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**Annex 2 to FEDIOL request for adjustments into the Nutriscore for bottled vegetable oils and fats
Scientific evidence regarding unsaturated fatty acids, polyunsaturated fatty acids and omega 3 fatty acids**

- 1. EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA); Scientific Opinion on health claims already evaluated (ID 215, 568, 674, 712, 1398, 1633, 1974, 4191, 4192, 4193, 4236, 4335, 4698, 4704) pursuant to Article 13(1) of Regulation (EC) No 1924/2006. EFSA Journal 2011; 9(6):2203. [22 pp.]. doi:10.2903/j.efsa.2011.2203. Available online: www.efsa.europa.eu/efsajournal and EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA); Scientific Opinion on the substantiation of health claims related to alpha-linolenic acid and maintenance of normal blood cholesterol concentrations (ID 493) and maintenance of normal blood pressure (ID 625) pursuant to Article 13(1) of Regulation (EC) No 1924/2006 on request from the European Commission. EFSA Journal 2009; 7(9):1252. [17 pp.]. doi:10.2903/j.efsa.2009.1252. Available online: www.efsa.europa.eu**

Following EFSA assessment, health benefits of alpha-linolenic acid (ALA) have been recognised as contributing to the maintenance of normal blood cholesterol levels, with a daily intake of 2 g of ALA, for food being at least a source of ALA as referred to in the claim "source of omega 3 fatty acids" as listed in the Annex to Regulation (EC) No 1924/2006.

Alpha-linolenic acid (ALA) (ID 568) The food constituent that is the subject of the health claim is "omega-3 fatty acids". From the proposed conditions of use and the references provided, the Panel assumes that the food constituent, which is the subject of the health claim, is alpha-linolenic acid (ALA). The Panel considers that the food constituent, alpha-linolenic acid (ALA), which is the subject of the health claim, is sufficiently characterised (EFSA Panel on Dietetic Products Nutrition and Allergies (NDA), 2009c). (...) The claimed effect is "cardiovascular system". The Panel assumes that the target population is the general population. In the context of the proposed wordings, the Panel assumes that the claimed effect refers to the maintenance of normal blood cholesterol concentrations. A claim on ALA and maintenance of normal blood cholesterol concentrations has already been assessed with a favourable outcome (EFSA Panel on Dietetic Products Nutrition and Allergies (NDA), 2009c).

Replacement of mixtures of saturated fatty acids (SFAs) as present in foods or diets with mixtures of polyunsaturated fatty acids (PUFAs) (ID 674, 4335) The food constituent that is the subject of the health claims is "polyunsaturated fatty acids". In the context of the proposed wordings, the Panel assumes that the food constituent, which is the subject of the health claim, is saturated fatty acids (SFAs), which should be replaced by cis-polyunsaturated fatty acids (cis-PUFAs) in foods or diets in order to obtain the claimed effect. The Panel considers that the food constituent, saturated fatty acids as present in

foods or diets, and the food constituent, mixtures of cis-PUFAs, which should replace SFAs in foods, and which are the subject of the health claim, are sufficiently characterised (EFSA Panel on Dietetic Products Nutrition and Allergies (NDA), 2011a). (...) The claimed effect is "cardiovascular system". The Panel assumes that the target population is the general population. In the context of the proposed wordings, the Panel assumes that the claimed effects refer to the maintenance of normal blood LDL-cholesterol concentrations. A claim on the replacement of mixtures of SFAs with cis-MUFAs and/or cis-PUFAs in foods or diets and maintenance of normal blood LDL-cholesterol concentrations has already been assessed with a favourable outcome (EFSA Panel on Dietetic Products Nutrition and Allergies (NDA), 2011a).

- 2. EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA); Scientific Opinion on the substantiation of health claims related to the replacement of mixtures of saturated fatty acids (SFAs) as present in foods or diets with mixtures of monounsaturated fatty acids (MUFAs) and/or mixtures of polyunsaturated fatty acids (PUFAs), and maintenance of normal blood LDL-cholesterol concentrations (ID 621, 1190, 1203, 2906, 2910, 3065) pursuant to Article 13(1) of Regulation (EC) No 1924/2006. EFSA Journal 2011;9(4):2069. [18 pp.]. doi:10.2903/j.efsa.2011.2069. Available online: www.efsa.europa.eu/efsajournal**

The Panel concludes that a cause and effect relationship has been established between the consumption of mixtures of dietary SFAs and an increase in blood cholesterol concentrations, and that replacement of a mixture of SFAs with cis-MUFAs and/or cis-PUFAs in foods or diets on a gram-per-gram basis may help maintain normal blood LDL-cholesterol concentrations.

- 3. EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA); Scientific Opinion on the substantiation of a health claim related to "low fat and low trans spreadable fat rich in unsaturated and omega-3 fatty acids" and reduction of LDL-cholesterol concentrations pursuant to Article 14 of Regulation (EC) No 1924/2006. EFSA Journal 2011;9(5):2168. [13 pp.]. doi:10.2903/j.efsa.2011.2168. Available online: www.efsa.europa.eu/efsajournal**

The Panel concludes that a cause and effect relationship has been established between the consumption of mixtures of dietary SFAs and an increase in LDL-cholesterol concentrations, and that replacement of a mixture of SFAs with cis-MUFAs and/or cis-PUFAs in foods or diets on a gram-per-gram basis reduces LDL-cholesterol concentrations.

- 4. EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA); Scientific Opinion on the substantiation of health claims related to oleic acid intended to replace saturated fatty acids (SFAs) in foods or diets and maintenance of normal blood LDL-cholesterol concentrations (ID 673, 728, 729, 1302, 4334) and maintenance of normal (fasting) blood concentrations of triglycerides (ID 673, 4334) pursuant to Article 13(1) of Regulation (EC) No 1924/2006. EFSA Journal 2011;9(4):2043. [17 pp.]. doi:10.2903/j.efsa.2011.2043. Available online: www.efsa.europa.eu/efsajournal**

The evidence provided by consensus opinions/reports from authoritative bodies and reviews shows that there is good consensus that a mixture of SFAs increases total and blood LDL-cholesterol concentrations relative to mixtures of cis-MUFAs (EFSA, 2004; EFSA Panel on Dietetic Products Nutrition and Allergies (NDA), 2010; IoM, 2005; Lichtenstein et al., 2006; Mensink et al., 2003; WHO/FAO, 2003), and that there is a

linear dose-response relationship between blood LDL-cholesterol concentrations and the amounts of long-chain SFAs consumed. It is also well established that consumption of a mixture of SFAs results in increased blood HDL-cholesterol concentrations compared with consumption of mixtures of cis-MUFAs (e.g. oleic acid), and that in comparison with other fatty acids, except trans fatty acids (TFAs), SFAs increase the total-to-HDL cholesterol ratio (Mensink et al., 2003). A claim on the replacement of mixtures of SFAs with cis-MUFAs and/or cis-PUFAs in foods or diets and maintenance of normal blood LDL-cholesterol concentrations has already been assessed with a favourable outcome (EFSA Panel on Dietetic Products Nutrition and Allergies (NDA), 2011). The scientific conclusions in that opinion apply to the replacement of mixtures of SFAs as present in foods or diets with oleic acid.

5. 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.]. doi:10.2903/j.efsa.2010.1461. Available online: <https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2010.1461>

There is a negative (beneficial), dose-dependent relationship between the intake of linoleic acid and blood LDL cholesterol concentrations, while this relationship is positive for HDL cholesterol concentrations. In addition, linoleic acid (LA) lowers fasting blood triacylglycerol concentrations when compared to carbohydrates. There is also evidence that replacement of saturated fatty acids by n-6 polyunsaturated fatty acids (without changing total fat intake) decreases the number of cardiovascular events in the population.

(...)the human body can synthesise eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) from alpha-linolenic acid. Intervention studies have demonstrated beneficial effects of preformed n-3 long-chain polyunsaturated fatty acids on recognised cardiovascular risk factors, such as a reduction of plasma triacylglycerol concentrations, platelet aggregation, and blood pressure. These effects were observed at intakes 1g per day, well above levels that were associated with lower cardiovascular disease (CVD) risk in epidemiological studies. With respect to cardiovascular diseases, prospective epidemiological and dietary intervention studies indicate that oily fish consumption or dietary n-3 long-chain polyunsaturated fatty acids supplements (equivalent to a range of 250 to 500 mg of eicosapentaenoic acid plus docosahexaenoic acid daily) decrease the risk of mortality from coronary heart disease (CHD) and sudden cardiac death. An intake of 250 mg per day of eicosapentaenoic acid plus docosahexaenoic acid appears to be sufficient for primary prevention in healthy subjects. Therefore, and taking into account that available data are insufficient to derive an Average Requirement, the Panel proposes to set an Adequate Intake of 250 mg for eicosapentaenoic acid plus docosahexaenoic acid for adults based on cardiovascular considerations.

6. WHO draft guideline on SAFA and TFA – draft for public consultation May 2018
[https://extranet.who.int/dataform/upload/surveys/666752/files/Draft%20WHO%20SAFA-TFA%20guidelines_04052018%20Public%20Consultation\(1\).pdf](https://extranet.who.int/dataform/upload/surveys/666752/files/Draft%20WHO%20SAFA-TFA%20guidelines_04052018%20Public%20Consultation(1).pdf)

Reduced intake of saturated fatty acids has been associated with a significant reduction in risk of coronary heart disease (CHD) when replaced with polyunsaturated fatty acids (PUFA) or carbohydrates from whole grains (3-6).

7. WHO draft guideline on total fats – draft for public consultation April 2021

Dietary fat, including essential fatty acids, which cannot be synthesized by the human body, is necessary for proper physiological function. To ensure an adequate intake of energy and essential fatty acids, and to facilitate the absorption of lipid soluble vitamins, total fat intake in most adults should be at least 15–20% of total energy intake (67), although energy requirements are increased during pregnancy and lactation (6, 7, 62).

(...)The recommendations in this guideline acknowledge that both quantity and quality of fat consumed are important for maintaining health. Public health interventions should therefore aim to reduce total fat intake where necessary, while reducing saturated fatty acid and trans-fatty acid intake, through replacement with unsaturated fatty acids and/or carbohydrates as needed (63, 64), and without increasing free sugars intake (58).

8. Fats and fatty acids in human nutrition: Report of an expert consultation. Rome: Food and Agriculture Organization of the United Nations 2010 (https://www.who.int/nutrition/publications/nutrientrequirements/fatsandfattyacids_humannutrition/en/)

Regarding polyunsaturated fatty acids (PUFA), controlled feeding and cohort studies of eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) intakes have demonstrated physiological benefits on blood pressure, heart rate, triglycerides, and likely inflammation, endothelial function, and cardiac diastolic function, and consistent evidence for a reduced risk of fatal CHD and sudden cardiac death at consumption of ~250 mg/day of EPA plus DHA (Burr et al., 1989; Gissi-Hf, 2008; Mozaffarian and Rimm, 2006; Yokoyama et al., 2007). DHA also plays a major role in development of the brain and retina during foetal development and the first two years of life (Cetin and Koletzko, 2008; Decsi and Koletzko, 2005; Helland et al., 2008), which is a "window of opportunity" also for preventing avoidable growth failure and undernutrition and reducing death and disease including the development of obesity and noncommunicable diseases later in life. As far as n-6 to n-3 ratio is concerned, the 2002 Joint WHO/FAO Expert Consultation on Diet, Nutrition and the Prevention of Chronic Diseases and its background scientific review had indicated a balanced intake of n-6 and n-3 PUFAs is essential for health (WHO, 2003; Reddy and Katan, 2004). But there is a debate that increasing LA intake does not result in increased arachidonic acid (AA) in plasma or platelet lipids, and does not increase formation of proinflammatory mediators (Adam et al., 2003). Furthermore, both n-6 and n-3 fatty acids have been shown to have anti-inflammatory properties that are protective of atherogenic changes in vascular endothelial cells (De Caterina et al., 2000).

CONCLUSIONS AND RECOMMENDATIONS FOR POLYUNSATURATED FATTY ACIDS (PUFA)

- *There is convincing evidence that linoleic acid (LA) and alpha-linolenic acid (ALA) are indispensable since they cannot be synthesized by humans.*
- *There is convincing evidence that replacing SFA with PUFA decreases the risk of CHD.*
- *There is convincing and sufficient evidence from experimental studies to set an acceptable intake to meet essential FA needs for linoleic acid (LA) and alpha-linolenic acid (ALA) consumption.*

The minimum intake values for essential fatty acids to prevent deficiency symptoms are estimated at a convincing level to be 2.5%E LA plus 0.5%E ALA. Based on epidemiologic studies and randomized controlled trials of CHD events, the minimum recommended value of total PUFA consumption for lowering LDL and total cholesterol concentrations, increasing HDL cholesterol concentrations and decreasing the risk of CHD events is 6%E. Based on experimental studies, risk of lipid peroxidation may increase with high (>11%E) PUFA consumption, particularly when tocopherol intake is low. Therefore, the resulting acceptable range for total PUFA (n-6 and n-3 fatty 16 Fats and fatty acids in human

nutrition: Report of an expert consultation acids) can range between 6 and 11%E. The adequate intake to prevent deficiency is 2.5–3.5%E. Thus, the recommended range (ADMR) for PUFA is 6–11%E.

9. Hooper L, Martin N, Abdelhamid A, Davey Smith G. Reduction in saturated fat intake for cardiovascular disease. Cochrane Database Syst Rev. 2015;6:CD011737. pmid:26068959.

A recent Cochrane review suggests that replacing foods that are rich in saturated fat (SFA), such as meat, butter, and cheese, with foods that are rich in polyunsaturated fat (PUFA), such as walnuts, fish, and vegetable oils such as sunflower and safflower oils, would lead to 27% less cardiovascular events

There is a large body of evidence, including almost 60,000 people who have been in studies assessing effects of reducing saturated fat for at least two years each. Together the studies provide moderate-quality evidence that reducing saturated fat and replacing it with polyunsaturated fats reduces our risk of cardiovascular disease.

10. Sioen I, van Lieshout L, Eilander A, Fleith M, Lohner S, Szommer A, Petisca C, Eussen S, Forsyth S, Calder PC, Campoy C, Mensink RP. Systematic Review on N-3 and N-6 Polyunsaturated Fatty Acid Intake in European Countries in Light of the Current Recommendations - Focus on Specific Population Groups. Ann Nutr Metab. 2017;70(1):39-50. doi: 10.1159/000456723. Epub 2017 Feb 11.

Fifty-three studies from 17 different European countries reported an intake of total n-3 and n-6 PUFAs and/or individual n-3 or n-6 PUFAs in at least one of the specific population groups: 10 in pregnant women, 4 in lactating women, 3 in infants 6-12 months, 6 in children 1-3 years, 11 in children 4-9 years, 8 in adolescents 10-18 years and 11 in elderly >65 years. Mean linoleic acid intake was within the recommendation (4 energy percentage [E%]) in 52% of the countries, with inadequate intakes more likely in lactating women, adolescents and elderly. Mean α -linolenic acid intake was within the recommendation (0.5 E%) in 77% of the countries. In 26% of the countries, mean eicosapentaenoic acid and/or docosahexaenoic acid intake was as recommended. These results indicate that intake of n-3 and n-6 PUFAs may be suboptimal in specific population groups in Europe.
