

Omega-3 Labelling and the Nutrition and Health Claims Regulations

This guidance note provides information that may be relevant to companies wishing to make claims about the Omega-3 content of their products and/or any health benefits associated with this.

The legal requirement for making this type of claim is in the process of changing. During this transition period some of the old rules remain and some new rules will come into force.

This guidance only gives information on the rules that relate to Omega-3 labelling. Other rules may apply to other claims that you wish to make.

The information given in this guide was taken from the Food Standards Agency (FSA) guide to compliance, which can be found at: <http://www.food.gov.uk/multimedia/pdfs/ec19242006complianceguide.pdf>

While every effort has been made to give the correct advice, the need to summarise the information and make it relevant to the use of Omega-3 claims may have led to some minor differences. Where inconsistencies are present, and these effect your labelling decisions, the Agency guide should take precedence. References to the relevant section of the FSA guide are given under each question.

The European Nutrition and Health Claims Regulation

EC 1924/2006 (NHCR) came into force on 1 July 2007. It controls any nutrition, health and disease reduction claims made about a food. It does not just apply to labelling, but all types of commercial communication.

Before this legislation came into force, the national law of the Member State applied. In the UK this was consumer protection legislation in the form of the Food Labelling Regulations 1996 and the Food Safety Act 1990; these require that labelling should not be false or misleading and claims for disease reduction are not permitted. Some of these laws remain during the transition period for the new Regulation. However, it was and will remain for the courts to decide whether a claim is misleading under the relevant legislation.

This document is not a definitive interpretation of the law, which only the courts can provide. It is the responsibility of the individual business to ensure compliance with the law.

The first version of this fact sheet was written in November 2008. The fact sheet has now been updated to include the latest developments up to July 2009

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1. What is a commercial communication?

[FSA guide Section 2.4 (page 14), section 9.4 (page 44)]

The Regulation only applies to positive claims made in commercial communications aimed at the final consumer. These are any way that information is passed to the consumer with the aim of influencing the consumer to purchase or use a product. Examples of what is and is not commercial are given in the FSA guidance.

However, in some cases it is not easy to determine if a communication is commercial. If there is a benefit to a company whether directly or indirectly then it would be seen as commercial. For example, if a seafood processor promotes his product through a general health article, on the benefits of Omega-3 in a magazine, or advertises in the same field of vision of such an article, then this would be commercial. The same article written with no particular product association or promotion would not be commercial.

2. What is a nutrition claim?

[FSA guide Section 2.2 (page 11)]

A nutrition claim is a claim that a food contains a particular nutrient, or words or pictorial representations that could be taken to mean the same thing. Declarations of the presence of a nutrient or ingredient that are required to be made by law¹ or declarations in a nutrition panel such as 0.225g of Omega-3 per 100g are not nutrition claims.

Only beneficial claims aimed at selling the product are considered to be nutrition claims so 'high in fat' would not be considered a claim in most products whereas 'low in fat' would be. This may depend on the product on which the claim is made. Omega-3 content claims are likely to be nutrition claims.

To make a nutrition claim, the claim must be included in the annex to the NHCR. The generic claim that a food 'contains' a named nutrient is already included in the annex, so if you wish to make this claim, you must comply with the provisions of the NHCR.

One of the requirements of the NHCR for making a nutrition claim is that the food contains significant amounts of the named nutrient to be a benefit to health. This would apply to companies wishing to make a 'contains Omega-3' claim.

What is deemed to be a significant amount is the amount that can be expected to produce the desired effect taking into account what quantities will be eaten. As there is no Recommended Daily Amount established for Omega-3, it would be advisable to use the amounts approved for the Joint Health Claims Initiative (JHCI)* claim to avoid making a misleading claim.

*JHCI - see page 3

3. What nutrition claims for Omega-3 can I make on my products and within what time frame will the rules be applied?

[FSA guide Section 4.2 (page 22), section 4.3 (page 23), Q60 (page 56)]

The annex to the Regulation includes a generic claim of 'contains' that could be used for Omega-3 (see Q.2). It is the Agency's view that 'source of' would mean the same as 'contains' to the average consumer and should be treated as the same claim and therefore comply fully with the NHCR.

For other nutrition claims that are not included in the annex there are agreed transitional arrangements. These allow any claims made before 1 January 2006 and not included in the annex of the NHCR to continue to be used until 19 January 2010. Nutrition claims new to the market from 1 January 2006 must comply with the regulation or be taken off the market by 31 July 2009.

'High in Omega-3' was not included in the original annex, but as it is the claim not the product that must have been in use before this date, then new products can claim to be 'high in Omega-3' until 19 January 2010. These claims must comply with existing food law which are the Food Labelling Regulations 1996 and the Food Safety Act 1990. Although in the case of Omega-3 the use of the JHCI conditions for making a claim would prevent a misleading claim.

As of July 2009 this has changed and the proposal is now to include the claims 'source of Omega-3' and 'high in Omega-3' within the annex. These will be set at 15% and 30% respectively of the recommended daily intake (RDI). The RDI is 200mg/day for long chain PUFA (polyunsaturated fatty acids) and 2000mg/day for short chain PUFA.

The scientific opinion is that short chain PUFA do not confer the same health benefits as long chain PUFA and should not be included in any Omega-3 claim.

¹ For example where the nutrient has been added and so must be included in the name of the food.

Scientific opinion is also that RDI for long chain PUFA should be 400-500mg day.

Because of the concerns over the details of the Omega-3 amendments, the amendments to the annex have been delayed while further evidence is assessed. This may mean that the transition period for existing claims (as explained above) will expire before the new claim is approved and comes into force. As no extension to the transition period has been discussed, it is hoped that the authorities will take a pragmatic approach in allowing existing claims to be used until the new claims come into force.

4. What is a health claim?

[FSA guide Section 1.5 (page 7), section 2.3 (page 12)]

A health claim states that the food or a nutrient it contains has a named health benefit. Health claims, once approved, will be published on a community list. Applications for inclusion onto this list must be submitted to the FSA who will pass them to the Commission for consideration. There was an initial process for approval of claims based on established science (article 13). Claims based on emerging science, claims for disease risk reduction or claims for products aimed at children must go through a more thorough process (articles 13 (5) and 14 of the NHCR).

The FSA has published the list for submission to the Commission for inclusion onto the approved list, including the JHCI claim and others relating to Omega-3. These claims can be viewed on the Agency website: <http://www.food.gov.uk/foodlabelling/ull/claims/>

The Commission list of health claims is expected to be published in 2010, so until this time, claims in use before 1 July 2007 can continue to be used according to national law. In the UK this states that claims should not be misleading. To ensure this, it is advisable to follow the guidelines of the JHCI approved claim.

5. What health claims for Omega-3 can I make on my products?

[FSA guide Section 5.1 (page 26)]

Health claims used on products before 1 July 2007, can continue to be used until 19 January 2010. It is the claim itself, not its use on a particular product that can be used under the transitional

arrangement. If the particular claim is approved before this date then the use of the claim must comply with the NHCR. Any claims not included on the list can continue to be used in accordance with national law until 19 January 2010.

If you wish to make a new health claim see Q.12

6. What is the JHCI approved claim for Omega-3?

Prior to the NHCR coming into force, to prevent claims being seen as misleading, nutrition and health claims could be approved for use by the JHCI. The JHCI approved the wording and terms and conditions of use, of a claim that could be used on products that contained certain amounts of Omega-3. Although the JHCI was disbanded with the NHCR coming into force the claims approved can continue to be used during the transition period. As the claim is a generic claim, rather than being linked to a particular product, it can be applied to new products during the transition period, if the product meets the terms and conditions of the approval. For details of the JHCI and the terms and conditions of any approved claims see: <http://www.jhci.org.uk>

7. Do I need to use the exact wording of any health or nutrition claims?

[FSA guide Q76 (page 60)]

To use the JHCI claim it was required that the exact wording was used. However under the requirements of the regulation it is the meaning of the claims that is approved. Any wording or presentations that the average consumer may understand to be a nutrition or health claim will fall within the scope of the NHCR. While this does allow more flexibility in the wording of claims it also increases the likelihood that wording or pictures will be seen as a claim.

8. What is the wording of the approved JHCI Omega-3 Health Claim?

'Eating 3g weekly, or 0.45g daily, long chain Omega-3 polyunsaturated fatty acids, as part of a healthy lifestyle, helps maintain heart health'. For terms and conditions of the use of this claim see: <http://www.jhci.org.uk>



9. Can the Omega-3 logo be used on new products?

[FSA guide Section 7 (page 34)]

The logo is owned and its use controlled by the Omega-3 group², who set the criteria for its use, although other logos could also be used. The use of such logos would be seen as a nutrition claim for the purpose of the Regulation. Therefore they would need to comply with the rules for the appropriate nutrition claim. The Omega-3 Group logo includes the words 'Rich in Omega-3', this is not an approved claim but as it was in use before 1 January 2006, it may continue to be used until 19 January 2010.

10. Is the '2 a week' logo considered a health or nutrition claim?

[FSA guide Q14 (page 42)]

No, government messages are not included in this Regulation, therefore the '2 a week' logo can be used on products without complying with the NHCR.

11. My product is high in salt, can I still make health and/or nutrition claims?

[FSA guide Section 6.2 (page 32)]

Yes, at the moment there are no requirements on the nutrients of a food other than those that the claim is being made for.

However, to prevent the use of claims misleading consumers as to the true nutritional composition of the food the NHCR originally required that nutrient profiles were established by 19 January 2009 and that businesses would need to comply with these additional rules by 19 January 2011 .

However due to complications in the setting of nutrient profiles and the priority of the claims approval process, nutrient profiling has been shelved for now.

Once nutrient profiles are established if a food meets the nutritional profile it will be able to make claims. Any food failing to meet the profile on one nutrient, for example salt, will be able to make claims but must

declare this nutrient with the same prominence as the health or nutrition claim. Any food failing on more than one nutrient will not be able to make health or nutrition claims. Although in some circumstances 'reduced' claims will be allowed.

Before nutrient profiling was shelved, a seafood product category had been created as any food product containing at least 50% seafood with limits of 10g/100g of saturated fat and 500mg/100g sodium.

12. What if I want to make a new Omega-3 health claim on my product?

[FSA guide Section 7 (page 34), Q. 94 (page 65)]

If the claim refers to the role of a nutrient or other substance in the growth development and functions of the body then new claims can be used until the approved list is published. This applies to claims that have been previously used on foods and those that have not. These claims would have to comply with the general requirements of the NHCR as well as national law.

13. Who will enforce the Regulation?

It will be enforced by your local authority food team, either Environmental Health or Trading Standards. However it has also been incorporated into the Advertising Standards Authority (ASA) codes on broadcast and non broadcast advertising, known as 'CAP' and 'BCAP' codes. This is to ensure that there is consistency between the Regulation and the advertising codes. There have been several rulings based on the requirements of this Regulation even though it is not yet fully in force. For more details on the codes and rulings of the ASA.

14. Where can I get further information?

The Food Standards Agency guide can be accessed at: <http://www.food.gov.uk/multimedia/pdfs/ec19242006complianceguide.pdf>

The Seafish website: <http://www.seafish.org> or contact your local Food Authority responsible for food standards.

² The Omega-3 Group was established in 2002 to investigate the potential for increasing the consumption of oil rich seafood through communicating the benefits of long-chain Omega-3 fatty acids. The Group evolved through the Scottish Food and Drink Health Enhancing Foods Initiative. Members of the Group include company representatives from industry and the main fish farming, seafood and economic development organisations operating in Scotland, such as Scottish Salmon Producers' Organisation, Sea Fish Industry Authority, Seafood Scotland and Scottish Enterprise. <http://www.richinomega3.com/about/group.html>

Omega-3 Nutrition and Health Claims Timeline

July 2003	New legislative proposal on nutrition and health claims adopted to prevent unsubstantiated claims being made about foods
Feb 2005	Joint Health Claims Initiative approve the claim for Omega-3. The dossier was submitted by the Omega-3 group, which included Seafish. The approved claim was 'Eating 3g weekly, or 0.45g daily, long chain Omega-3 polyunsaturated fatty acids, as part of a healthy lifestyle, helps maintain heart health.' http://www.jhci.org.uk/
Jan 2007	After a lot a debate and numerous revisions the Nutrition and Health Claims Regulation (NHCR) is adopted. It contains a limited annex of nutrition claims, which come into force with the Regulation. This includes a general claim of 'contains' for named nutrients, this can be used for a food that contains 15% of the RDI for Omega-3. http://eur-lex.europa.eu/LexUriServ/site/en/oj/2007/l_012/l_01220070118en00030018.pdf
1 July 2007	The Regulation enters into force. Transition periods are agreed until 19th Jan 2010 for existing claims.
Dec 2007	Seafish submit JHCI claim to the FSA for inclusion on UK list of health claims. This is to go for EFSA opinion on approval under NHCR. Other bodies submit other health claims for Omega-3.
March 2008	Due to the large number of claims and differences in approach by Member States, the Commission needs to clarify and codify claims to speed up processing.
March 2009	Database of claims published by the Commission with clarification of many claims. The JHCI claim needs clearer wording, which can be backed by submitted references. The claim 'decreased risk of heart arrhythmias' is submitted as suggested wording. The database, details of the screening process and progress of the JHCI claim (ID 504) can be found at: http://www.efsa.europa.eu/cs/Satellite?c=Page&childpagename=EFSA%2FPPage%2Fntp_A&cid=1211902055970&pagename=efsa
June 2009	Proposal for additions to the annex are published. This includes 'source of Omega-3' and 'high in Omega-3', at 15% and 30% of RDI respectively. There is no differentiation between long chain and short chain PUFA. RDI are set at 200mg/day for long chain and 2000mg/day for short chain. Seafish responds requesting different claims for short and long chain.
June 2009	EFSA opinion on Omega-3 RDI published. This recommends an RDI of 250mg/day for long chain. The opinion can be found at: http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902671518.htm
July 2009	Leading academics petition the Commission that RDI is too low. There also needs to be differentiation between short and long chain types to prevent the consumer being misled. They recommend 400-500mg/day for long chain.
July 2009	Publication of annex delayed whilst more evidence is assessed on Omega-3 benefits and recommended RDI.
July 2009	Seafish responds to the Commission backing the academic petition. The Commission website on the Nutrition and Health Claims Regulation can be found at: http://ec.europa.eu/food/food/labellingnutrition/claims/index_en.htm