ANNEX

Assessment of the allegations included in the request for internal review of Commission Implementing Decisions on GM soybeans MON 87769, MON 87705 and 305423

Preliminary considerations

You claim that the Commission Implementing Decisions authorising the placing on the market of the three GM soybeans do not meet the requirements of Regulation (EC) No 178/2002[1], Regulation (EC) No 1829/2003[2] and Commission Implementing Regulation (EU) No 503/2013.[3]

We would like to clarify that Commission Implementing Regulation (EU) No 503/2013 was not applicable to the authorisations of the GM soybeans MON 87769, MON 87705 and 305423 since that Regulation only applies to applications submitted after its entry into force on 28 June 2013.[4]

1. Lack of EFSA guidance for health impacts of GM crops with significantly altered nutritional content

You claim that the authorisations of the GM soybeans are premature because specific requirements for the authorisation of nutritionally-altered GM crops have not yet been adopted. In particular, you claim that no guidance for the risk assessment of GM plants with altered nutrient content has been developed by EFSA and that, therefore, there is no legal basis for the assessment and approval of nutritionally-altered GM plants in the EU.

You refer to Regulation (EC) No 178/2002, which mandates EFSA to "*promote and coordinate the development of uniform risk assessment methodologies in the fields falling within its mission*"[5], and to Regulation (EC) No 1829/2003, which requests EFSA to develop specific "*guidance to assist the applicant in the preparation and the presentation of the application*"[6]. You also refer to EFSA's Policy on Independence and Scientific Decision-Making Processes from 2011[7], which recognizes the importance of

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1 Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1–24).

2 Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed (OJ 2003, L 268, p. 1).

3 Commission Implementing Regulation (EU) No 503/2013 of 3 April 2013 on applications for authorisation of genetically modified food and feed in accordance with Regulation (EC) No 1829/2003 of the European Parliament and of the Council and amending Commission Regulations (EC) No 641/2004 and (EC) No 1981/2006 (OJ L 157, 8.6.2013, p. 1–48).

4 The application for the authorisations of the GM soybeans MON 87769, MON 87705 and 305423 were submitted on 14 September 2009, 18 February 2010 and 14 June 2007, respectively.

5 Article 23(b) of Regulation (EC) No 178/2002.

6 Articles 5(8) and 17(8) of Regulation (EC) No 1829/2003.

7 EFSA (European Food Safety Authority), Policy on Independence and Scientific Decision-Making Processes of the European Food Safety Authority, adopted on 15 December 2011. http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf

developing general good risk assessment practices and methodologies to ensure a coherent scientific output.

You also claim that EFSA has recognized the need to develop a strategy for the assessment of nutritionally-altered plants by mandating an expert report in 2012 and that EFSA and the Commission have not followed-up on the conclusions and recommendations of that report, which, in your view, would have undermined the quality of the risk assessment and the legality of the three GM soybeans authorisations. You argue that EFSA recognised the need for specific guidance but that it did not adequately inform other EU bodies or the public.

These claims are unfounded.

First, the lack of specific guidance for assessing nutritional consequences of a significantly altered nutrient content in GM crop is not a valid argument to disqualify EFSA's assessment of the three GM soybeans and the subsequent adoption by the Commission of the above mentioned decisions of authorisation based on this assessment.

EFSA has developed a large body of risk assessment methodologies to ensure a comprehensive evaluation of all data needed to reach a conclusion on the safety of GM food and feed, including the assessment of the nutritional aspects of that food and feed. In addition, EFSA constantly monitors for developments in risk assessment methodologies and updates its guidance documents when necessary.

EFSA has developed, where needed, guidance documents on specific aspects of the risk assessment of GM food and feed. This includes, for instance: the guidance document on stacked transformation events[8]; the opinion on statistical considerations for the safety evaluation of GMOs[9]; the opinion on the assessment of allergenicity of GM plants and microorganisms[10]; the guidance on the selection of comparators[11]; and the guidance on post-market environmental monitoring of GM plants[12].

The scientific assessment of the three GM soybeans was carried out by EFSA taking into account the principles and methodologies described in its Guidance for the risk assessment of GM plants for food and feed uses ('2006 EFSA Guidance'[13] and its updated version '2011 EFSA Guidance'[14]). This Guidance requires specific analyses in case of nutritionally-altered GM crops, such as the inclusion of a fatty acid profile for oil-rich plants (for the compositional analysis), or an exposure assessment to estimate the food intake. In addition, the Guidance determines that GM plants and derived food and feed

8 EFSA Journal, 2007; 512, 1-5

9 EFSA Journal 2010; 8(1):1250

10 EFSA Journal 2010; 8(7):1700

11 EFSA Journal 2011; 9(5):2149

12 EFSA Journal 2011;9(8):2316

13 EFSA Panel on Genetically Modified Organisms (GMO), 2006. Guidance Document of the Panel on Genetically Modified Organisms for the risk assessment of genetically modified plants and derived food and feed. The EFSA Journal 2006, 99, 1–100. doi:10.2903/j.efsa.2006.99.

14 EFSA Panel on Genetically Modified Organisms (GMO), 2011. Guidance for risk assessment of food and feed from genetically modified plants. EFSA Journal 2011; 9(5):2150. 37 pp. doi:10.2903/j.efsa.2011.2150.

with modified nutritional properties may require post-market monitoring to confirm the conclusion of the exposure assessment.

The body of EFSA guidance documents provide principles, strategy and data requirements for assessing the safety of all GM food and feed for human and animals, including GM food and feed with nutritional traits. Therefore, a specific guidance for the assessment of nutritionally enhanced crops would not change the EFSA assessment of the soybeans at stake.

Moreover, for nutritionally altered GM crops, as for any other GM crop assessed by EFSA, experimental data may be required on a case-by-case basis if considered necessary.

In substance, EFSA considers that the issues raised by GM crops with altered nutritional content do not differ in principle from those of non-GM novel foods.

A considerable body of knowledge exists within EFSA with regard to the assessment of nutritional aspects. For example, EFSA has to set Dietary Reference Values (DRVs) for macronutrients and essential micronutrients, characterising the habitual level of intake of a nutrient which will satisfy the needs of nearly all members of a population group, and which is unlikely to pose a risk of adverse health effects to humans. DRVs derived by EFSA are always based on a comprehensive review and evaluation of the relevant literature. They have been established for the fatty acids whose concentrations are modified in the three GM soybeans 305423, MON 87705 and MON 87769.[15]

Second, contrary to your claim, the external scientific report "Review of the strategies for the comprehensive food and feed safety and nutritional assessment of GM plant per se"[16] (hereafter referred to as the “report”) did not indicate the need for a specific guidance to assess novel traits.

This report reviews the scientific literature and risk assessment frameworks for assessing food and feed safety of GM plants in cases where the comparative approach, as applied by EFSA, might not be fully applicable.

The report found no evidence in the scientific literature or from international risk assessment bodies of GM plants that have not been compared to an appropriate comparator or a database and recalled that comparisons are *“a cornerstone of food and feed risk assessment of GM plants, whether traits were ‘novel’ or otherwise.”* The contractor in charge of the report considered that by using the comparative assessment, EFSA had applied the most reliable method to identify any unintended effects.

Through case studies, the report found that GM crops with novel traits already approved in third countries have been assessed using the same approach and the same risk assessment criteria followed for the assessment of any other GM crop. The report concluded that methods for risk-assessing GM plants without using a comparator are not currently well understood and are neither applied by international risk assessment bodies nor proposed by the scientific literature.

15 EFSA Panel on Dietetic Products, Nutrition, and Allergies (NDA) Scientific Opinion on Dietary Reference Values for fats, including saturated fatty acids, polyunsaturated fatty acids, monounsaturated fatty acids, trans fatty acids, and cholesterol. EFSA Journal 2010;8(3):1461, 107 pp.

16 ADAS UK Ltd. & Rothamsted Research, 2013. Review of the strategies for the comprehensive food and feed safety and nutritional assessment of GM plants per se. EFSA supporting publication 2013:EN-480, 115 pp.

The report also found that exposure assessment is a key stage of the risk assessment of "novel" traits (as it should be assessed whether the trait in question may induce changes in consumption patterns, displace any other food/feed in the diet or allow consumers to make informed choices over consumption) and highlighted the importance of the post-market monitoring for quality traits in order to validate the results of exposure assessment. In this regard, the Commission Implementing Decisions authorising the three GM soybeans in question require the applicant to submit post-market monitoring reports and to redo the exposure assessment in case of imports of oil from those GM soybeans or those GM soybeans for oil extraction (more information in section 4 of this annex).

Finally, the report was produced following an internal mandate proposed by EFSA to its GMO unit and in accordance with EFSA rules. It was prepared by a contractor on the basis of a procurement to perform a review of the strategies to carry out risk assessment of GM plants in cases where a comparative assessment may not be fully applicable. It is not a scientific study but a review of studies already existing in the scientific literature and therefore EFSA was not obliged to inform the Commission, the European Parliament or Member States under Article 32 of Regulation (EC) No 178/2002.

Based on the conclusions of the report, EFSA considered that no new guidance was needed to assess 'novel' traits. Therefore, EFSA did not develop any further strategy for the assessment of nutritionally-altered crops that might have needed to be communicated to the public.

In conclusion, your claim that the authorisations of the GM soybeans should have not been granted due to the lack of specific guidance on the assessment of nutritionally altered crops is not substantiated. The safety of GM food and feed, including GM food and feed with nutritionally-altered traits, is guaranteed by the application of existing EFSA guidance documents. The report did not contradict this conclusion; on the contrary, it confirmed that the comparative assessment used by EFSA constitutes the most reliable method to identify any unintended effects.

Therefore, your allegation on this point must be rejected.

2. Inadequate and inconsistent nutritional risk assessment of the GM soybeans

You claim that the inadequate nutritional risk assessment resulting from the lack of specific guidance for the assessment of nutritionally altered crops has led to an infringement of the safety requirements of Regulation (EC) No 1829/2003 and Regulation (EC) No 178/2002. In particular, you claim that the EFSA's opinions on these three GM soybeans provide an inadequate basis for their authorisation because they do not cover the potential risks arising from the alteration of the nutritional composition.

As explained in section 1 of this annex, the issues raised by nutritionally altered crops do not differ from those arising from non-GM novel foods, of which a considerable body of knowledge exists within EFSA. A specific guidance for the assessment of GM crops with altered nutritional composition would not change the assessment of the GM soybeans. Therefore, the lack of specific EFSA guidance for the assessment of nutritionally altered crops does not entail a violation of the safety requirements enshrined in Regulation (EC) No 1829/2003 and Regulation (EC) No 178/2002.

Your specific allegations on the inadequacy of the nutritional risk assessment are assessed below.

2.1- Inadequate or missing literature reviews on health impacts

You claim that Regulation (EC) No 1829/2003 requires applications to include a systematic review of studies published in the scientific literature and studies performed by the applicant on the potential effects on human and animal health of the GM food.

With regard to MON 87769 soybean, you claim that the applicant cites studies which are inadequate to assess long-term effects, did not include studies on the reduced linoleic acid levels in that soybean and that there is no conclusive evidence of the health benefit from increased omega-3 fatty acids.

In relation to MON 87705 and 305423 soybeans, you claim that no literature review of health impacts is included for the altered fatty acid content of the soybeans, which, in your opinion, would have identified potential risks (such as cancer or memory loss) and benefits associated to these fatty acids.

Your claims cannot be accepted.

First, the Commission would like to observe that the requirement that the applicant has to provide a systematic review of the studies published in the scientific literature has been introduced by Implementing Regulation (EU) No 503/2013 which, as already explained, was not applicable at the time the applications for authorisation of the three soybeans were lodged.

In accordance with Articles 5(3)(e) and 17(3)(e) of Regulation (EC) No 1829/2003, applicants must provide all available studies (including independent studies, where available) to demonstrate that the GM food and feed complies with the requirements (Articles 4(1) and 16(1)) of the Regulation), and this includes providing relevant scientific publications.

This requirement has been met by the applicants and, in parallel, a literature search has also been performed on its own by EFSA. While EFSA has considered all these sources for the assessment of the GM soybeans, only relevant literature of sufficient scientific quality is cited in the scientific opinions.

Second, contrary to your claim, EFSA has not neglected important publications in the assessment of the three GM soybeans. The publications you cited have been reviewed by EFSA, which considers that they did not provide evidence of adverse health effects associated with the consumption of monounsaturated fatty acids (MUFA) or omega-3 long-chain polyunsaturated fatty acids (PUFA).

In the case of MON 87769 soybean, while the publication by Djoussé et al. (2003)[17] considered linolenic acid, rather than linoleic acid, the study by Lemke et al. (2010)[18] was considered in the EFSA scientific opinion. Moreover, publications by Brasky et al. (2011 and 2013)[19,20] and Chua et al. (2013)[21] reported meta-analysis of nested case–control and case–control studies investigating the association between blood biomarkers of

17 Djoussé L, Hunt SC, Arnett DK, Province MA, Eckfeldt JH, Ellison RC. Dietary linolenic acid is inversely associated with plasma triacylglycerol: the National Heart, Lung, and Blood Institute Family Heart Study. Am J Clin Nutr. 2003;78(6):1098–1102.

18 Lemke, S. L., Vicini, J. L., Su, H., Goldstein, D. A., Nemeth, M. A., Krul, E. S., & Harris, W. S. (2010). Dietary intake of stearidonic acid-enriched soybean oil increases the omega-3 index: randomized, double-blind clinical study of efficacy and safety. The American Journal of Clinical Nutrition, 92(4), 766–775.

eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) and risk of prostate cancer. The EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA Panel) appraised these studies and found no evidence for a role of EPA and/or DHA intake in the development of prostate cancer[22]. It is worth noting that the conclusion of the Brasky et al. (2013) was also debated in several published responses (e.g., McCarty et al., 2014).[23]

Regarding soybeans MON 87705 and 305423, the publication by Chajès et al. (2008)[24], an observational case-control study, found a positive association between the concentration of trans-MUFAs (but not cis-MUFA) in serum phospholipids and breast cancer. The publication by Saadatian-Elahi et al. (2004)[25], a meta-analysis of three cohort and seven case-control studies, reported a positive association between biomarkers of MUFA and saturated fatty acids (SFA) intake, and risk for breast cancer, and a negative (protective) association between biomarkers of omega-3 PUFA intake and risk of breast cancer. According to EFSA, this does not prove a causal relationship between dietary intake of omega-3 PUFA and risk of cancer.

The study by Gibson et al. (2013)[26], reported only associations (positive and negative) of different fatty acid groups (SFA, trans-fatty acids, PUFA and MUFA) with memory and learning tests in 38 women. In particular, of the many traits tested, only poorer word recall was positively associated with MUFA intake. EFSA considers that this study does not provide evidence for a negative effect of MUFA intake and notes that no quantitative data were provided.

Finally, it is important to highlight that the EU risk assessment on GMOs focuses on the safety of the products and not on potential benefits.

Pursuant to Articles 4(1)(a) and 16(1)(a) of Regulation (EC) No 1829/2003, for a GM food or feed to be authorised under the Regulation, it must be demonstrated, inter alia, that it has not adverse effects on human and animal health or the environment and that it is not nutritionally disadvantageous in comparison to the food or feed it intends to

19 Brasky TM, Till C, White E, et al. Serum phospholipid fatty acids and prostate cancer risk: results from the prostate cancer prevention trial. Am J Epidemiol. 2011;173(2):1429-1439.

20 Brasky TM, Darke AK, Song X, et al. Plasma phospholipid fatty acids and prostate cancer risk in the SELECT trial. J Natl Cancer Inst. 2013;105(15):1132–1141.

21 Chua ME, Sio MCD, Sorongon MC, Morales ML Jr. The relevance of serum levels of long chain omega-3 polyunsaturated fatty acids and prostate cancer risk: A meta-analysis. Can Urol Assoc J. 2013;7(5-6):E333–343.

22 EFSA Journal 2014;12(10):3843, 17 pp. doi:10.2903/j.efsa.2014.3843.

23 McCarty MF, DiNicolantonio JJ, Lavie CJ, O'Keefe JH. 2014. RE: Plasma phospholipid fatty acids and prostate cancer risk in the SELECT trial. Journal National Cancer Institute. 106(4):dju020. doi: 10.1093/jnci/dju020.

24 Chajès V, Thiébaut ACM, Rotival M, et al. 2008. Association between serum trans-monounsaturated fatty acids and breast cancer risk in the E3N-EPIC study. Amercian Journal Epidemiology. 167(11):1312–1320.

25 Saadatian-Elahi M, Norat T, Goudable J, Riboli E. 2004. Biomarkers of dietary fatty acid intake and the risk of breast cancer: A meta-analysis. International Journal of Cancer. 111(4):584–591.

26 Gibson EL, Barr S, Jeanes YM. 2013. Habitual fat intake predicts memory function in younger women. Frontiers in Human Neuroscience. 7:838.

replace. The provision of evidence of potential benefits of the food or feed is not relevant for the purposes of obtaining an authorisation.

In this regard, the publications by Hooper et al. (2006)[27], Rizos et al. (2012)[28], Fezeu et al. (2014)[29] and Kwak et al. (2012)[30], targeted to investigate the beneficial effects of omega 3 supplementation in cardiovascular disease, were not considered in the risk assessment of the three GM soybeans.

In sum, the Commission considers that EFSA has assessed the safety of the soybeans based on relevant literature available at that time in accordance with the requirements of Regulation (EC) No 1829/2003. Your claim as regards the alleged inadequate literature review on health impacts of these three GM soybeans is therefore unfounded.

2.2- Inadequate food safety and nutritional assessment

You claim that the nutritional content of the GM soybeans authorised by the Commission Implementing Decisions is not substantially equivalent to that of conventional soybeans and that, therefore, the nutritional/safety assessment should have been carried out as for novel foods. You refer in this regard to the EFSA guidance documents on the selection of comparators for the risk assessment of GM plants and on the risk assessment of food and feed from GM plants, which consider the need for a comprehensive safety/nutritional assessment on the GM plant per se in cases where no appropriate comparators are available.

In addition, you refer to the Codex Alimentarius "Guideline for the conduct of food safety assessment of foods derived from recombinant-DNA plants"[31] ('Codex Alimentarius Guideline') to claim that studies of the effects of the nutritional changes in the three soybeans are inadequate because they have adopted a narrow approach consisting in the comparison with dietary reference values for individual fatty acids. You also claim that other important aspects identified by that Guideline have been omitted, such as the use of EU-wide consumption data and the assessment of changes in the overall nutritional profile.

In addition, you highlight that a first study of the metabolic effects of GM high oleic soybean in mice[32], which was presented at a conference, showed effects on the liver and overall weight.

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27 Hooper, L., Thompson, R. L., Harrison, R. A., Summerbell, C. D., Ness, A. R., et al. 2006. Risks and benefits of omega 3 fats for mortality, cardiovascular disease, and cancer: systematic review. BMJ (Clinical Research Ed.), 332(7544), 752–760.

28 Rizos EC, Ntzani EE, Bika E, Kostapanos MS, Elisaf MS. 2012. Association between omega-3 fatty acid supplementation and risk of major cardiovascular disease events: A systematic review and meta-analysis. The Journal of the American Medical Association, 308(10), 1024–1033.

29 Fezeu LK, Laporte F, Kesse-Guyot E, Andreeva VA, Blacher J, Hercberg S, Galan P. 2014. Baseline Plasma Fatty Acids Profile and Incident Cardiovascular Events in the SU.FOL.OM3 Trial: The Evidence Revisited. PLoS ONE, 9(4). doi:10.1371/journal.pone.0092548.

30 Kwak SM, Myung, SK, Lee YJ, Seo HG. Korean Meta-analysis Study Group. 2012. Efficacy of omega-3 fatty acid supplements (eicosapentaenoic acid and docosahexaenoic acid) in the secondary prevention of cardiovascular disease: a meta-analysis of randomized, double-blind, placebo-controlled trials. Archives of Internal Medicine, 172(9), 686–694.

31 Codex Alimentarius. Guideline for the conduct of food safety assessment of foods derived from recombinant-DNA plants. CAC/GL 45-2003.

Your claims cannot be accepted.

EFSA considers, in line with the abovementioned report "Review of the strategies for the comprehensive food and feed safety and nutritional assessment of GM plant per se"[33], that a dietary exposure assessment is a key stage of the nutritional assessment of the three GM soybeans. EFSA assessed the potential risks of derived products in the context of specific use. EFSA took into consideration worst-case scenarios that included 100% replacement of conventional vegetable oils by the GM soybean oils in target and untargeted food groups. EFSA considered this conservative scenario to be unlikely, but useful to demonstrate the potential full impact of the genetic modification on dietary intakes.

The nutritional assessment was made by comparing the specific fatty acid intake in the habitual diet following the replacement scenarios, to the corresponding DRVs for fats, including the Tolerable Upper Intake Level of the omega-3 long-chain PUFAs, EPA, DHA and decosapentaenoic acid[34]. DRVs are quantitative reference values derived for different population groups in order to guide energy and nutrient intakes that are needed to support adequate growth, development and health, while reducing the risk of deficiencies and non-communicable diseases[35]. EFSA considered this approach appropriate to assess the effects of introducing modified GM soybean oils into the diet on consumer's health.

With regard to the use of geographically limited consumption data, the data to estimate the dietary intake of fatty acids from the GM soybean oils submitted by the applicants were taken from the UK National Diet and Nutritional Survey. The EFSA GMO Panel accepted this approach for two reasons: the UK is one of the few countries that publishes consumption information from individual consumers (which are valuable for risk assessment) and the UK National Diet and Nutritional Survey collects information also on food composition (which can be linked directly to the food consumption data). These two features together made a complete dietary exposure assessment possible.

In addition, the UK's food consumption of fatty acids is representative for many other European countries, as it is shown by summary statistics from the EFSA Comprehensive Consumption Database.

The outcome of this conservative dietary exposure assessment did not identify health risks for consumers in any of the three risk assessments of the GM soybeans. Nevertheless, EFSA acknowledged the possibility of shifting dietary preferences in consumers following the market authorisation of the GM soybeans and recommended a post-market monitoring to confirm the assessment made in the pre-market phase.

According to the EFSA NDA Panel, nutrient profile refers to the nutrient composition of a food or diet and is used to rank foods based on their nutrient composition[36]. Replacing

32 Deol, P., Fahrmann, J. F., Grapov, D., Yang, J., Evans, J. R., Rizo, A., Sladek, F. M. (2015). Metabolic Effects of Genetically Modified High Oleic Soybean Oil in Mice. In Obesity: Basic Science (Vols. 1–158, pp. PP19–4–PP19–4). Endocrine Society. Retrieved from http://press.endocrine.org/doi/abs/10.1210/endo-meetings.2015.OABA.5.PP19-4

33 See note 16.

34 EFSA Journal 2010;8(3):1461, 107 pp.; EFSA Journal 2012;10(7):2815. 48 pp.

35 EFSA Journal 2010; 8(3):1458. 30 pp.

conventional vegetable oils with soybean oils derived from these GM soybeans is unlikely to impact the overall diet composition.

The study about metabolic effects of GM high oleic soybean oil in mice appeared in 2015, after the publication of the three EFSA scientific opinions and was still preliminary. In any case, this study does not add evidence that would change the previous assessment and conclusions from EFSA on the safety of soybean 305423.

In conclusion, the Commission considers that EFSA has adequately performed the nutritional assessments of the three GM soybeans in a comprehensive manner. Therefore, your claims must be rejected.

2.3- Inadequate considerations of the potential impact of altered nutritional content on potentially vulnerable subpopulations

You claim that whereas '2011 EFSA Guidance' and 'Codex Alimentarius Guideline' require population subgroups to be considered in the nutritional and safety assessment, the data provided for the three GM soybeans is inconsistent between applications and too limited to assess risks to vulnerable subpopulations.

DRVs were used as references to assess the nutritional consequences of consuming these three GM soybean oils following a full replacement of conventional vegetable oils in healthy consumers. EFSA acknowledges that, in the three cases, dietary intake estimates were made for adults (19-64 years old) and, in only one case (305423 soybean), also for other age groups (< 19 years old). In the EFSA Scientific Opinion on DRVs for fats[37], intakes of omega-6 PUFA (expressed as percentages of total energy intake) were similar for adults and for children in four European countries. Therefore, the EFSA GMO Panel considered that a separate assessment for children was not necessary. Similar considerations apply also to pregnant and lactating women and the elderly, as they are considered to be healthy consumers.

Regarding the subjects with chronic diseases and compromised immune system, which constitute potentially vulnerable population subgroups, it must be noted that they would be under medical care and presumably supervision of their diets. This applies particularly to patients with inherited inborn errors of fatty acid oxidation and organic acid oxidation. Patients with such disorders are under medical supervision and receive diets composed according to their capacity to metabolise fatty acids of different chain lengths and organic acids.

According to EFSA, a separate risk assessment on the use of the three GM soybean derived oils in the diet of infants, although desirable, was not strictly needed, because infants are either breast-fed, or fed with infant or follow-on formulae in which the content of linoleic acid, alpha-linolenic acid and omega-3 long-chain PUFA is regulated by specific EU legislation[38]. The content of linoleic acid in cereal-based foods for older infants and young children is also specifically regulated.[39] If older infants were provided

36 The EFSA Journal (2008) 644, 1-44.

37 EFSA Journal 2010;8(3):1461, 107 pp.

38 Commission Directive 2006/141/EC of 22 December 2006 on infant formulae and follow-on formulae and amending Directive 1999/21/EC (OJ L 401, 30.12.2006, p. 1–33).

39 Commission Directive 2006/125/EC of 5 December 2006 on processed cereal-based foods and baby foods for infants and young children (OJ L 339, 6.12.2006, p. 16–35).

with home-made complementary food, the use of GM soybean derived oils would result in changes in the dietary fatty acid pattern similar to those calculated for adults and children above three years of age that are considered of no concern.

Moreover, regarding your concerns about the decrease in linoleic acid, EFSA has proposed an adequate intake of 4 E %, based on the lowest estimated mean intakes of the various population groups from a number of European countries, where linoleic acid deficiency symptoms are not present. Replacement of vegetable oil with GM soybean 305423 oil would result in 4 E % for adults and the elderly. Reduction below the adequate intake was observed for toddlers, children and teenagers (3.2-3.8 E %), but the EFSA GMO Panel is of the opinion that this is not a matter of concern, as linoleic acid deficiency symptoms have not been observed at intakes > 1 E %.[40]

Consumption data on individuals with specific dietary preferences (e.g. vegans) are not available. Consequently, separate exposure assessments for these groups could not be made.

In summary, the Commission considers that the assessment of the potential risks to vulnerable subpopulations posed by the three GM soybeans is in line with the requirements set out in the '2011 EFSA Guidance' and 'Codex Alimentarius Guideline'. Therefore, your claim in this regard cannot be accepted.

2.4- Failure to consider all processed forms of foods

You claim that not all forms of the processed soybeans were fully tested before the authorisations were granted. In particular, you claim that no specific studies have looked at the effects of consuming trans-stearidonic acid, which you claim is formed during the processing of the oil from MON 87769 soybean.

Due to the nature of that genetic modification, the nutritional assessment considered extensively products obtained with oils derived from the GM soybeans and also food and feed products made with fractions after the oil had been extracted.

To estimate dietary intake of fatty acids from products made with vegetable oil or containing vegetable oils as ingredient, an extensive list of food groups was considered, without distinguishing between commercial or domestic uses. For all three soybeans, the applicants showed that the fatty acid pattern of the purified oils is similar to that in the corresponding unprocessed beans. This was the basis for the EFSA GMO Panel to accept the use of fatty acids concentration measured in the unprocessed beans to calculate dietary intake of fatty acids in foods.

The fatty acid content in foods derived from defatted soybean meal is negligible and contributes little to the total exposure of fatty acid in habitual diets.

For food and feed made with GM soybean fractions after oil extraction, the nutritional assessment relied on the outcome of the compositional analysis, where a large list of nutrients and anti-nutrients was compared between the GM soybean and its conventional counterpart. As the comparative compositional analysis did not identify differences requiring further assessment, the nutritional quality of these products is expected to be similar to that of those from non-GM conventional soybeans.

40 EFSA Journal 2010;8(3):1461, 107 pp.

Regarding the trans-fatty acids, it is true that both conventional and GM soybean oils generate small amount of trans-fatty acids during processing. The content of trans-stearidonic acid in the oil of soybean MON 87769 is however low (0.17-0.39% total fatty acids), contributing marginally to the total exposure of trans-fatty acids, which in all cases was below 1 E% (percentage of total energy intake). The EFSA GMO Panel is not aware of any data attributing specific risks to trans-stearidonic acid in comparison to other trans-fatty acids.

Therefore, your allegation in this respect must be rejected.

2.5- Inadequate feed safety assessment and nutritional assessment

You claim that the EFSA GMO Panel did not consider the nutritional effects on humans resulting from the consumption of products derived from animals fed with whole fat MON 87769 soybean or its oil. More generally, you claim that EFSA did not assess the impact of the GM soybeans on the nutritional content of animal products, such as meat, milk or eggs.

Only small amounts of full-fat soybeans (1% of the total soybean feed) are directly fed to food-producing animals. The use of soybean oil in animal feed is limited, and only small amounts (0.5–3%) are added to mixed feed (especially for poultry and pigs) in order to avoid dust, improve the quality/stability of pellets and add energy to the diets. Defatted toasted soybean meal represents the most common soybean by-product, left after oil extraction, used in animal feed formulations. Since the compositional analysis in defatted and toasted meal, produced from the three soybeans 305423, MON 87705 and MON 87769 and from their conventional counterparts were similar, the EFSA GMO Panel concluded that the incorporation of feeding stuff derived from those GM soybeans in nutritionally balanced diets has no impact on health and performance of the target species.

Although EFSA recognises that the deliberate introduction of modified soybean oil into animal diet with intention of changing the fatty acid profile of animal products is possible, to date there has been no commercial uptake and consequently, at present no human exposure assessment of this nature can be made.

Regarding the scope of the applications, products obtained from animals fed GM feed are not within the scope of Regulation (EC) No 1829/2003.[41]

Moreover, in 2007 EFSA published a statement on the fate of recombinant DNA or proteins in meat, milk and eggs from animals fed with GM feed.[42] It concluded that after ingestion of the recombinant DNA, a rapid degradation into short DNA or peptide fragments is observed in the gastrointestinal tract of animals and humans.

In conclusion, your claims regarding the inadequacy of the nutritional and safety assessment of the feed are unfounded. Therefore, your allegation in this regard must be rejected.

2.6- Inconsistency in field trials required to characterise the altered nutritional content of the soybeans

41 See Recital 16 of Regulation (EC) No 1829/2003.

42 The EFSA Journal 2007; 5(7):744

You claim that data provided in the applications for the three nutritionally-altered GM soybeans is inconsistent between applications and in some cases clearly inadequate to deal with the case of nutrient-altered crops. In particular, you claim that, due to the impact that different environmental conditions may have on the nutritional composition of the GM soybeans, it is essential that data on nutrient composition is obtained from a wide variety of agronomic conditions. In addition, regarding soybean MON 87769, you claim that since that soybean is already authorised for cultivation in Canada, data from Canadian trial sites should also be required to determine the nutritional composition.

The assessment of the field trials data provided in the three GM soybeans applications was carried out according to the EFSA Guidance for risk assessment of food and feed from genetically modified plants applicable to each of the applications: '2006 EFSA Guidance' in the case of soybeans MON 87769 and MON 87705 and '2011 EFSA Guidance' for soybean 30542.

The 2006 EFSA Guidance requires that "*the comparison between GM plants and the most appropriate comparator should cover more than one representative growing season and multiple geographical locations representative of the various environments in which the GM plants will be cultivated*". A minimum number of field trial locations is not defined.

For the soybeans MON 87769 and MON 87705 applications, the EFSA GMO Panel came to the conclusion that the above requirements were fulfilled. Indeed, for soybean MON 87769, the applicant performed the field trials in the USA in 2006 and 2007, each including five sites representative of the soybean cultivation areas. At each site, soybean MON 87769, the conventional counterpart and three non-GM commercial varieties were planted following a randomized complete block design with three replicates. For soybean MON 87705, field trials were carried out in Chile at five sites in the season 2007/2008 and in the USA at five sites in the season 2008. In both seasons, soybean MON 87705, its conventional counterpart and non-GM soybean reference varieties were grown in replicated plots.

Regarding soybean 30542, for the field trials performed in 2011, materials were grown in a randomised complete block design with four replicates: soybean 305423 treated and untreated with the intended herbicide, its conventional counterpart and non-GM reference varieties (ten across all sites). The EFSA GMO Panel considers that these field trials were performed in accordance with the '2011 EFSA Guidance' and data from this field trial formed the basis for the assessment.

All field trial sites for the three soybeans were selected within major soybean producing areas[43] and followed the scientific principles laid down in the applicable EFSA guidance documents. The differences in field trials design reflect exclusively the flexibility provided for by the case-by-case approach embedded in both Codex Alimentarius and EFSA guidance documents. Therefore, a direct comparison between applications is not scientifically possible.

In addition, regarding soybean MON 87769 and Canadian sites, the field trial sites must be chosen within the areas where the GM line can be grown, according to EFSA guidance documents. The maturity group of soybean MON 87769 being III.5 (the same as A3525, the variety used for the transformation), the field trial sites were chosen within US soybean maturity zones from II to IV.[44] Considering the distribution of cultivated

43 The top five exporters of soybean in 2004-2013 are in North and South America; source FAOSTAT.

soybean in Canada[45], and using the same constraint on maturity zones, the suitable area for Canadian field trials with the same GM line would be relatively close to the Northernmost US locations chosen in 2006 and 2007. Therefore, the EFSA GMO Panel considered that the selected sites were representative of the range of receiving environments where the GM line was likely to be grown.

Consequently, your allegations regarding the inconsistency between applications for conducting field trials are not pertinent and must be rejected.

3. Inadequate and inconsistent labelling for GM soybeans with altered nutritional composition

You claim that the absence of specific guidance for the assessment of nutritionally-altered crops resulted in a violation of the labelling requirements for GM food. In particular, you claim that the labelling proposed for the three GM soybeans fail to meet the requirements of Regulation (EC) No 1829/2003 insofar as they do not set out an obligation to inform in the label about the characteristics that render the GM soybeans different from their conventional counterparts with regard to their nutritional value or effects, and about the health implications on different sections of the population.

In addition, you claim that the labelling of MON 87769 also conflicts with the legislation on food claims.

Without prejudice to the other requirements of EU law concerning the labelling of food and feed, GM food and feed falling under the scope of EU legislation on GMOs is subject to labelling requirements set out in Regulation (EC) No 1829/2003 and Regulation (EC) No 1830/2003.[46] Articles 13(2) and 25(2) of Regulation (EC) No 1829/2003 set out specific requirements for the labelling of GM food and feed which are different from their conventional counterparts regarding composition, nutritional value or nutritional effects, intended use of the food and feed or implications for the health of certain sections of the population.

Due to the nature of their genetic modification, all three GM soybeans 305423, MON 87705 and MON 87769 fall under those specific labelling requirements. Therefore, the applicants were obliged to submit proposals for specific labelling reflecting the intended compositional changes. After a thorough analysis of the proposals submitted, the Commission agreed to specific labelling for the three GM soybeans.

For 305423 and MON 87705 soybeans, the label must contain the words "with increased monounsaturated fat and reduced polyunsaturated fat", which reflects the changes in the compositions of both soybean oils. The intended change in these GM soybeans was the increase in oleic acid (monounsaturated fatty acid). However, as the modification also

44 Zhang LX, Kyei-Boahen S, Zhang J, Zhang MH, Freeland TB, Watson CE, Liu X. 2007. Modifications of optimum adaptation zones for soybean maturity groups in the USA. Crop Management, 6(1). http://dx.doi.org/10.1094/CM-2007-0927-01-RS.

45 Monfreda C, Ramankutty N and Foley JA. 2008. Farming the planet: 2. Geographic distribution of crop areas, yields, physiological types, and net primary production in the year 2000. Global biogeochemical cycles. 22(1).

46 Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC (OJ L 268, 18.10.2003, p. 24–28).

results in a decrease in linoleic acid (polyunsaturated fatty acid), it was decided that the label should reflect both effects.

In the case of MON 87769, the soybean was modified to contain stearidonic acid, which is absent in conventional soybeans. In order to reflect this change in the GM soybean composition, the words "with stearidonic acid" must appear on the label.

Regarding your claim that the labelling should be more detailed, the Commission considers that the labelling requirements for the three GM soybeans are in line with Regulation (EU) No 1169/2011 on the provision of food information to consumers.[47] That Regulation clearly states that the nutrition information provided on the label should be simple and easily understood to appeal to the average consumer and to serve the informative purposes for which it is introduced.

Furthermore, the proposal of the applicant to include the mention "omega-3" on the label of soybean MON 87769 was not accepted, as it constitutes a nutrition claim. The authorisation of that type of claim falls outside the scope of the GMO legislation; it is governed by Regulation (EC) No 1924/2006, on nutrition and health claims made on foods[48], and Commission Regulation (EU) No 116/2010, amending Regulation (EC) No 1924/2006 regarding fatty acids claims[49]. The specific labelling required by the GMO legislation is not a claim but a regulatory obligation.

Regarding the possible modification of the information on the label should new information about risks derived from the genetic modification or with specific types of fatty acids become available, under Articles 9(3) and 21(3) of Regulation (EC) No 1829/2003 the authorisation-holder has an obligation to inform the Commission of any new scientific or technical information which might influence the evaluation of the safety in use of the GM food and feed which became available after the authorisation. In such cases, the Commission must immediately inform EFSA and the Member States and proceed with appropriate measures where necessary, including a possible amendment of labelling requirements.

The Commission would also like to observe that, as parts of its missions, EFSA monitors the scientific studies that are published after that the authorisation has been granted and that the Commission does not hesitate to consult EFSA when it is made aware of new information concerning the safety of an authorised GM food or feed. When necessary, Regulation (EC) No 1829/2003 provides adequate tools for the Commission to take appropriate measures as regards the placing on the market of an authorised GM food and feed, including on labelling aspects.

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47 Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004 (OJ L 304, 22.11.2011, p. 18–63).

48 Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods (OJ L 404, 30.12.2006, p. 9–25);

49 Commission Regulation (EU) No 116/2010 of 9 February 2010 amending Regulation (EC) No 1924/2006 of the European Parliament and of the Council with regard to the list of nutrition claims (OJ L 37, 10.2.2010, p. 16–18).

Finally, regarding the labelling of products obtained from animals fed with the GM soybeans, as already explained in section 2.5 of this annex, such products are not within the scope of Regulation (EC) No 1829/2003.

In conclusion, the Commission is of the opinion that the labelling requirements of the GM soybeans are adequate and compliant with the Regulation (EC) No 1829/2003. Therefore, your claim in this regard must be rejected.

4. Inadequate and inconsistent post-market monitoring plans for the GM soybeans

You claim that the absence of specific guidance for the assessment of crops with altered nutritional content has led to inadequate and inconsistent post-market monitoring plans. In particular, you claim that due to the alleged shortcomings in the risk assessment of the GM soybeans regarding the adequate intakes of relevant nutrient levels and the potential health effects associated to changes in fatty acid levels, it is not possible for the post-market monitoring to fulfil its role.

In this regard, you make specific reference to alleged deficiencies in the collection of consumption data regarding the excessive reliance on UK data and the lack of specific data on vulnerable subpopulations. You also refer to Implementing Regulation (EU) No 503/2013, which indicates that post-market monitoring is appropriate to confirm, inter alia, the expected consumption of the products.

Your allegations relating to the inadequacy of the food safety and nutritional assessment, including on the origin of the consumption data, and the potential impact on vulnerable groups, are addressed in sections 2.2 and 2.3 of this annex.

Under Regulation (EC) No 1829/2003, post-market monitoring regarding the use of the food may be considered necessary on the basis of the conclusion of the risk assessment, as it is the case with the three GM soybeans. The ‘2011 EFSA Guidance’ states that particular attention should be paid to GM plants and derived food and feed with modified nutritional properties as they may require post-market monitoring to confirm the conclusion of the exposure assessment. Therefore, post-market monitoring does not substitute a thorough pre-market assessment, rather complements it in order to confirm the conclusions of the risk assessment.

The purpose of post-market monitoring is therefore to assess whether the product is used as predicted, whether the known effects are as predicted and whether the product induces any unexpected side effects.

For this reason, the three Commission Implementing Decisions require the authorisation holders to collect information on the quantities of the three GM soybeans oil and GM soybeans for oil extraction, imported into the EU. In case of such import, the authorisation holders have to collect results of FAOSTAT database searches on the quantities of vegetable oil consumption by Member State, including shifts in quantities between different types of oils consumed. In addition, for soybean MON 87769, in case of import of soybean for oil extraction or of the oil itself, data on the different categories of food and feed uses of the soybean oil in the EU is requested.

Based on the above-mentioned information, a review of the nutritional assessment conducted as part of the risk assessment shall be carried out by the authorisation holders.

The proposed and adopted post-market monitoring plans have been discussed with Member States and operators and the Commission considers that they are in line with 'EFSA 2011 Guidance' and fulfil the requirements of GMO legislation. Therefore, your claim in this regard must be rejected.

5. Herbicide residues are not considered in the health impacts of GM food and feed consumption as regards MON 87705 and 305423

You claim that the presence of herbicide residues on GM soybeans MON 87705 and 305423 was not taken into account with regard to the limitations you described regarding the safety and nutritional assessment.

The Commission would like to remind you that the assessment of the effects of herbicide residues on human and animal health is not regulated by the EU legislation on GMOs, but under Regulation (EC) No 396/2005[50] on maximum residue levels of pesticides in or on food and feed of plant and animal origin.

6. Inadequate assessment of the unintended effects of Ribonucleic acid (RNA) interference as regards MON 87705

You claim that the use of RNA interference (RNAi) in GM soybean MON 87705 can give rise to unintended off-target effects and that this possibility has not been adequately investigated. To support your claim, you made reference to two scientific publications (Lundgren and Duan (2013)[51] and Heinemann et al. (2013)[52]), without providing additional elements specifying the type of off-target effects due to the use of RNAi.

RNAi is a technique that can be used to down-regulate target genes in plants or in target pests. Since at the time of the assessment of the GM soybeans, only few RNAi-based GM crops had reached the pre-market risk assessment and considering the novelty of the technique, EFSA organised in 2014 an international scientific workshop on 'Risk assessment considerations for RNAi-based GM plants'.[53] One of the outcomes of this workshop was that "*molecular characterisation and comparative analysis, consisting of compositional and agronomic/phenotypic characterisation of the GM plant, should remain the basis of the risk assessment, as they support the identification of potential intended and unintended changes in the RNAi-based GM plant that may arise, and that may plausibly lead to harm*."

As for any other GM crop, for GM soybean MON 87705 EFSA assessed both intended and unintended effects by a thorough molecular characterisation, extended comparative analysis, and a dedicated toxicological and nutritional assessment of the altered fatty acids. The information reported by the two cited publications does not change the

50 OJ L 70, 16.3.2005

51 Lundgren JG, Duan JJ. 2013. RNAi-Based Insecticidal Crops: Potential Effects on Nontarget Species. BioScience, 63(8):657–665.

52 Heinemann JA, Agapito-Tenfen SZ, Carman JA. 2013. A comparative evaluation of the regulation of GM crops or products containing dsRNA and suggested improvements to risk assessments. Environment International. 55:43–55.

53 International scientific workshop 'Risk assessment considerations for RNAi-based GM plants' (4–5 June 2014, Brussels, Belgium). EFSA supporting publication 2014:EN-705, 38 pp.

previous assessment and conclusions from EFSA on the safety of GM soybean MON 87705.

The Lundgren and Duan (2013) publication refers to the environmental risk assessment of the cultivation of RNA interference-based plants and more specifically the effects on target and non-target organisms of insecticide RNA interference-based plants during cultivation. However, the Decision on soybean MON 87705 excludes the cultivation of this soybean in the EU and potential interactions with non-target organisms, in case of imports, are not considered to be a relevant issue by EFSA in its scientific opinion on this GM soybean, owing to its intended uses and the low level of exposure to the environment.

The other publication, Heinemann *et al*. (2013), brought together findings of different research areas on RNAi mechanisms, claiming that small double-stranded RNAs generated in RNAi-based GM plants can create unintended effects and consequently pose biosafety risks, and suggesting changes to the safety assessment approach to identify all possible unintended effects. However, according to EFSA, this publication cannot be considered relevant for GMO safety assessment since the evidences reported have not been consolidate nor validated.

Consequently, your claim on this point must also be rejected.