Regulatory Decision on the Application for Field Trial of Glyphosate Tolerant Corn MON 87427

I. Brief Identification of the Genetically Modified Organism

Designation: Corn MON 87427

Host Plant: *Zea mays* L. (Maize)

Trait Description: Glyphosate Tolerant

Trait Introduction Method: *Agrobacterium tumefaciens*-mediated transformation

Donor organisms (s): *Agrobacterium* sp. strain CP4 produces EPSPS protein which confers tolerance to the herbicide glyphosate

Proposed Use: For field trial

II. History of Safe Use of the Host Plant

Corn is the most widely cultivated crop worldwide followed by wheat (*Triticum* sp.) and rice (*Oryza sativa* L.). Corn is a well-known plant extensively researched for its significance as a staple food and animal feed with a long history of safe use.

Corn has two major uses: (1) as animal feed in the form of grain, forage or silage; and (2) as a raw material for wet- or dry-milled processed products such as high fructose maize syrup, oil, starch, glucose, dextrose, and ethanol; by-products of the wet- and dry- mill processes can also be used as animal feed. These processed products are used as ingredients in many industrial applications and in human food products. Most maize produced in industrialized countries is used as animal feed or for industrial purposes, but maize remains an important food staple in many developing regions. Corn is a significant component of global trade of agricultural commodities and provides economic benefits for farmers.

III. Characteristics of Host Plant

Corn is a highly domesticated crop that requires human assistance for the dispersal of its seeds to survive and reproduce (OECD, 2003). Its development can be divided into vegetative and reproductive stages. The vegetative stages start from emergence (VE) and continue until tasseling (VT) while the reproductive stages begin with silking (R1) and end with physiological maturity (R6) (Abendroth et al., 2011).

Corn is wind-pollinated and can hybridize with certain species or subspecies of teosinte when in close proximity (Wilkes, 1972). However, the probability of natural gene transfer from corn to other wild plant species is considered negligible.

Due to its domestication and past selection, corn is not capable of surviving as a weed; traits often associated with weediness, such as seed dormancy, a dispersal mechanism, or the ability to establish reproducing populations outside of cultivation, have not been selected.

IV. Characteristic and safety assessment of the GM product

MON 87427 was developed through *Agrobacterium*-mediated transformation of immature corn embryos following the procedure outlined by Sidorov and Duncan (2009) using the PV-ZMAP1043 vector. The T-DNA contains one expression cassette consisting of the *cp4 epsps* coding sequence under the regulation of the *e35S* promoter, the *hsp70* intron, the *CTP2* targeting sequence, and the *nos* 3′ untranslated region. The backbone region of PV-ZMAP1043, located outside of the T-DNA, contains two origins of replication for maintenance of the plasmid vector in bacteria (*ori V*, *oripBR322*), a bacterial selectable marker gene (*aadA*), and a coding sequence for repressor of primer (*rop*) protein for maintenance of plasmid vector copy number in *E. coli.*

This modification involves the introduction of a *cp4 epsps* coding sequence, which results in the production of the same 5-enolpyruvylshikimate-3-phosphate synthase (CP4 EPSPS) protein found in commercially available Roundup Ready® crop products. The tissue-selective expression of CP4 EPSPS protein allows for the extended use of glyphosate-tolerant corn, thereby enabling it to be utilized as a tool for hybrid corn seed production.

Furthermore, MON 87427 utilizes a unique combination of a promoter and intron (*e35S-hsp70)* to activate the expression of the CP4 EPSPS protein in vegetative and female reproductive tissues conferring tolerance to glyphosate in the leaves, stalk, and root tissues which develop into seed or grain and silks. The specific combination of the promoter and intron further contributes to the minimal or absence of CP4 EPSPS protein production in two key male reproductive tissues: pollen microspores, which develop into pollen grains, and tapetum cells which provide nutrients to the pollen. Therefore, in MON 87427, male reproductive tissues crucial for male gametophyte (pollen) development are not glyphosate tolerant.

Southern blot analyses and DNA sequencing techniques have characterized the DNA insert and demonstrated that MON 87427 contains a single copy of the *cp4 epsps* expression cassette, referred to as transfer DNA (T-DNA) that is stably integrated at a single locus of the genome. The results confirmed the absence of plasmid vector backbone sequences on MON 87427. Moreover, the stability of the T-DNA insert across multiple generations was analyzed. It was reported that the single integration locus was maintained through five generations of breeding which confirms the stability of the insert.

The potential for MON 87427 outcrossing to sexually compatible species is unlikely since the wild relative teosinte has been reported only as an occasional botanical garden specimen in the Philippines.

V. Proposed Field Trial

The objectives of the field trial are to demonstrate under field conditions that appropriately timed glyphosate applications produce a male sterile phenotype in corn MON 87427 and to generate local data to support the application for the biosafety permit for commercial propagation of corn MON 87427.

The field trial will be conducted in three (3) trial sites for one (1) season. The field trial sites are Purok 2E, Brgy. Katangawan, General Santos City; Brgy. Kalabaza, Aurora, Isabela; and Brgy. Anulid, Alcala, Pangasinan.

The selection of these trial sites was based on several factors, including favorable climatic conditions, minimal risk of typhoon occurrences, a high rate of GM corn adoption in the area, a well-secured location (fences and presence of security guards), and appropriate isolation from nearby corn farms. Moreover, Bayer CropScience in coordination with the concerned regulatory agencies, will be responsible for the maintenance and control of the trial sites to facilitate the effective compliance management of the proposed activity.

To prevent the dispersal of the regulated planting materials beyond the approved site of release, preventive measures shall be implemented which involve spatial and/or temporal isolation for a minimum period of 21 days, installation of physical barriers, and restricted access to authorized personnel.

After the final data gathering, all viable plant parts will be heat-killed and buried at a designated spot inside the trial site. Afterwards, the area will be flooded and plowed under to monitor possible volunteers.
All movement of the materials to and from the trial site areas will be in closed packaging or containers and shall be supervised by the personnel of the Department of Agriculture-Bureau of Plant Industry (DA-BPI) Biotechnology Office.

In the event of damage caused by natural or man-made factors, Bayer CropScience is hereby instructed to inform the DA-BPI through the Institutional Biosafety Committee (IBC) of the necessary steps and actions it will undertake. Additionally, in cases of *force majeure* or intrusions at the field trial site, the contingency plan submitted by Bayer Crop Science will be diligently adhered to.

VI. Regulatory Decision

Following a thorough evaluation of the scientific data and relevant information provided by Bayer CropScience, DA-BPI has approved the conduct of the field trial activity in the following sites: Purok 2E, Brgy. Katangawan, General Santos City; Brgy. Kalabaza, Aurora, Isabela; and Brgy. Anulid, Alcala, Pangasinan.

The DA-BPI has issued a biosafety permit for the field trial of corn MON 87427, subject to specific conditions that Bayer CropScience must comply with. A copy of the biosafety permit is accessible through the DA-BPI Biotechnology website.

References:

Abendroth, L. J., R. W. Elmore, M. J. Boyer, & S. K. Marlay. (2011). Corn Growth and Development. PMR 1009. Iowa State University Extension, Ames, Iowa.

OECD. (2003) Consensus document on the biology of *Zea mays subsp. mays (maize)*. ENV/JM/MONO(2003)11. Series on Harmonisation of Regulatory Oversight in Biotechnology No. 27. Organisation for Economic Co-operation and Development, Paris, France.

Sidorov, V., & Duncan, D. (2009). Agrobacterium-mediated maize transformation: immature embryos versus callus. Methods in molecular biology (Clifton, N.J.), 526, 47–58. https://doi.org/10.1007/978-1-59745-494-0_4

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