EXECUTIVE SUMMARY
to
Application to Food Standards Australia New Zealand for the Inclusion of Soybean MON 87705 in Standard 1.5.2 - Food Derived from Gene Technology

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EXECUTIVE SUMARRY

Monsanto Company has developed biotechnology-derived soybean MON 87705 with an improved fatty acid profile that results in enhanced nutritional characteristics. Given its high proportion of polyunsaturated fatty acids, commodity soybean oil requires hydrogenation to improve its stability for use in many foods. Plant oils such as canola and olive oil are relatively high in monounsaturated 18:1 oleic acid and low in polyunsaturated fatty acids providing stability advantages over commodity soybean oil. MON 87705 was developed to have an unsaturated fatty acid profile similar to olive oil and canola oil, while having less than half the levels of saturated fatty acids of commodity soybean oil. Saturated fats, notably 16:0 palmitic acid, have also been shown to contribute to cardiovascular disease and other chronic diseases. As a result, the reduced saturated fat levels in MON 87705 soybean oil, particularly palmitic acid, can positively impact the goal of limiting dietary saturated fat intake. MON 87705 contains the same five major fatty acids that are found in conventional soybean: 16:0 palmitic and 18:0 stearic (saturated); 18:1 oleic (monounsaturated); and 18:2 linoleic, and 18:3 linolenic acids (polyunsaturated), but in different proportions. MON 87705 has a fatty acid profile comparable to other widely consumed vegetable oils including olive oil and canola oil and is well suited for use in bottled vegetable oil, salad dressings, margarine and other similar food products for which commodity soybean oil is used.

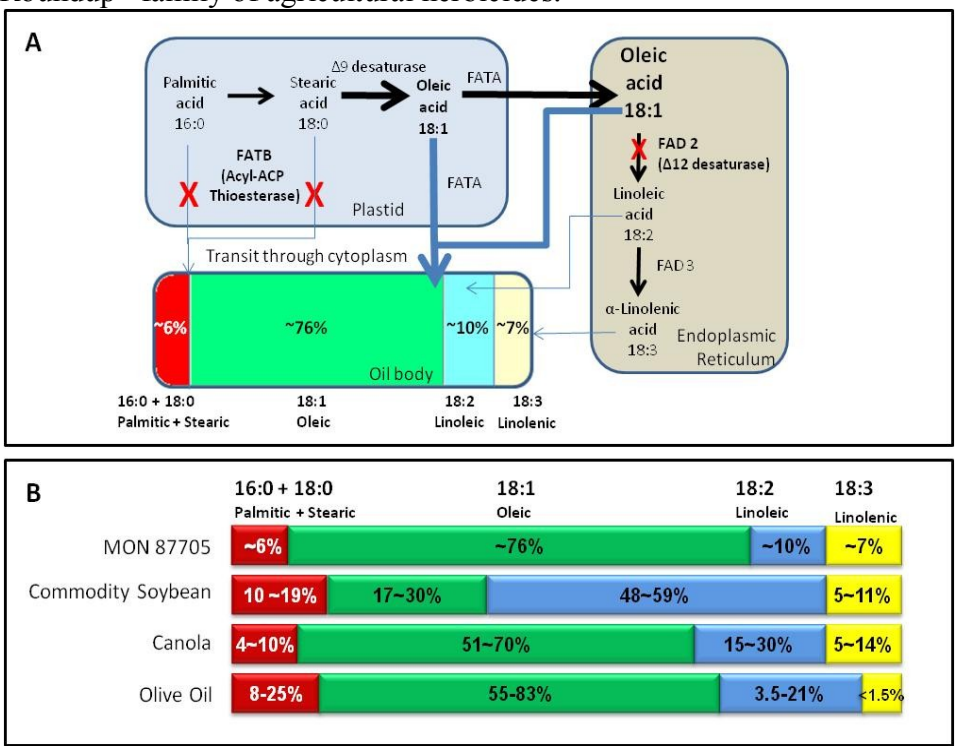
The data and information presented in this safety summary demonstrate that the food and feed derived from MON 87705 are as safe and nutritious as those derived from commercially available conventional soybean. This safety assessment was conducted utilizing established methods for the evaluation of biotechnology-derived products as articulated in guidelines from the Codex Alimentarius Commission and Organisation for Economic Co-operation and Development (OECD).

MON 87705 Mechanism of Action

The improved fatty acids profile in MON 87705 soybean oil was achieved through the use of RNA-based suppression of two key enzymes, FATB and FAD2, involved in the soybean seed fatty acid biosynthetic pathway (See figure below.) The acyl-acyl carrier protein (ACP) thioesterases (referred to herein as FATB enzymes) are localized in plastids and hydrolyze saturated fatty acids from the acyl-acyl carrier protein (acyl-ACP)-fatty acid moiety. The RNA-based suppression of *FATB* results in a decrease in transport of saturated fatty acids out of the plastid, thus increasing their availability for desaturation to 18:1 oleic acid (see figure above). Therefore, suppression of *FATB* decreases the levels of saturated fatty acids and increases the levels of 18:1 oleic acid in the plastids that are then delivered to the oil body or to the endoplasmic reticulum for further desaturation. The delta-12 desaturases (referred to as FAD2 enzymes) desaturate 18:1 oleic acid to 18:2 linoleic acid. The RNA-based suppression of *FAD2* in MON 87705 soybean seed causes reduced desaturation of 18:1 oleic acid to 18:2 linoleic acid resulting in an increase in 18:1 oleic acid levels and a decrease in 18:2 linoleic acid levels that are available for transport from the endoplasmic reticulum to the oil body. Therefore, the net effect of the RNA-based suppression of *FATB* and *FAD2* is a reduction in saturated 16:0 palmitic and 18:0 stearic acid levels, an increase in monounsaturated 18:1 oleic acid levels, and a decrease in polyunsaturated 18:2 linoleic acid levels in MON 87705 relative to commodity soybean oil.

As a result, MON 87705 soybean oil contains lower levels of saturated fatty acids (6% vs. 15%) than currently available commodity soybean oil, and is suitable for a range of food

applications. In addition, soybean meal derived from MON 87705, which contains very low levels of residual oil is compositionally similar to other commodity soybean meal. MON 87705 also contains the 5-enolpyruvylshikimate-3-phosphate synthase gene derived from *Agrobacterium sp*. strain CP4 (*cp4 epsps*), which encodes the CP4 EPSPS protein that is expressed throughout the plant to confer tolerance to glyphosate, the active ingredient in the Roundup® family of agricultural herbicides.



Soybean Fatty Acid Biosynthetic Pathway (Panel A) and Comparison of the Fatty Acid Content of MON 87705 Soybean Oil with Other Vegetable Oils (Panel B)

Characterization and Safety of Expression Products in MON 87705

The food and feed safety of MON 87705 was confirmed based on multiple, well established lines of evidence:

1. A detailed molecular characterization of the inserted DNA demonstrated a single copy of both the *FAD2-1A/FATB1-A* suppression cassette and the *cp4 epsps* expression cassette, integrated in a single locus within the soybean genome that segregates in subsequent progeny according to Mendelian laws of inheritance.

2. The suppression cassette in MON 87705 is extremely unlikely to produce a protein. The RNA-based suppression of *FATB* and *FAD2* soybean genes in MON 87705 is mediated by dsRNA molecules. Double stranded RNAs are commonly used by eukaryotes, including plants, for endogenous gene suppression and pose no novel risks from a food or feed perspective. Nucleic acids, such as RNA, have a long history of safe consumption and are considered GRAS by the U.S. FDA.

3. An extensive set of biochemical evaluations demonstrate the equivalence of the MON 87705-produced CP4 EPSPS to the *E. coli*-produced CP4 EPSPS used for safety evaluation, and that its amino acid sequence is identical to CP4 EPSPS protein expressed in other Roundup Ready crops that were the subject of previous consultations with the U.S. FDA.

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4. Finally, except for the intended fatty acid changes in oil, the compositional and nutritional assessment of MON 87705 supports the conclusion that soybean seed, forage and key processed fractions produced from MON 87705 are compositionally equivalent to those of conventional soybean. Within the analytical limits of the present studies, MON 87705 soybean oil does not contain any fatty acids that are not observed in commodity soybean oil, and the fatty acid profile of MON 87705 soybean oil is similar to other commercially available plant-derived oils.

These data strongly support the conclusion that food and feed derived from MON 87705 will be as safe and nutritious as food and feed derived from conventional soybean.