

Due to scientific studies published after the issue of this advisory report, it is no longer up to date.



Recommendations and claims made on omega-3-fatty Acids (SHC 7945)

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EXECUTIVE SUMMARY

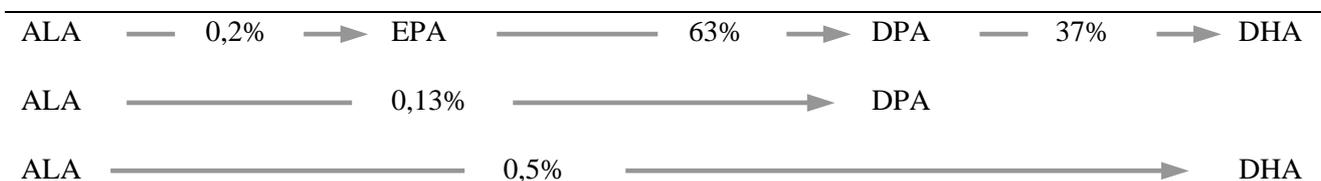
1. Biochemistry

ALA (alpha-linolenic acid) is the precursor of the n-3 family.

The human body is not able to manufacture this fatty acid, which is one of the PUFAs (Poly Unsaturated Fatty Acids). It is therefore an essential fatty acid that must be obtained from food.

Conversely, the human body can produce EPA (eicosapentaenoic acid) and DHA (docosahexaenoic acid), which, as a result, are not strictly essential. Thus, their intake through food is not strictly necessary. However, the problem is that the human body appears to produce insufficient quantities of these fatty acids. This can be attributed to the fact that the enzyme systems involved in the conversion of the n-3 acids are also involved in the conversion of the n-6 and n-9 acids. The affinity for the enzyme system reduces from n-9 to n-3 via n-6 (DGE 2000). This in turn means that they compete against each other and that the composition of the edible fats determines which reaction chain has priority over the others. It appears from the literature that under average circumstances, the following efficiency can be noted: normally, only 10% at best of the essential fatty acids (linoleic acid, alpha-linolenic acid) are converted into the corresponding long-chain derivatives (Demmelair et al. 1999, Gerster et al. 1998). More precise measurements have yielded the following efficiencies for the most important conversions (Pawlosky et al. 2001).

Figure: *Efficiency of the conversions*



With EPA and DHA synthesis thus highly insufficient, these fatty acids must therefore be obtained from food.

ALA does not perform any particular function; it is the precursor to the n-3 family and is simply one of the triglycerides and phospholipids.

EPA plays an essentially functional role in the transmission and transfer of signals.

DHA is primarily a structural element of the neuronal membranes.

2. Summary of the scientific arguments in support of the polyunsaturated omega-3 fatty acids

2.1. Pregnant & nursing women and small children

Fatty acids of the omega-3 family are important building blocks for the nervous tissues, where their incorporation is most intense during growth and the need for them is the highest.

The key question is whether the human body is able to satisfy its own physiological needs to a sufficient extent at all stages of life and especially at times of increased use. As a result of the varying ability to synthesize displayed by these fatty acids and the very heterogeneous diet found amongst the population (and in the different seasons), no uniform scientific answer can be provided to this question at present. Still, it is reasonable to recommend a minimal intake for foetuses and infants via the diet of pregnant and nursing women or infant milk, respectively.

This basic intake contributes to ensuring a safe pregnancy and enhances the neurological development of the foetus and the infant. The most convincing evidence for this is provided by the swiftness with which visual acuity is acquired.

2.2. Adult population

2.2.1. Primary prevention

Long term epidemiological studies as well as clinical and fundamental research have yielded convincing evidence in support of the view that omega-3 fatty acids of both animal and vegetable origin have a favourable effect on the risk of ischaemic cardiopathies. In addition, the evidence suggesting they have a positive effect on the prevention of cerebral vascular accidents of ischaemic origin has been rated as "likely". Finally, there is likely to be evidence that suggests that they have a favourable effect on the prevention of certain types of cancer.

2.2.2. Secondary prevention

The evidence in support of the view that the omega-3 fatty acids have a favourable effect on the cardiovascular mortality rate is also very convincing. Particularly worth mentioning are the randomised clinical trials with an experimental group and a reference group, in which a supplementation of omega-3 fatty acids of both animal and vegetable origin with fish, fish oil supplements and foods that are rich in alpha-linolenic acid have reduced the risk of cardio-vascular death in the experimental group as compared with the reference group.

Also on the subject of secondary prevention, there is "possible" evidence that suggests that they have a potentially favourable effect on chronic inflammatory affections of the gastro-intestinal tract, such as Crohn's disease and ulcerous colitis, by reducing the frequency of the acute attacks. This is also said to hold for rheumatoid arthritis and other auto-immune disorders.

3. Safety-related aspects

As regards the safety of the omega-3 fatty acids, two important points need to be mentioned, viz. the issue of contaminants and that of potential modifications in the structure of these fatty acids, especially oxidation.

The issue of contaminants (heavy metals, dioxins as well as PCBs of the dioxin-type) is particularly important for fish.

Lately, several authorities have been looking into the question whether it is reasonable to advise the population to tend towards an increased fish-consumption.

Given our knowledge on the subject of fish-consumption in our country and on the presence of contaminants, there are elements that can be adduced in support of recommending the consumption of fish twice a week, with one of these two meals involving fatty fish. Particular emphasis should be placed on the recommendation to consume different species of fish of different origins.

All relevant species of fish fall under the scope of this recommendation, including farmed salmon and other species of fatty fish, though there are a few exceptions.

As far as tuna is concerned, there is a restriction that holds for pregnant and nursing women as well as for young children. In the light of the methylmercury issue, it is advisable for them to restrict their tuna-consumption to max. once a week.

It is not advisable to eat fish from sporting fishing due to the general issue of contaminants.

The data at our disposal have shown that in our country, predatory fish such as shark, swordfish, and marlin are only moderately consumed. In this case too, a restriction would be justified.

It is necessary to pay detailed attention to the presence of contaminants in supplements, esp. in oils. The contaminant amounts in these supplements can be kept within bounds with appropriate technology.

As far the issue of secondary reactions and oxidation is concerned, it is advisable that these should be kept to a minimum. Indeed, the structure of the omega-3 fatty acids makes them particularly vulnerable for reactions of degradation. Precautions must be taken not only in order to keep them within bounds at the stages of extraction, refining, secondary treatment, incorporation in the foodstuffs but also during the preparation of food. This can be achieved by avoiding as much as possible any thermal load and contact with oxygen. It is also advisable that detailed attention be paid to the presence of protective minor components, like certain vitamins and antioxidants.

As far as this issue is concerned, we suggest that the necessary monitoring be carried out on the foodstuffs and the food supplements that contain omega-3-fatty acids. This holds both for vegetable-ALA and EPA and DHA obtained from marine animals.

Apart from ensuring that there are sufficient amounts of omega-3 fatty acids, we advise that care be taken that the degree of oxidation is always kept within bounds. Consequently, we put forward a PO number (peroxide) of max. 5.0 meq O₂ per kg.

4. Nutrition-related recommendations

4.1. Pregnant & nursing women and small children

We advise that pregnant and nursing women increase their energy intake (approximately 15% after the 12th week of the pregnancy and 20 % to 25% during breast-feeding) without changing the composition of their diet - at least if the latter is balanced.

In both cases, the linoleic acid (omega 6) intake should be approximately between 9 and 11 g/day.

In order to maintain a linoleic/ linolenic ratio of 5, the linolenic acid intake should be approximately 2 g/day (1.8 to 2.2 g).

In order to simplify supplying DHA to foetuses and nursed infants, pregnant and nursing women are advised to consume approximately 250 mg (200 to 300 mg) of these fatty acids on a daily basis, bearing in mind that this does not exempt them from consuming the precursor fatty acids.

In paediatrics, the following recommendations are currently applicable for essential fatty acids:

Ideally, they should represent between 2 and 5% of the total energy intake for linoleic acid (omega 6) and between 0.5 and 1.5% at least of the energy for linolenic acid (omega 3). High intakes of linoleic acid (>5%) are not desirable, nor are high intakes of other omega 6 fatty acids (they should not total more than 10% of the energy intake). The total intake of polyunsaturated fatty acids (omega 3 + omega 6) should not exceed 15% of the total energy intake. The above allows us to deduce the importance of omega-3 fatty acids: it appears to be desirable that this fatty acid should be consumed to a greater extent, allowing it to total up to 2% or more of the total energy consumed.

4.2. Adult population (primary prevention of cardio-vascular disorders)

At present, we can recommend 2 servings of preferably fatty fish per week, but of different species. As far as polyunsaturated omega-3 fatty acids of vegetable origin (ALA) are concerned, we can recommend the use of rapeseed oil and/or soybean oil or oil blends that contain omega-3 fatty acids and monounsaturated fatty acids (olive oil).

4.3. Secondary prevention of cardio-vascular disorders

We can recommend an almost daily serving of fatty fish of varied species or alternatively, capsules of fatty fish oil (EPA + DHA) to the amount of 1 g per day within a balanced diet.

As regards foods that have been enriched with ALA and/ or EPA + DHA, it is necessary to take into account the overall profile of the foods with respect to the extent to which they contain fat. We recommend that labels be applied that indicate their overall fat supply per 100 g, as well as the extent to which they supply saturated fatty acids, polyunsaturated omega-3 fatty acids and cholesterol.

Turning to the benefits that can be reaped for diabetes, certain cancers, chronic illnesses of the gastrointestinal tract and autoimmune diseases, the scientific arguments remain insufficient and no recommendation can be made for these disorders.

5. Nutrition and health claims

5.1. Position of the French food authority Afssa (France)

Enrichment procedures and nature of the omega-3 fatty acids to be used:

Enhancing the omega-3 fatty acid supply can be performed according to different procedures:

1. by promoting the consumption of food that is naturally rich in omega-3 fatty acids, such as an increase in alpha-linolenic acid intake through an enhanced consumption of rapeseed oil, soybean oil or oil that was especially made, or through an increase of the consumption of long-chain polyunsaturated omega-3 fatty acids (EPA + DHA) by means of an enhanced fish consumption.

2. by making use of the potential enrichment of certain foods.

- Indirect enrichment by using flaxseeds that have been extruded into animal food (in Belgium: eggs, milk), or direct enrichment by using ingredients or extracts that are intrinsically rich in omega-3 fatty acids (fish oil) (In Belgium: margarine).

- Finally, the enrichment can be carried out directly by means of well-defined quantities of DHA+EPA that have been added to the food.

3. the use of capsules that are rich in fish oil containing EPA + DHA. These capsules, which have been available in Belgium for over 15 years, have not been submitted to pharmaceutical inspection. As a result, they are not looked upon as medicine, but as real “food supplements” (Beromegan, Betasitol, Omega-3-6-9, Similepa, etc.). These products have been put on the market mainly because of their ability to reduce triglyceridemia.

On the other hand, there is only one product currently available on the Belgian market that has been registered as medicine. All European countries except the Scandinavian countries have accepted this product. Each capsule contains 460 mg EPA and 380 mg DHA, i.e. a total of 840 mg. Recall that this dose corresponds to that used in the GISSI-Prevenzione study. The instruction leaflet recommends 2 to 4 capsules per day!

The summary of the properties of this product mentions as an indication adjuvant treatment in the secondary prevention of myocardial infarction. In this case, the recommendation is one capsule per day (this recommendation is probably based on GISSI-Prevenzione).

The instruction leaflet points out that there are no data available on the use of this product with children, patients above the age of 70, or patients suffering from liver insufficiency. The firm advises regular monitoring of the liver and caution with respect to the risk of haemorrhage, especially in cases of severe traumatism or surgery. Finally, it advises closer monitoring of patients that are being treated with anti-coagulants.

These potential side-effects hold for all products put on the market that contain similar doses of omega-3 fatty acids (class effect).

The French working group has also revised the upper limit for their intake: the group has decided to fix upper limits which will have to be looked upon as levels of daily intake beyond which the nutritional benefit of the omega-3 fatty acids can no longer be shown. The group emphasizes that this limit should not be considered a safety limit, i.e. a level of intake beyond which there are health risks. As far as long-chain polyunsaturated fatty acids are concerned, the upper limit for their daily intake has been fixed at approximately 2 g/day. On the other hand, the Food and Drug Administration has granted the GRAS (Generally Recognized As Safe) status to oils whose levels of daily intake of EPA + DHA are estimated at less than 3 g/day. In addition, the French working group advises that the LC-PUFA-content per daily consumption unit of the enriched food lie under 100 % of the RDA for an adult male, higher contents being considered hazardous.

The experts point out that the likely increase in the number of foods that are enriched with omega-3 fatty acids and the accumulation of the different foods ingested throughout a single day will for an unknown percentage of the population result in their exceeding the 100% limit of the RDA. This likely turn of events will require nutritional monitoring of public health (food consumption survey).

Finally, the Afssa group makes the following important observation, with which we agree: **choosing the relevant enrichment vectors also raises the question what the effect will be of claims which attribute a positive image to the products and which may therefore lead to an increased consumption of the enriched food.**

They provide the example of full milk and butter as an illustration of this issue: indeed, an increased consumption of these products would result in an increased intake of saturated fatty acids, which may be harmful for the cardiovascular system. According to the French group, it is therefore vital that the overall nutritional composition of the enriched food be taken into account.

Quantitative nutrition claims (cf. figure)

Consequently, it is necessary to determine the intake levels that are required for a foodstuff to be looked upon as a "source for omega-3 fatty acids" and "rich in omega-3 fatty acids" and this level must be significant to cardiovascular physiology.

According to the French working group, **these claims are in line with claims whose scientific foundation is subject to the lowest requirements.** In what follows, we will call these claims "**level 1 claims**".

Suggestions made by Afssa:

- a foodstuff is considered a "source of omega-3 fatty acids" if it contains 15 % of the RDA of alpha-linolenic acid (2 g/day) or DHA (0.12 g/day) for an adult male per 100 g, 100 ml or 100 kcal;
- a foodstuff is considered "rich in omega-3 fatty acids" if it contains more than twice the threshold value posited for the "source" claim, i.e. 30 % of the RDA in alpha-linolenic fatty acids or DHA for an adult male per 100g, 100 ml or 100 kcal.

It stands to reason that the use of claims of this type should result in mandatory nutrition labelling concerning the nutritive value of the foodstuffs.

Functional and "health-related" qualitative claims (cf. figure)

→"level 2 claim"

- The food is a "source of omega-3 fatty acids" or is "rich in omega-3 fatty acids"
- the LA/ALA equivalent ratio is smaller than or equal to 5
- the product either supplies reasonable amounts of fats (intake <33 % of the total energy intake from the product) or it is rich in fats (intake ≥33 %) but supplies reasonable quantities of saturated fatty acids (intake <30 %).

These criteria are stricter than the ones that have been put forward with respect to the RDA. Indeed, products that have received a positive image as a result of such a claim should be factors that contribute towards rebalancing the overall diet as far as the fat-intake is concerned.

When all these conditions are met, the product qualifies for the claim "this product helps rebalance the omega-3 fatty acid intake".

→ "level 3 claim"

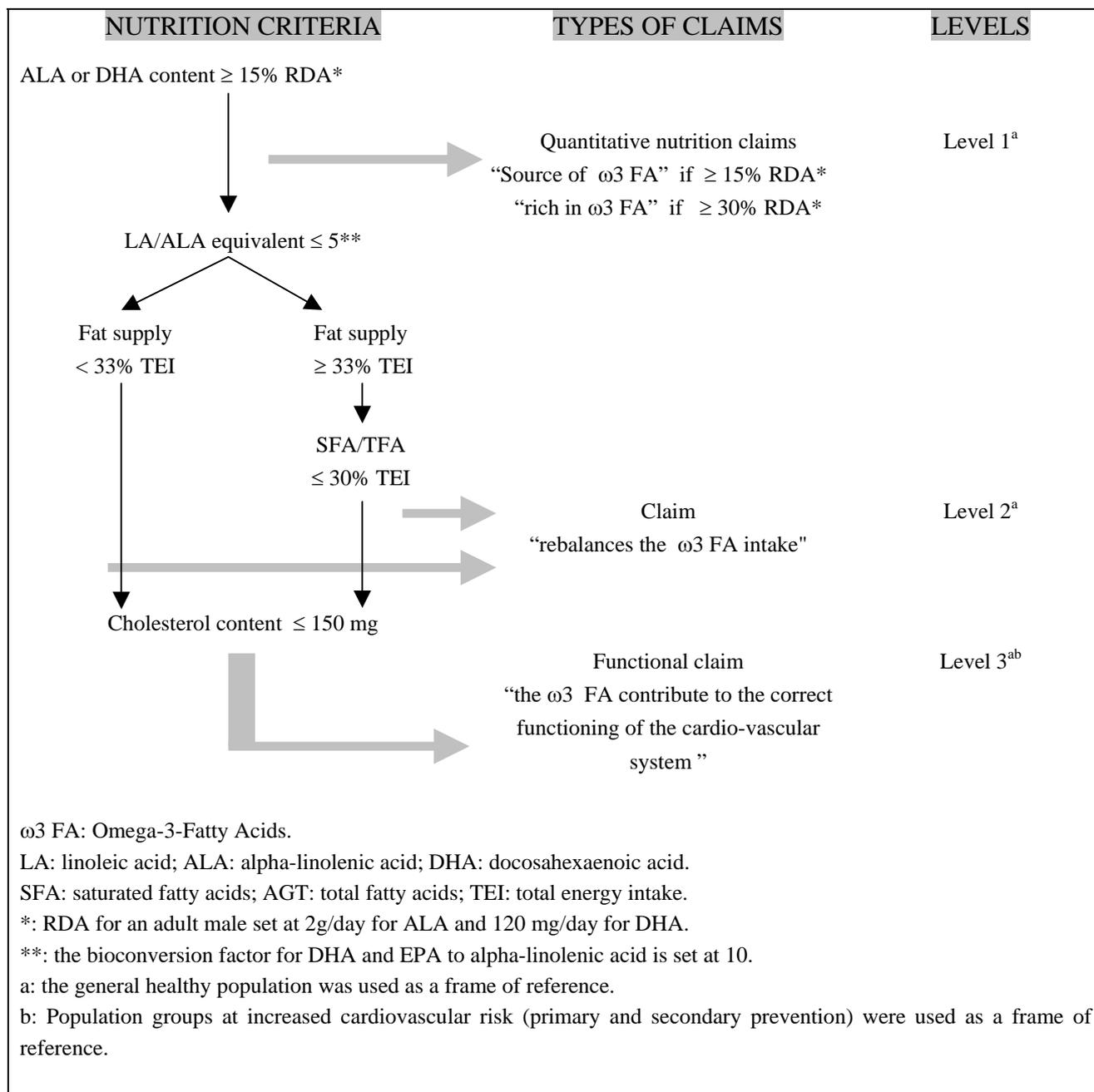
When the conditions mentioned below are met, the product is qualified to make the following claim: "the omega-3 fatty acids contribute to the correct functioning of the cardio-vascular system":

- the foodstuff is a "source of omega-3 fatty acids" or is "rich in omega-3 fatty acids"
- the product "helps rebalance the omega-3 fatty acid intake"
- this product contains no more than 150 mg of cholesterol per 100 g or 100 ml

As a result, it turns out that for a given foodstuff that has been enriched with omega-3 fatty acids, there is a close connection between meeting the requirements that allow the use of level 2 and level 3 claims and showing that there is an unmistakable nutritional advantage (taking into account the overall composition of the food vector). **As a result, the French working group recommends that a specific evaluation be required when the nutritional benefit of the food is subject to debate.**

This is an extremely important observation, which therefore confirms the view that enriching food with omega-3 fatty acids does not entail that it is wholesome, given the fact that its remaining components must also be taken into account. Consequently, it is necessary to factor in all the components of the food, especially the saturated fatty acids, cholesterol and mono- or disaccharides it contains.

Figure: Omega-3 fatty acids: potential claim-types depending on the nutritional quality of the foods.



5.2. Proposal for a Regulation of the European Parliament and of the Council on Nutrition and Health Claims made on foods (COM (2003)424) (16.7.2003-Final)

This section mentions the most crucial points made by the Proposal for a Regulation of the European Parliament and the Council on Nutrition and Health Claims in order to determine what the differences are between this document and that produced by Afssa.

The complete document is available on the following website:
http://europa.eu.int/comm/food/fs/fl/fl07_en.pdf

We noted the following relevant points:

Specific issues of the proposal

When a claim is granted to a foodstuff, the latter gains the advantage of a positive image. Thus nutrition labelling should become mandatory for all foods bearing nutrition and health claims. It should be complete in order to give a better overall picture of the food (profile of the food). In addition, it is essential to avoid the use of specialised claims that are so complicated as to be meaningless to consumers.

Moreover, it is considered advisable to disallow claims according to which the food influences psychological and behavioural functions (e.g. "enhances memory and concentration").

Nutrition claims

Clear and simple rules should be set. At international level Codex Alimentarius has developed guidelines for the most commonly used nutrition claims (such as "low", "rich", "light", etc.). Similar criteria exist in some Member States. The Annex to this proposal provides a list of nutrition claims and their specific conditions of use.

Health claims

Reminder: Directive 2000/13/EC on labelling, presentation and advertising of foods specifically prohibits attributing to foods any properties of **prevention, treatment or cure** of a human disease, or any reference to such properties. This prohibition is maintained in the proposal for a Regulation of the European Parliament and of the Council on nutrition and health claims made on foods. However, a difference is made between "prevention" and "reduction of a disease risk factor" and a derogation is provided. As a matter of fact, a European Parliament Resolution of 1998 stipulates that claims referring to the reduction of the risk of disease should be allowed if "they are based on sufficient and recognised scientific findings and if they are tested and confirmed by an independent body within the European Union."

COMMENT

As far as omega-3 fatty acids are concerned, it follows that a claim according to which "omega-3 fatty acids reduce triglyceridemia" could be allowed because it concerns the reduction of a risk factor. Conversely, the claim "reduces triglycerides, which lessens the risk of infarction" could not be allowed, except if an independent body within the European Union - which apparently still has to be created - were to determine under which scientific conditions one can speak of a reduction of the risk of disease.

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