GOED

TECHNICAL REPORT: MEETING LABEL CLAIMS FOR EPA AND DHA

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Meeting Label Claims for EPA and DHA

To ensure that finished products consistently contain the amount of EPA and DHA stated on the label, a few simple steps must be taken. These depend on whether you are creating a new product (approach A, below) or need to adjust the content claims for an existing product (approach B).

Note that this technical report is intended as helpful information and good practice for GOED members only and should not to be interpreted as mandatory. In specific geographies, dietary supplements may be required to contain both a minimum level and maximum level of declared nutrients of the claimed content. Members are expected to understand and follow regulatory requirements for the market in which the product is being sold. It is understood that natural oils experience variations in fatty acid profiles which may, at times, make it challenging to meet label claims. Members who work with natural oils should have policies in place to address this situation when it arises.

Information is available from GOED about regulations for EPA/DHA label claim tolerances in different countries – please contact GOED.

A. For the creation of new products.

1. Establish your label claim based on the amount of EPA and DHA you intend to provide the consumer. The finished product specification, and the certificate of analysis (COA), must align with the label claim.
2. Determine the desired serving size of the finished product in grams.
3. Calculate the desired raw material specification for EPA and DHA accordingly, using the serving size and desired label claim. In some cases, it may be necessary to adjust the dosage size to achieve the label claim, especially if there are limited options for raw materials.

Example 1:

Calculation to determine which raw material should be used to produce a softgel containing 400 mg EPA and 300 mg DHA per capsule.

Softgel formulation (triglyceride):

Formula	Input %
Fish Oil	98.9
Orange Flavour	1
Rosemary Extract	0.1
Capsule Fill Weight (g)	0.9

Label claim = Mass of Fish Oil Per Serving (g) x Potency (mg/g) / mass of fish oil per serving (g)

Mass of fish oil per serving = 98.9% x 0.9g = 0.89 g

(This calculation considers the amounts of added flavour and antioxidants in the formulation. If there are no flavours, antioxidants or other additives in the formulation then the percentage of fish oil will be 100%).

Potency of raw material = targeted dosage (mg) / mass of fish oil per serving (g)

Required EPA in raw material (mg/g) = (400 mg EPA) / (0.89 g fish oil per serving) = 449 mg/g EPA in raw material

Required DHA in raw material (mg/g) = (300 mg DHA) / (0.89 g of fish oil per serving) = 337 mg/g DHA in raw material

Conclusion: The desired raw material to produce this formulation should contain a minimum of 449 mg/g EPA and 337 mg/g of DHA as TG.

Example 2:

Calculation to determine fill weight of softgel containing 400 mg EPA and 300 mg DHA per capsule, using a raw material containing 400 mg/g EPA and 300 mg/g DHA:

Softgel formulation (triglyceride):

Formula	Input %
Fish Oil	98.9
Orange Flavour	1
Rosemary Extract	0.1
Capsule Fill Weight (g)	XX

Mass of Fish Oil Per Serving (g) = Label claim / Potency (mg/g)

Fish oil required to achieve 400 mg/capsule of EPA = (400 mg EPA) / (400 mg/g EPA) = 1 g of fish oil per softgel

Fish oil required to achieve 300 mg/capsule of DHA = (300 mg DHA) / (300 mg/g DHA) = 1 g of fish oil per softgel

Capsule fill weight = Mass of fish oil per serving / % of fish oil in formulation

Capsule fill weight (XX) = 1g / 98.9% = 1.012 g

(This calculation considers the amounts of added flavour and antioxidants in the formulation. If there are no flavours, antioxidants or other additives in the formulation then the percentage of fish oil will be 100%).

Conclusion: To achieve a dosage of 400 mg EPA and 300 mg DHA per softgel, a fill weight of 1.012 g would need to be used.

Example 3:

Calculation to determine the raw material specification for a liquid product with a serving size of 4.65 g (5 ml) and a targeted label claim of 1800 mg EPA and 1300 mg DHA.

Liquid Product formulation:

Formula	**Input %**
Fish Oil	98.9
Orange Flavour	1
Rosemary Extract	0.1
Serving Size (ml)	5
Serving Size (g)	4.65*

*Density of the formulation was measured to be 0.93 g/ml. If no additional ingredients are added, the density of the fish oil as stated on the fish oil specification can be used.

Potency of raw material (mg/g) = Label claim (mg) / Mass of Fish Oil Per Serving (g)

Mass of fish oil per serving = 98.9% x 4.65 g = 4.60 g

(This calculation considers the amounts of added flavour and antioxidants in the formulation. If there are no flavours, antioxidants or other additives in the formulation then the percentage of fish oil will be 100%).

Required EPA in raw material = (1800 mg EPA) / (4.60 g fish oil per serving) = 387 mg/g EPA in raw material

Required DHA in raw material = (1300 mg DHA) / (4.60 g fish oil per serving) = 283 mg/g DHA in raw material

Conclusion: A raw material containing a minimum of 387 mg/g of EPA and 283 mg/g DHA is required to produce a liquid product with a label claim of 1800 mg EPA and 1300 mg DHA per 4.65 g (5 ml) serving.

B. Adjusting the content claims of an existing product.

This approach would be used by companies to determine what the claims should be for their already-existing products, for example when a company has a softgel product on the market and wants to update their label claims. For existing products, it would be easier for a company to source a raw material fish oil that meets their label claim (and value proposition) than to change their label claim and consumer expectations. But if it is not possible to source a material to meet that, or if it has become less cost-effective, they would then have to adjust their specifications and label claim accordingly. Companies that are not formulating their product themselves and rely on a contract manufacturer to do that, and discover that they are not meeting the content claims of the product, may also find useful advice below.

1. Determine label claims by using the minimum amount of EPA and DHA stated on the raw material specification in mg/g. If your oil is a triglyceride, make sure to use the TG values. If your product is an ethyl ester, then you would use EE values.
2. Take amounts of added antioxidants, flavours, etc. into account.
3. Determine the serving size of the finished product in grams. For encapsulated products, this should be based on the target fill weight of the capsule. For liquid products, this should be calculated using the density or specific gravity of the product.
4. Use the minimum amounts of EPA and DHA on raw material specification, the percentage of fish oil in the finished product and the mass of the product to determine the label claim of the finished product.

Example 4:

Determining the appropriate label claim for an existing softgel product formulation where there is no desire to adjust the formulation or input ingredients.

Supplier Certificate of Analysis:

Quality Attribute	Limit	Unit	Result
EPA (Eicosapentaenoic acid as TG)	min. 400	mg/g	425
DHA (Docosahexaenoic acid as TG)	min. 300	mg/g	323
Total omega-3 fatty acids as TG	min. 800	mg/g	859
EPA (Eicosapentaenoic acid as FFA)	min. 384	mg/g	407
DHA (Docosahexaenoic acid as FFA)	min. 289	mg/g	311
Total omega-3 fatty acids as FFA	min. 760	mg/g	826

Softgel formulation (triglyceride):

Formula	Input %
Fish Oil	98.9
Orange Flavour	1
Rosemary Extract	0.1
Serving Size (ml)	5
Serving Size (g)	0.9

Label claim = Mass of Fish Oil Per Serving (g) x Potency (mg/g)

Mass of fish oil per serving = 98.9% x 0.9g = 0.89 g

(This calculation considers the amounts of added flavour and antioxidants in the formulation. If there are no flavours, antioxidants or other additives in the formulation then the percentage of fish oil will be 100%).

EPA = (0.89 g fish oil) x (400 mg/g EPA) = 356 mg EPA per capsule

DHA = (0.89 g fish oil) x (300 mg/g DHA) = 267 mg DHA per capsule

Total omega-3 = (0.89 g fish oil) x (800 mg/g total omega-3) = 712 mg total omega-3 per capsule

Conclusions: The label claims for this product should be set at 356 mg EPA and 267 mg DHA per capsule.

Example 5:

Determining the appropriate label claim for an existing liquid formulation where there is no desire to adjust the formulation or input ingredients.

Supplier certificate of analysis:

Quality Attribute	Limit	Unit	Result
EPA (Eicosapentaenoic acid as TG)	min. 400	mg/g	425
DHA (Docosahexaenoic acid as TG)	min. 300	mg/g	323
Total omega-3 fatty acids as TG	min. 800	mg/g	859
EPA (Eicosapentaenoic acid as FFA)	min. 384	mg/g	407
DHA (Docosahexaenoic acid as FFA)	min. 289	mg/g	311
Total omega-3 fatty acids as FFA	min. 760	mg/g	826

Liquid product formulation:

Formula	Input %
Fish Oil	98.9
Orange Flavour	1
Rosemary Extract	0.1
Serving Size (ml)	5
Serving Size (g)	4.65*

*Density of the formulation was measured to be 0.93 g/ml. If no additional ingredients are added, the density of the fish oil as stated on the fish oil specification can be used.

Label claim = Mass of Fish Oil Per Serving (g) x Potency (mg/g)

(This calculation considers the amounts of added flavour and antioxidants in the formulation. If there are no flavours, antioxidants or other additives in the formulation then the percentage of fish oil will be 100%).

Mass of fish oil per serving = 98.9% x 4.65 g = 4.60 g

EPA = (4.60 g fish oil) x (400 mg/g EPA) = 1840 mg EPA per 5 ml serving

DHA = (4.60 g fish oil) x (300 mg/g DHA) = 1380 mg DHA per 5 ml serving

Total omega-3 = (4.60 g fish oil) x (800 mg/g total omega-3) = 3279 mg total omega-3 per capsule ml serving

Conclusions: The label claim for this liquid formulation should be set at 1840 mg of EPA and 1380 mg of DHA per 4.65 g (5 ml) serving.

Other considerations

- Note that for both approaches (A and B), your ingredient supplier and/or contract manufacturer should meet, and continue to meet, your specification. Thereto you should test the quality of the oil ingredient you receive. GOED advises that both you and your oil supplier employ a third-party laboratory that has recently achieved a high score in the AOCS GOED Nutraceutical Oils Laboratory Proficiency Program (LPP) (link) to quantify the EPA, DHA and Total Omega-3 content. That also means that the laboratory you use, as well as that used by your oil supplier, has employed a method that is suitable for the quantification of EPA, DHA and Total Omega-3 content.

GOED provides industry advice on correct content expression and suitable methods on its website in the following documents:

- Guidance Documents: https://www.goedomega3.com/goed-monograph (information on suitable methods for quantification of EPA, DHA and Total Omega-3 in EPA/DHA ome-

ga-3 oils)

- GOED Industry Advisory: Correct Expression of EPA, DHA and Total Omega-3 Fatty Acid Content in Oils (this Industry Advisory outlines the correct way to express the content of EPA, DHA, and fatty acid content in omega-3 oils).
- Industry Advisory on accurate quantification of EPA, DHA and Total Omega-3 content of omega-3 oils by GC-FID (this Industry Advisory provides practical approaches and tips to improve the accuracy of EPA and DHA quantification by GC-FID).

- As a general note regarding the information in this report, in some cases, a small overage of raw material is included in the formulation to compensate for variability in processes and analytical methods. If an overage is used, a calculation adjustment will be needed when setting desired raw material amount to address these sources of variability. Some companies choose not to include overages as part of their "lean manufacturing" processes.
- Qualification and testing of raw materials is a part of any good Quality Management or Preventative Control Program. It is recommended that GOED members have a system in place to ensure that all materials used meet the desired specifications. Requirements for these systems vary from country to country and it is recommended that you check with your local regulatory authority to determine what your program requires.