January 2020

Safety Assessment of Dicamba-Tolerant MON 87708 Soybean

Monsanto Company has developed biotechnology-derived soybean MON 87708 soybean that is tolerant to dicamba (3,6-dichloro-2-methoxybenzoic acid) herbicide. MON 87708 offers growers an expanded use of dicamba in soybean production from the current preplant and preharvest labeled uses. The tolerance of MON 87708 to dicamba facilitates a wider window of application in soybean, allowing preemergence application up to the day of crop emergence and in-crop postemergence applications up to the early reproductive (R1/) growth stage. Dicamba provides effective control of over 95 annual and biennial weed species, and suppression of over 100 perennial broadleaf and woody plant species. Dicamba is efficacious on broadleaf weeds that are hard-to-control, such as common lambsquarters, hemp sesbania, morning glory species, nightshade, Pennsylvania smartweed, prickly sida, velvetleaf, waterhemp and wild buckwheat. Hard-to-control weeds generally require a higher rate and/or application at a smaller growth stage in order to consistently achieve commercially acceptable control. Additionally, dicamba provides effective control of herbicide-resistant broadleaf weeds, including glyphosate-resistant weeds such as marestail, common ragweed, giant ragweed, palmer amaranth and waterhemp.

MON 87708 soybean contains a gene from *Stenotrophomonas maltophilia* that expresses a monooxygenase enzyme that rapidly demethylates dicamba rendering it inactive, thereby conferring tolerance to dicamba. The demethylation of dicamba produces 3,6-dichlorosalicylic acid (DCSA), a known soybean, soil, and livestock metabolite whose safety has been evaluated by the United States Environmental Protection Agency (US EPA). DCSA, in addition to dicamba, is included in the current 10 ppm pesticide residue tolerance for soybean seed that supports the existing uses of dicamba on commercial soybean (40 CFR § 180.227). Even with the expanded use of dicamba on MON 87708, compared to commercial soybean uses, the rapid metabolism of dicamba results in residues in dicamba-treated MON 87708 seed, including the DCSA metabolite, that are well below the established 10 ppm tolerance, and therefore no modification to the existing soybean seed tolerance is needed. Consequently, registration of the expanded use pattern of dicamba on MON 87708 soybean was approved by EPA.

MON 87708 soybean 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:

- Soybean is a familiar crop that does not possess any of the attributes commonly associated with weeds and has a history of safe consumption.
- A detailed molecular characterization of the inserted DNA demonstrated a single, intact copy of the T-DNA insert in a single locus within the soybean genome.
- Data confirmed that the dicamba mono-oxygenase (DMO) in MON 87708 (MON 87708 DMO) is unlikely to be a toxin or allergen based on extensive information collected.
- A compositional assessment of seed and forage confirmed that MON 87708 is compositionally equivalent to conventional soybean.
- An extensive evaluation on phenotypic and agronomic characteristics and environmental interactions of MON 87708 demonstrated no increased plant pest potential compared to conventional soybean.

- An assessment of potential impact on non-target organisms (NTOs) and endangered species indicated that, under normal agricultural conditions, MON 87708 is unlikely to have adverse effects on these organisms compared to conventional soybean.
- Evaluation of MON 87708 using current cultivation and management practices for soybean concluded that deregulation of MON 87708 will not significantly impact soybean agronomic practices or land use, with the exception of the expanded window of dicamba application.

These studies establish the food, feed and environmental safety of MON 87708 soybean by demonstrating the safety to humans and animals, establishing equivalent nutritional composition and wholesomeness compared to conventional soybean varieties, and confirming that the potential impact on the environment is no different than conventional soybean varieties.