues; 4) examination of the similarity of the expressed protein to known allergens, toxins or other biologically active proteins known to have adverse effects on humans and animals; 5) evaluation of the susceptibility of the expressed protein to the digestive enzymes pepsin and pancreatin; 6) evaluation of the stability of the expressed protein after heat treatment. The data collected to address these elements collectively supports the conclusion that dietary exposure to DMO, PAT, FT_T.1 and TDO proteins derived from MON 94313 poses no meaningful risk to human or animal health.

The comprehensive compositional assessment demonstrated that MON 94313 grain and forage are compositionally equivalent to grain and forage from conventional soybean.

8. Brief Summary of Potential Benefits (Describe how the new trait will benefit farming, the farmer, the environment, and society as a whole).

MON 94313 soybean is an herbicide tolerant product designated for North and South American farmers, offering multiple choices for effective weed management including tough-to-control and herbicide-resistant broadleaf and grass weeds.

No difference of this product will bring to the Filipino farmers or farming as this application in the Philippines is for direct use purpose, but not for commercial propagation. The commodities derived from MON 94313 maybe imported into the Philippines from the cultivation regions, but there are no differences in regards of food and feed safety comparing to non-GM soybeans or previously approved GM soybeans.

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

Canada (Food and Feed, 2023) and United States of America (Food and Feed, 2024)

10. Brief Summary on Socio-economic, Cultural and Ethical considerations;


Soybean is widely produced and consumed and is a significant component of global trade of agricultural commodities. The Philippines feed industry is highly dependent on imported soybean meal as local production is really small and used primarily on food industry. In 2023 alone, Philippines imported 2.45 MMT of soybean meal valued at US \$1.27 billion. The increasing imports reflect the continuous growth of the local livestock industry congruent to the increasing consumption of the country's population.

The approval of this GM soybean will help maintain global trade of soybean products that are imported into the Philippines that would meet the requirement of the local feeds industry.

As our application pertains to the importation of FFP (agricultural commodities), not intended to be commercially grown and marketed for propagation and cultivation, cultural practices of specific ethnic and cultural groups will not be affected. Once approved, FFPs from GM soybean will be traded no differently from the FFPs from non-GM soybean. FFP derived from GM crops are believed to positively and not negatively affect the basic human need of food, regardless of ethnicity.


The public is hereby invited to submit their comments to the BPI Director (within 15 days from date of publication) on the Proposal for the direct use as food and feed, or for processing Soybean MON 94313.

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Director
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Date: Nov. 4, 2024

SUBSCRIBED AND SWORN TO BEFORE ME THIS NOV. 14, 2024

DOC. NO. 262
PAGE NO. 51
BOOK NO. 209
SERIES OF 2024


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TIN-116-095-254 Not. Com. No. 11-2023-C
MCLE Compliance VII - No. 0017987, 04-14-2025