



**Paper for information: Government Updates on Nutrition
Related Activities
EFSA**

Agenda Item: 9

Please see attached paper for information.

**Scientific activities of the EFSA Panel on
Dietetic Products, Nutrition and Allergies (NDA Panel)**

(submitted by Dr. Rodríguez Iglesias, scientific co-ordinator of the NDA Panel)

- 1) At its last plenary meeting in July, the NDA Panel adopted three opinions, one of which was on the scientific substantiation of nutrition claims concerning omega-3 fatty acids, monounsaturated fat, polyunsaturated fat and unsaturated fat. The other two opinions were on the tolerable upper intake level (UL) of the two outstanding nutrients for which a UL has been required, i.e. phosphorus and tin, respectively. Details about these evaluations are provided in the Annex.

Annex. Opinions adopted by the NDA Panel at its last plenary meeting**Opinion on nutrition claims concerning omega-3 fatty acids, monounsaturated fat, polyunsaturated fat and unsaturated fat**

The European Commission has requested EFSA to issue an opinion on the scientific substantiation of nutrition claims relating to omega-3 fatty acids, mono-unsaturated fat, polyunsaturated fat and unsaturated fat. In this context EFSA was asked to review the scientific merits of the following proposed claims and advise on their addition to the Annex of the Regulation on the use of nutrition and health claims on foods proposed by the Commission in July 2003.

- *Omega-3 fatty acid source*: The food must contain more than 15% of the Recommended Nutritional Intake (with RNI set at 2 g/day for an adult male) for an adult male of the omega-3 fatty acids concerned per 100 g or 100 mL or 100 kcal.
- *High in omega-3 fatty acids*: The food must contain more than 30% of the Recommended Nutritional Intake for an adult male of the omega-3 fatty acids concerned per 100 g or 100 mL or 100 kcal.
- *High monounsaturated fat*: A claim that a food is high in monounsaturated fat, and any claim likely to have the same meaning for the consumer, may only be made where at least 45% of the fatty acids present in the product derive from monounsaturated fat under the condition that saturated fat must not provide more than 10% of energy.
- *High polyunsaturated fat*: A claim that a food is high in polyunsaturated fat, and any claim likely to have the same meaning for the consumer, may only be made where at least 45% of the fatty acids present in the product derive from polyunsaturated fat and saturated fat must not provide more than 10% of energy.
- *High unsaturated fat*: A claim that a food contains high amount of unsaturated fat and any claim likely to have the same meaning for the consumer may only be made where the amount of unsaturated fat is 70% of the total fat content in the product.

The Scientific Panel on Dietetic Products, Nutrition and Allergies has considered the proposed claims and concludes as follows.

Omega-3 fatty acids claims

There are two categories of omega-3 fatty acids (n-3 polyunsaturated fatty acids [n-3 PUFA]) - α -linolenic acid (ALA) and long chain n-3 polyunsaturated fatty acids (LC n-3 PUFA, mainly eicosapentaenoic acid [EPA] and docosahexaenoic acid [DHA]) - which differ in function and requirements. The proposed claims do not distinguish between ALA and LC n-3 PUFA which have different nutritional roles. ALA is a nutritionally essential fatty acid required for synthesis of important fatty acids and eicosanoids. Available evidence suggests that LC n-3 PUFA (EPA and DHA) may reduce the risk of cardiovascular disease, possibly mediated by prevention of cardiac arrhythmias.

The RNI proposed in the claim (2 g/day) is in the same range as intakes of ALA recommended by some national and international authorities to meet dietary requirements in adults (1-3 g/day). However, it is much greater than intakes recommended by some authorities for LC n-3 PUFA (EPA and DHA) in adults for cardio-protective effects (200-500 mg/day). In many EU populations intakes of both ALA and LC n-3 PUFA are typically lower than these recommendations.

Claim: Omega-3 fatty acid source - more than 15% of the Recommended Nutritional Intake (2 g/day) of the omega-3 fatty acids concerned per 100 g or 100 mL or 100 kcal

As outlined, the claim could be made for a number of foods both on an energy and weight/volume basis, e.g. most plant oils, some nuts, some vegetables (mainly as ALA) and most fish (mainly as LC n-3 PUFA).

Some foods would qualify for the claim on a weight/volume, but not energy basis (e.g. safflower oil, soy bean, peanut, butter) while other foods (e.g. radish, cod) would qualify on an energy, but not weight/volume basis. Some foods qualify although a typical serving provides little n-3 PUFA (e.g. radish, safflower oil, butter). These anomalies arise because the reference food quantity (100 g, 100 mL, 100 kcal) is not linked to the typical intake of the food.

Claim: High in omega-3 fatty acids - more than 30% of the Recommended Nutritional Intake (2 g/day) of the omega-3 fatty acids concerned per 100 g or 100 mL or 100 kcal

As outlined, the claim could be made for a number of foods both on an energy and weight/volume basis, e.g. most vegetable oils and some nuts (mainly as ALA) and fatty fish (mainly as LC n-3 PUFA).

Some foods would qualify for the claim on a weight/volume, but not energy basis (e.g. pecan nut, some vegetable margarines). Other foods qualify on an energy, but not a weight/volume basis although a typical serving provides only modest amounts of n-3 PUFA (e.g. kale). These anomalies arise because the reference food quantity (100 kcal) is not linked to the typical intake of the food.

Monounsaturated fat claim

Monounsaturated fatty acids (MUFA) are not nutritionally essential as they can be synthesised from other (saturated) fatty acids and carbohydrates. Substitution of saturated fatty acids (SFA) in the diet by an equal amount of MUFA reduces low density lipoprotein (LDL) cholesterol; elevated plasma LDL-cholesterol has been causally linked to coronary heart disease. Because SFA intakes of many EU populations exceed levels (about 10% energy) widely recommended for maintenance of lower plasma levels of LDL-cholesterol, MUFA consumption plays an important nutritional role in limiting SFA intake. In some EU populations, intakes of MUFA are at the lower end of recommended levels (in the range 10-18% of energy, which corresponds to about 30-50% of fatty acids for a diet containing 35 E% from total fat).

Claim: High monounsaturated fat - at least 45% of the fatty acids derive from monounsaturated fat and saturated fat must not provide more than 10% of energy

The claim as outlined may be made for a range of foods. These include good sources of MUFA, e.g. rapeseed oil, some fluid margarines, some nuts (e.g. hazelnuts, peanuts, pistachio nuts, almonds). However, the claim could also be made for some foods which provide only low amounts of MUFA in a typical serving, e.g. some fish (e.g. whiting), lean meat (e.g. veal, beef, pork), white bread and some biscuits. These anomalies arise because the MUFA threshold is expressed as % of total fatty acids content which is not directly related to the typical intake of the food. In addition, some foods which provide significant amounts of MUFA may not qualify for the claim e.g. foods that are naturally high in MUFA such as olive oil and fatty fish (e.g. herring, salmon) and some margarines. This anomaly arises because the SFA content of these foods may exceed the disqualifying threshold of 10 E%.

Polyunsaturated fat claim

In addition to n-3 PUFA (ALA and the LC n-3 PUFA, EPA and DHA), PUFA also include n-6 PUFA (mainly linoleic acid). Linoleic acid is nutritionally essential and is required for synthesis of long chain fatty acids and eicosanoids and linoleic acid and its metabolites have important roles in membrane function and regulation of metabolism.

In addition to the evidence for a cardio-protective effect of the LC n-3 PUFA and a nutritional requirement for ALA and linoleic acid, the substitution of SFA in the diet by an equal amount of *cis*-PUFA reduces LDL-cholesterol. Thus PUFA consumption plays an important nutritional role in limiting SFA intake. In EU populations, intakes of total PUFA are generally

within the recommended range (about 5-10% of energy), which corresponds to about 15-30% of fatty acids for a diet containing 35 E% from total fat.

Claim: High polyunsaturated fat - at least 45% of the fatty acids derive from polyunsaturated fat and saturated fat must not provide more than 10% of energy

The claim as outlined may be made for some vegetable oils (e.g. safflower oil), some nuts (e.g. walnut) and seeds (e.g. sunflower, seed, linseed) which are good sources of PUFA. However, several vegetable oils which provide significant amounts of PUFA may not qualify for the claim, e.g. corn oil, grapeseed oil, rapeseed oil, soya oil, sunflower oil. This is because the SFA content of these foods may exceed the disqualifying threshold of 10 E%. In addition, the claim could be made also for some foods which provide only low amounts of PUFA in a typical serving, e.g. some breads, cereal products, beans, and white fish (e.g. cod, turbot). This anomaly arises because the PUFA threshold is expressed as % of total fatty acids content which is not directly related to the typical intake of the food.

Unsaturated fat claim

(*Cis*) unsaturated fatty acids (UFA) comprise MUFA, n-6 PUFA (mainly linoleic acid) and n-3 PUFA (ALA and the LC n-3 PUFA, EPA and DHA) and represent the balance of total fatty acids when SFA and *trans* fatty acids (TFA) are excluded. Specific nutritional roles have been identified for n-6 PUFA and n-3 PUFA (ALA and the LC n-3 PUFA). In addition to the evidence for a cardio-protective effect of the LC n-3 PUFA and a nutritional requirement for ALA and linoleic acid, substitution of SFA in the diet by an equal amount of *cis*-UFA (both MUFA and PUFA) reduces LDL-cholesterol. Thus UFA consumption may play an important nutritional role in limiting SFA intake.

Claim: High unsaturated fat - the amount of unsaturated fat is 70% of the total fat content

The claim as outlined may be made for a wide range of foods which are good sources of UFA, e.g. most vegetable oils, some fat spreads, nuts and seeds (mainly n-6 and n-3 PUFA) and fatty fish (mainly LC n-3 PUFA). The claim could be made for some foods which have a relatively high content of SFA and/or TFA, e.g. foods such as oils and fat spreads, in which most or all of the energy is derived from fat, could qualify for the claim while containing up to 30 E% from SFA and/or TFA. The claim could be made also for some foods which provide only low amounts of UFA in a typical serving, e.g. beans and lentils, berries, cereals and white fish. This anomaly arises because the UFA threshold is expressed as % of total fat content which is not directly related to the level of fat in the food or to typical intake of the food.

Opinion on the tolerable upper intake level of phosphorus

Phosphorus as phosphate is an essential nutrient involved in many physiological processes, such as the cell's energy cycle, regulation of the whole body acid-base balance, as a component of the cell structure (as phospholipids), in cell regulation and signalling, and in the mineralisation of bones and teeth (as part of the hydroxyapatite).

Estimates of habitual dietary intakes in European countries are on average around 1000-1500 mg/day, ranging up to about 2600 mg/day. The contribution of food supplements to phosphorus intake is low.

Adverse effects of excessive phosphorus intake, such as hyperphosphatemia, leading to secondary hyperparathyroidism, skeletal deformations, bone loss, and/or ectopic calcification have been reported in animal studies. However, such effects were not observed in studies in humans, except in patients with end stage renal disease. Although in acute or short term loading studies an increase in serum parathyroid hormone (PTH) levels has been found, no significant changes could be demonstrated in longer term studies with dosages up to 3000 mg/day (for 6 weeks). In these studies no evidence was found for effects on markers of bone remodelling and the Panel does not consider these to be adverse effects. Similarly, the Panel found no convincing evidence to support suggestions that high phosphorus diets would aggravate the effects of a state of secondary hyperparathyroidism induced by inadequate calcium intakes, or an inadequate vitamin D status.

Gastrointestinal symptoms, such as osmotic diarrhoea, nausea and vomiting, have been seen in some healthy subjects taking phosphorus (phosphate) supplements with dosages >750 mg/day. The Panel considered that these are not a suitable basis to establish an upper level for phosphorus from all sources.

The Panel concludes that the available data are not sufficient to establish an upper level for phosphorus.

The available data indicate that normal healthy individuals can tolerate phosphorus (phosphate) intakes up to at least 3000 mg/day without adverse systemic effects. In some individuals, however, mild gastrointestinal symptoms have been reported if exposed to supplemental intakes >750 mg phosphorus per day. There is no evidence of adverse effects associated with the current dietary intakes of phosphorus in EU countries.

Opinion on the tolerable upper intake level of tin

The European Food Safety Authority is asked to derive an upper level for the intake of tin from food that is unlikely to pose a risk of adverse health effects.

Tin has not been shown to be nutritionally essential for humans. Tin occurs naturally in foods as stannous and stannic salts, and stannous chloride (SnCl_2) is a permitted food additive (E512). Data on tin intake in EU countries are limited. In the UK mean intake in adults from food is estimated at 1.8 mg/day, ranging up to about 6 mg/day, and appears to be decreasing, while in France the mean daily intake was estimated to be 2.7 mg tin/day. The main dietary sources of tin are tinned fruit and vegetables.

The absorption of inorganic compounds of tin from the gastrointestinal tract in humans and animals is very low with as much as 98% being excreted directly in the faeces. Because of their limited absorption, inorganic tin compounds have low systemic toxicity in man and animals.

In man and animals, gastrointestinal effects are the main acute manifestation of toxicity associated with ingestion of tin. These are caused by the irritant action of soluble inorganic tin compounds on the mucosa of the gastrointestinal tract. In humans, acute effects resulting from consumption of tin-contaminated foods and drinks have resulted in gastrointestinal symptoms, including abdominal distension and pain, vomiting, diarrhoea, and headache. The balance of evidence suggests that the concentration of tin in contaminated foods is critical to the development of acute gastrointestinal effects, and that tin concentrations of 250 mg/kg in canned foods and 150 mg/kg in canned beverages are more likely to be associated with this.

In rats, growth depression, loss of appetite and reduced feed conversion efficiency are observed at doses of stannous chloride greater than 150 mg tin/kg diet. This appears to be due to reduced absorption and status of trace elements, particularly zinc, but also iron and copper, as a result of formation of insoluble complexes (probably with phosphates) in the gastrointestinal tract. There is evidence of reduced status of iron, zinc and copper when rats are fed diets containing 50 mg tin/kg diet or greater. It is likely that other effects which occur at this or higher levels e.g. reduced calcium content of bone at 50 mg tin/kg diet or pancreatic atrophy at a dose level of 2000 mg tin/kg diet, are not systemic effects of absorbed tin but rather manifestations of deficiency of one or more trace elements.

Short term studies in human adults indicate that high intakes of tin (about 30-50 mg tin/day or per meal) may reduce the absorption of zinc, but not other minerals such as iron, copper, manganese or magnesium. However, the possible long-term effects, if any, of such intake levels on status of zinc or other minerals have not been investigated.

The Panel considered that the available data from human or animal studies are insufficient to derive a tolerable upper intake level for tin. The current daily intake of tin in the EU (e.g. ranging up to about 6 mg/day in the UK) appears to be well below the lowest intakes reported to cause adverse effects on zinc absorption. Regulatory limits of 200 and 100 mg/kg for the concentration of tin in canned foods and beverages, respectively, have been established to protect against the occurrence of acute gastrointestinal effects of tin.