

ANNEX F

PAMPUBLIKONG IMPORMASYON UKOL SA IMPORTASYON HINGGIL SA DIREKTANG PAGGAMIT BILANG PAGKAIN, PAKAIN SA HAYOP, O PARA SA PAGPOPROSESO

PANUKALA PARA SA DIREKTANG PAGGAMIT BILANG PAGKAIN, PAKAIN SA HAYOP, O PARA SA PAGPOPROSESO NG Soybean MON 87705

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- 5. Deskripsyon ng Regulated Article ukol sa Impormasyon para sa Direktang Paggamit**

Monsanto Company has developed biotechnology-derived soybean MON 87705 with decreased levels of saturated fats (16:0 palmitic acid and 18:0 stearic acid) and increased levels of 18:1 oleic acid with an associated decrease in 18:2 linoleic acid that results in enhanced nutritional characteristics. This improved oil is produced in the soybean through biotechnology-mediated gene suppression of FATB and FAD2, two key enzymes in the fatty acid biosynthetic pathway. Suppression of the FATB enzyme results in a decrease in the levels of saturated fats (16:0 palmitic acid and 18:0 stearic acid), while suppression of the FAD2 enzyme results in an increase of oleic acid (18:1) and associated decrease in linoleic acid (18:2). Oil from MON 87705 has enhanced storage and processing stability, an improved nutritional profile, and better food functionality.

Ang Monsanto ay binuo ang soybean MON 87705 sa pamamagitan ng biotechnology. Ang soybean MON87705 ay may mababang level ng saturated fats (16:0 palmitic acid and 18:0 stearic acid) at may mataas na level ng 18:1 oleic acid na may kaugnay na pagbaba ng 18:2 linoleic acid na nagbibigay ng mahusay na nutrisyonal na karakter. Ang pinahusay na langis na galing sa soybean ay dumaan sa pamamamagitan ng biotechnology-mediated gene suppression ng FATB at FAD2 na dalawa sa mahahalagangenzymes sa fatty acid biosynthetic pathway. Ang pagpapatigil ng FATB enzyme ay resulta sa pagbaba ng level ng

saturated fats (16:0 palmitic acid and 18:0 stearic acid), samantala ang pagpapatigil naman ng FAD2 enzyme ay nagresulta sa pagtaas ang oleic acid (18:1) at pagbaba ng linoleic acid (18:2). Ang langis na nagmumula sa MON87705 ay may pinahusay na storage at processing stability, na pinahusay na nutritional profile at mas maayos na pagkain.

MON 87705 also contains the 5-enolpyruvylshikimate-3-phosphate synthase gene derived from *Agrobacterium* sp. strain CP4 (*cp4 epsps*). Expression of the gene product (CP4 EPSPS) confers tolerance to glyphosate, the active ingredient in the Roundup® family of agricultural herbicides. The *cp4 epsps* gene was used as a selectable marker during plant transformation.

Ang MON87705 ay naglalaman ng 5-enolpyruvylshikimate-3-phosphate synthase gene na nagmula sa *Agrobacterium* sp. strain CP4 (*cp4 epsps*). Ang pagpapahayag ng produkto ng gene (CP4 EPSPS) ay nagtatakda ng mabisang paglaban sa glyphosate, ang aktibong sangkap sa pamilyang Roundup® na herbisidyo sa agrikultura. Ang *cp4 epsps* gene ay ginamit bilang isang selectable marker sa panahon ng transformation ng halaman.

MON 87705 ay nabuo sa pamamagitan ng *Agrobacterium*-mediated transformation method.

6. Kung iaangkat, sa mga bansang pinanggagalingan ng bahagi ng artikulo sa United States. Ang mag-aangkat ng kalakal ay kailangan makapagbigay ng sariling pagkukunan

7. Maikling Buod ng mga Potensyal na Epekto sa Kalusugan ng Tao at ng Kapaligiran

Direct use of soybean MON 87705 as food and feed will not result in harmful effects on humans and animals. Multiple, well-established lines of evidence confirm the food and feed safety and the lack of plant pest potential of soybean MON 87705.

Ang direktang paggamit ng soybean MON87705 bilang pagkain and pakain sa hayop ay ligtas at walang epekto sa tao at sa hayop. Sa mahabang pagaaral napatunayan na ang pagkain at pakain sa hayop ay ligtas at ang Soybean MON 87705 ay hindi nakikitaan ng potensyal na maging pesteng halaman.

- The CP4 EPSPS protein (identical with those expressed in other Roundup Ready® crops) has previously been evaluated and found to not pose food or feed safety issues and crops containing these proteins have been grown and consumed for many years.

Ang CP4 EPSPS protein (kapareho ng ibang uri Roundup Ready® na pananim) ay matagal nang napag-aralan at napatunayang hindi hindi magdudulot ng mga isyu sa kaligtasan ng pagkain o pakain sa hayop. Ang mga pananim na naglalaman ng mga protinang ito ay itinanim at kinukunsumo sa loob mahabang panahon

- MON 87705 was fully characterized to confirm the integrity and stability of the inserted *FAD2-1A/FATB1-A* suppression cassette and *cp4 epsps* expression cassette.

Ang MON 87705 ay ganap na napag-aralan upang kumpirmahin ang integridad at katatagan ng ipinasok na FAD2-1A / FATB1-A cassette suppression at cp4 epsps expression cassette.

- The suppression cassette in MON 87705 is extremely unlikely to produce a protein. The suppression of *FATB* and *FAD2* soybean genes in MON 87705 is mediated by double stranded RNA molecules. They 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 generally recognized as safe by the U.S. FDA.

Ang cassette ng pagsugpo sa MON 87705 ay malamang na hindi makagawa ng isang protina. Ang pagsupil sa mga *FATB* at *FAD2* gene sa Soybean MON 87705 ay pinagsama sa pamamagitan ng double stranded RNA molecules. Ang mga ito ay kadalasang ginagamit ng mga eukaryote, kabilang ang mga halaman, para sa endogenous gene suppression at nagtatala ng anumang panganib bilang pagkain o pakain sa hayop. Ang mga nucleic acids, tulad ng RNA, ay may mahabang kasaysayan ng ligtas na pagkonsumo at itinuturing na karaniwang kinikilala bilang ligtas ng U.S. FDA.

- The CP4 EPSPS protein in MON 87705 exhibits no relevant sequence similarities to known allergenic or toxic proteins, is rapidly degraded by simulated gastric fluid, loses activity upon heating at temperatures below standard food processing temperatures, and has no adverse toxicity in mice at the level tested.

Wala ring natuklasan o nakitang pagkakatulad ang protinang CP4 EPSPS sa mga sequence ng mga kilalang allergenic o toxic na protina, nakita rin na ang protinang ito ay mabilis na nadudurog gamit ang gastric fluid, kawalan ng activity matapos mainitan sa temperatura at walang epekto sa toxicity ng daga sa ganun pagsusuri.

- A comprehensive compositional assessment supports the conclusion that MON 87705 seed and forage are compositionally equivalent, except for the intended fatty acid changes in oil, to that of conventional soybean.

Sa komprehensibong pagsusuri sa komposisyon ng MON 87705 ay sumusuporta sa konklusyon na binhi at pakain sa kabayo ay katumbas sa kombensyonal na uri ng soybean maliban na lamang sa intensyonal na pagbago may fatty acids ng langis.

- An extensive evaluation of soybean MON 87705 phenotypic and agronomic characteristics and environmental interactions demonstrated that soybean MON 87705 has no increased plant pest risk potential compared to conventional soybean and does not negatively affect non-targeted organisms differently from conventional soybean under normal agricultural practices.

Ang malawak na pagaaral ng phenotypic at agronomic na katangian ng soybean MON 87705 at interaksyon nito sa kapaligiran ay nagpapakita na ang Soybean MON 87705 ay walang kakayahang maging pesteng halaman at walang anumang epekto

sa non-targeted organisms na kaiba sa kombensyonal na soybean sa ilalim ng normal na paraan ng pagsasaka.

Taken all these together, the soybean MON 87705 is as safe as conventional soybean and does not pose greater risks to biodiversity, human and animal health than its conventional counterpart.

Sa pagsama-sama ng mga ito, ang magkakasamang katangian ng produktong soybean MON 87705 ay ligtas katulad ng kombensyonal na soybean at ito ay hindi nagpapakita ng higit ng panganib sa biodiversity, kalusugan ng tao at hayop na kaiba sa kombensyonal na soybean

8. Maikiling Buod ng Potensyal na Epekto

Soybean is grown as a commercial crop in over 35 countries and domestication of this crop can be traced back to approximately 1000 B.C. A major food use for soybean is as purified oil for use in margarines, shortenings, cooking, and salad oils. 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.

Ang Soybean ay lumago bilang isang komersyal na pananim sa mahigit na 35 na bansa at at ang pagpapakain ng crop na ito ay maaaring masubaybayan pabalik sa humigit-kumulang na 1000 B.C. Ang pangunahing paggamit ng pagkain para sa soybean ay ang purified oil bilang gamit sa margarines, shortenings, pagluluto, at salad oils. Ang MON87705 ay naglalaman ng 5 major fatty acids na nakikita sa kombensyonal na soybean: 16:0 palmitic at 18:0 stearic (saturated); 18:1 oleic (monounsaturated); at 18:2 linoleic, at 18:3 linolenic acids (polyunsaturated), ngunit sa ibat ibang sukat. Ito rin ay may fatty acid profile na na maihahambing sa iba pang madalas gamitin na vegetable oils kasama na rito ang olive oil and canola oil.

The improved fatty acid profile of MON 87705 soybean oil is expected to increase oxidative stability and enable formulation of foods with lower saturated fat content. Hydrogenation of soybean oil is often necessary to reduce levels of polyunsaturated fatty acids; however, the hydrogenation process produces *trans* fatty acids that are linked to increased cardiovascular disease risk. Because MON 87705 soybean oil has reduced levels of polyunsaturated fatty acids, it is expected to have higher oxidative stability, while also containing lower levels of saturated fats. 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 to below 10% of total energy intake¹.

Ang pinaayos na fatty acid profile ng MON 87705 soybean oil ay nagbibigay ng mataas na oxidative stability at nagbibigay ng kakayahan upang makabuo ng pagkain na may

¹Department of Health and Human Services, *Dietary Guidelines for Americans*, 2005. www.health.gov/dietaryguidelines [Accessed June 7, 2009]

mababang saturated fat. Ang hydrogenation ng soybean oil ay madalas na kinakailangan upang mabawasan ang produksyon ng polyunsaturated fatty acids; subalit ang proseso ng hydrogenation ay naglalabas ng trans fatty acids na maaring maging sanhi ng pagtaas ng cardiovascular disease risk. Dahil ang MON87705 soybean oil ay nabawasan ang mga antas ng polyunsaturated fatty acids, inaasahang magkaroon ng mas mataas na oxidative stability habang naglalaman din ng mas mababang antas ng saturated fats.. Ang saturated fats, ay may 16:0 palmitic acid na nagigiging sanhi ng cardiovascular disease at iba pang malalang sakit. Dahil dito, ang mababang lebel ng saturated fatty acids sa MON 87705 soybean oil, lalo na palmitic acid, ay maaaring positibong makaapekto sa layunin ng paglilimita ng dietary saturated fat intake sa ibaba 10% ng kabuuang paggamit ng enerhiya.

The fatty acid profile of MON 87705 soybean oil is also well suited for industrial applications. The fatty acid profile of MON 87705 provides an industrial oil with improved stability that could serve as a lubricant without needing hydrogenation. In addition, soybean oil with elevated oleic acid is an attractive source for other industrial applications, such as a replacement for petrochemical-derived plasticizers. The higher oleic acid and lower saturated fat levels of MON 87705 also make it much more suitable for use in biodiesel due to its greater stability, improved cold weather performance, and reduced nitrous oxide emissions.

Ang MON87705 na soybean oil ay maaring magamit sa industrial na pamamaraan. Ang fatty acid profile ng MON 87705 ay ay nagbibigay sa industrial oil ng stability upang magamit bilang lubricant na hindi na kinakailangan ng hydrogenation. Sa karagdagan, soybean oil na may oleic acid na maaring gamitin sa industrial na paggamit katulad ng pamalit sa petrochemical-derived plasticizers. Sa mataas na oleic acid at sa mababang saturated fat levels ng MON87705 maari itong gamitin bilang biodiesel dahil sa matibay na kalidad, pinahusay na pagtatanim sa malamig na panahon and mabawasn ang nitrous oxide emissions

9. Mga Bansang NagApruba (para sa FFP; para sa Komersyal na Pagpapalaganap)

Australia/ New Zealand (Food, 2011), Canada (Feed, Environment, 2011; Food, 2011), China (Food, Feed, 2017), Colombia (Feed, 2012; Food, 2014), EU (Food, Feed, 2015), Indonesia (Food, 2013), Japan (Food, 2012; Feed, 2013; Environment, 2013), Korea (Food, 2013; Feed, 2012), Mexico (Food, Feed, 2011), Philippines (Food, Feed, 2014), Singapore (Food, Feed, 2015), Taiwan (Food, 2018; Feed, 2018), United States (Food, Feed, 2011; Environment, 2011), Vietnam (Food, Feed, 2015).

The public is hereby invited to submit their comments to the BPI Director (within 60 days from date of publication) on the Proposal for the Importation of soybean MON 87705 for direct use as food and feed, or for processing

Inimbitahan ng publiko na isumite ang kanilang mga komento sa Direktor ng BPI (sa loob ng 60 araw mula sa petsa ng paglalathala) sa Proposal para sa Pag-angkat ng soybean MON 87705 para sa tuwirang paggamit bilang pagkain at feed, o para sa pagproseso

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