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Safety Assessment of Glyphosate-Tolerant MON 87427 Maize

Monsanto Company has developed biotechnology-derived MON 87427 maize with tissue-selective glyphosate tolerance to facilitate the production of viable hybrid maize seed. MON 87427 produces the same 5-enolpyruvylshikimate-3-phosphate synthase (CP4 EPSPS) protein that is produced in commercial Roundup Ready® crop products, via the incorporation of a *cp4 epsps* coding sequence. CP4 EPSPS confers tolerance to the herbicide glyphosate. Tissue-selective expression of CP4 EPSPS protein in MON 87427 enables an extension of the use of glyphosate tolerant maize as a tool in hybrid maize seed production. MON 87427 utilizes a specific promoter and intron combination (e35S-hsp70) to drive CP4 EPSPS protein expression in vegetative and female reproductive tissues, conferring tolerance to glyphosate in the leaves, stalk, and root tissues and tissues that develop into seed or grain and silks. This specific promoter and intron combination also results in limited or no production of CP4 EPSPS protein in two key male reproductive tissues: pollen microspores which develop into pollen grains, and tapetum cells that supply nutrients to the pollen. Thus, in MON 87427, male reproductive tissues critical for male gametophyte development are not tolerant to glyphosate. This allows glyphosate-treated MON 87427 containing inbred lines to serve as a female parent in the production of hybrid seed. Specifically, timed glyphosate applications to MON 87427 plants serving as a female parent inhibit pollen development and self-pollination, thus eliminating or greatly reducing the need for manual or mechanical methods of detasseling plants in order to facilitate cross-pollination from a nearby male parent.

MON 87427 was intensively tested in the laboratory and across multiple field sites in the USA. Data from those studies were used to conduct the product safety assessment and achieve government regulatory approvals. The product safety was based on the following:

- Conventional maize is a familiar crop that does not possess any of the attributes commonly associated with weeds, has a history of safe consumption, and serves as an appropriate basis of comparison for MON 87427.
- A detailed molecular characterization of the introduced DNA demonstrated a single, intact copy of the transgenic insert in a single locus within the maize genome.
- The CP4 EPSPS protein in MON 87427 is identical to the CP4 EPSPS protein produced in several other commercially available crops that have been reviewed by USDA (and other global regulatory authorities) and previously de-regulated (e.g. Roundup Ready soybean, Roundup Ready 2 Yield soybean, Roundup Ready corn 2, Roundup Ready canola, Roundup Ready cotton and Roundup Ready Flex cotton). The safety of CP4 EPSPS proteins present in biotechnology-derived crops has been thoroughly assessed and is the subject of numerous publications. The mode of action of CP4 EPSPS protein and how it confers glyphosate tolerance has been extensively studied and is well documented in peer reviewed publications.
- A compositional assessment confirmed that MON 87427 grain and forage are compositionally equivalent to grain and forage of conventional maize.
- An extensive evaluation of MON 87427 phenotypic and agronomic characteristics and environmental interactions demonstrated MON 87427 has no increased plant pest risk compared to conventional maize.

- An assessment of potential impact to non-target organisms (NTO) and endangered species indicated that, under normal agricultural conditions, MON 87427 is unlikely to have adverse effects on these organisms, similar to conventional maize.
- Evaluation of MON 87427 using intended and current cultivation and management practices for maize concluded that deregulation of MON 87427 will not significantly impact maize agronomic practices or land use.

These studies establish the food, feed and environmental safety of MON 87427 corn by demonstrating the safety of the CP4 EPSPS to humans and animals, establishing equivalent nutritional composition and wholesomeness of MON 87427 corn compared to conventional corn hybrids and confirming that the potential impact of MON 87427 corn on the environment is no different than that of conventional maize.

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