Regulatory Decision on the Application for Commercial Propagation of Glyphosate Tolerant Corn MON 87427

I. Brief Identification of the Genetically Modified Organism

Designation:	Corn MON 87427
Applicant:	Bayer Crop Science, Inc.
Host Plant:	*Zea mays* L. (Corn)
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 commercial propagation

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, as well as its economic benefits for farmers. In the Philippines, through the implementation of the robust corn development program, the local production of corn has achieved stability.

Most of the human consumption of corn is in the form of corn-based ingredients such as high fructose corn syrup, starch, sweeteners, cereals, oil and alcohol. (Morris, M.L. 1998). Corn and corn products only form 2.2% of total food consumed on a per capita basis in the country. This is equivalent to 67 g/day or 25 kg/year per capita consumed in various forms: milled, on the cob, cornstarch and other. Rice and rice products remain as the most consumed energy-giving food in the Philippines raking 35.2% of the total food consumption equivalent to a 1064 g/day or 389 kg/year (DOST-FNRI, 2022). Corn is the preferred material for the production of livestock feed because of its high nutrient value and relative low cost. Corn gluten meal, corn gluten

feed, and distillers dried grains, derived as co-products by wet and dry milling, are also important components of livestock feed. Corn silage (as forage) is a major forage ingredient to be fed to livestock. (OECD, 2002). Conventional corn has a history of safe use as food, feed, and for processing.

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 sexually compatible with certain species or subspecies of teosinte. Both species are wind-pollinated and hybridize when near each other e.g., in areas of Mexico and Guatemala (Wilkes, 1972) while the distribution of teosinte in the Philippines is very unlikely.

IV. Characteristic and safety assessment of the GM product

Corn 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, regulated by the e35S promoter, hsp70 intron, 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 (oriV, oripBR322) for plasmid maintenance in bacteria, a bacterial selectable marker gene (*aadA*), and a coding sequence for the repressor of primer protein (rop) for plasmid copy number regulation in E. coli.

Molecular characterization through Southern blot, PCR, and sequencing analyses confirmed that the genetic modification is stably integrated at a single insertion site, with no detectable additional insertions or unintended genetic elements, and that no plasmid backbone sequences were present. Additionally, stability assessments demonstrated that the T-DNA insert remained intact across five generations of breeding, confirming its heritable stability.

This modification introduces the *cp4 epsps* coding sequence, which enables the production of the CP4 EPSPS protein, identical to that in commercially available

Roundup Ready® crops. The tissue-selective expression of this protein facilitates the extended use of glyphosate-tolerant corn as a tool for hybrid seed production. A unique promoter-intron combination (e35S-hsp70) drives CP4 EPSPS expression in vegetative and female reproductive tissues, ensuring glyphosate tolerance in leaves, stalks, roots, seeds, and silks. However, the same regulatory elements minimize or prevent CP4 EPSPS protein production in key male reproductive tissues, specifically pollen microspores and tapetum cells, which are critical for pollen development. Consequently, male reproductive tissues remain glyphosate-sensitive, ensuring effective glyphosate-induced male sterility and eliminating the need for manual detasseling in hybrid seed production.

The food and feed safety assessment adhered to internationally recognized guidelines, including those from Codex Alimentarius, OECD, and the U.S. FDA. Extensive protein characterization studies confirmed that the CP4 EPSPS protein in corn MON 87427 is biochemically and functionally equivalent to the CP4 EPSPS proteins expressed in previously approved Roundup Ready® crops. Toxicological and allergenicity assessments demonstrated that the protein is non-toxic, non-allergenic, rapidly digestible, and heat-stable, presenting no risk to human or animal health. Additionally, compositional analysis compared corn MON 87427 with conventional corn across multiple parameters, including proximates, amino acids, fatty acids, minerals, vitamins, anti-nutrients, and secondary metabolites. The results confirmed that all analyzed components fall within the natural variability range of commercial corn hybrids, supporting the conclusion that corn MON 87427 is nutritionally equivalent to its non-GM counterparts.

Environmental risk assessments were conducted through field trials in the Philippines (2023) and other locations, including the U.S., Brazil, and South Africa. These trials evaluated the impact of corn MON 87427 on non-target organisms, biodiversity, and ecosystem functions. The results confirmed that MON 87427 does not exhibit characteristics of a weed or invasive species and does not alter agricultural pest and disease dynamics. Insect population monitoring confirmed that common arthropod species in corn fields were not significantly affected by the cultivation of MON 87427. Additionally, weed and disease prevalence remained consistent with those observed in conventional corn fields, indicating that corn MON 87427 does not confer any unintend\ed agronomic advantage beyond glyphosate tolerance. The genetic modification does not enhance the ability of corn to persist in unmanaged ecosystems, further confirming its environmental safety.

The transformation event corn MON 87427, is compositionally, agronomically, and phenotypically comparable to conventional corn except for the introduced trait which

is glyphosate tolerance. Thus, it is unlikely to pose greater risk to human and animal health and the environment.

V. Regulatory Decision

After reviewing the scientific data and information relevant to the application of the Bayer Crop Science, Inc., the Bureau of Plant Industry (BPI) has approved the commercial propagation for Corn MON 87427 with conditions that need to be complied with by Bayer Crop Science, Inc. Copy of the Biosafety Permit issued may be accessed through the BPI Biotechnology website.