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Safety Assessment of Insect-Resistant MON 87701 Soybean

Monsanto Company has developed biotechnology-derived insect-protected soybean MON 87701 that produces the Cry1Ac insecticidal crystal (Cry) protein (δ -endotoxin) derived from *Bacillus thuringiensis* (Bt) subsp. *kurstaki*. The Cry1Ac protein provides protection from feeding damage caused by targeted lepidopteran pests. The cry1Ac gene was transferred into the genome of soybean cells using *Agrobacterium tumefaciens*-mediated transformation. The MON 87701 product concept is to reduce or replace current insecticide applications to control lepidopteran pests in tropical and subtropical soybean production regions where these insects cause significant plant damage and yield loss. MON 87701 will offer growers in these regions an effective pest management tool and help to maintain soybean yield potential.

Soybean production in the U.S. can be impacted by insect pests that require insecticide treatments to control infestations that reach economic thresholds. The impact and severity of insect pest infestations vary greatly across soybean production regions primarily due to the different climate and weather conditions, insect species distributions, insect species environmental tolerances, and agricultural practices. In the U.S., the most economically important soybean lepidopteran pests are the defoliating and pod-feeding insects. The most damaging lepidopteran defoliators are velvetbean caterpillar, *Anticarsia gemmatilis*; soybean looper, *Chrysodeixis includens*; and green cloverworm, *Plathypena scabra*.

MON 87701 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:

- A detailed molecular characterization of the inserted DNA, where the results confirm the insertion of a single functional cry1Ac expression cassette at a single locus within the soybean genome.
- An extensive set of biochemical evaluations that demonstrate the identity of the full-length Cry1Ac produced in MON 87701.
- An assessment of toxicity and allergenicity potential of the Cry1Ac protein based on extensive information collected and evaluations performed on Cry1Ac. The results demonstrate that the Cry1Ac protein is not likely to be a toxin or allergen.
- The compositional and nutritional assessment confirmed that MON 87701 harvested seed and forage are compositionally and nutritionally equivalent to and as safe as those of conventional soybean.
- An extensive evaluation of the MON 87701 phenotypic and agronomic characteristics and environmental interactions that demonstrate MON 87701 is not likely to have increased plant pest potential compared to conventional soybean.
- An assessment on the potential impact to non-target-organisms (NTOs) and endangered species concludes that MON 87701 is unlikely to have adverse effects on these organisms under normal agricultural practices.

These studies establish the food, feed and environmental safety of MON 87701 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.

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