NSF International Standard for Dietary Supplements — Dietary supplements

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5.3 Contaminants

5.3.1 Metals

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5.3.3 Microbiological contaminants

Raw materials shall not contain aflatoxins at levels greater than 20 ppb and shall not contain microorganisms in quantities greater than permitted in tables 5A and 5B.

Finished products shall not contain aflatoxins at levels greater than 20 ppb and shall not contain microorganisms in quantities greater than permitted in tables 6A and 6B.

Finished products in a liquid form with an alcohol content less than or equal to 50% shall not contain *Pseudomonas aeruginosa*.

Finished products with an alcohol content greater than or equal to 50% are exempt from microbial testing.

5.3.4 Natural toxins

Botanicals listed in annex A shall not contain aristolochic acid (limit of detection is 0.5 μg/gm).

5.3.5 Known adulterants

Products shall be evaluated to ensure that they do not contain known adulterants including, but not limited to, the following:

- *Eleutherococcus senticosus* shall not contain *Periploca sepium* root.
- *Plantago lanceolata* shall not contain *Digitalis lanata* leaf.
- *Scutellaria lateriflora* shall not contain *Teucrium chamaedrys*.
- *Stephania tetranda* shall not contain *Aristolochia fangchi*.

5.3.6 Industrial Contaminants

For ingredients and products containing natural fish oil, manufacturers shall have controls in place to screen for polychlorinated biphenyls (PCBs), polychlorinated dibenzo-para-dioxins (PCDDs), polychlorinated dibenzofurans (PCDFs) and dioxin-like PCBs in the oil ingredient.

The content of dioxins and furans expressed as the sum of PCDDs and PCDFs shall not exceed 2 pg WHO-TEQ per gram of oil, dioxin-like PCBs shall not exceed 3 pg WHO-TEQ per gram of oil, and total PCBs shall not exceed 0.09 mg/kg of oil (w/w).[1] Total PCBs shall, at a minimum, include IUPAC congeners 28, 52, 101, 118, 138, 153, and 180.

[1] Council for Responsible Nutrition, Omega 3 Fatty Acids Voluntary Monograph, March 2006. Dioxin limits include the sum of polychlorinated dibenzo-*para*-dioxins (PCDDs) and polychlorinated dibenzofurans (PCDFs) and are expressed in World Health Organization (WHO) toxic equivalents using WHO-toxic equivalent factors (TEFs). This means that analytical results relating to 17 individual dioxin congeners of toxicological concern are expressed in a single quantifiable unit: TCDD toxic equivalent concentration or TEQ.

5.3.~~6~~7 Other product claims

Claims that a product is free of a particular contaminant or substance shall be verified in accordance with 7.4 and/or 8.

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7.4 Test methods for chemical contaminants

Testing shall be performed based on USFDA's Method for Determination of Aristolochic Acid in Traditional Chinese Medicines and Dietary Supplements.

The most appropriate method shall be used to confirm claims for the product under evaluation. The source of these methods may include AOAC International, USP, EPA, FDA, AHP, European, German, Japanese monographs, INA, industry standards, etc. The use of any new method shall require that a validation be performed which includes an evaluation of specificity, linearity, reproducibility, spike recovery, and method detection limit. More rigorous validation could follow according to the guidelines of ICH, FDA, CEN, GLP, and/or AOAC, as appropriate.

Unless a manufacturer has controls in place to assess the rancidity of oil ingredients, the following testing shall be performed. The Peroxide Value of the oil shall be tested according to AOAC Method 965.33 (which is equivalent to AOCS 8-53). The p-Anisidine Value of the oil shall be tested by AOCS Cd 18-90.[7] The Totox Number shall be calculated as the sum of the p-Anisidine Value and two times the Peroxide Value.

7.5 Test methods for industrial contaminants

Testing of fish oil samples for PCBs and dioxin-like PCBs shall be performed utilizing a high resolution gas chromatography-high resolution mass spectrometry (HRGC-HRMS) method, EPA Method 1668, Revision A: Chlorinated Biphenyl Congeners in Water, Soil Sediment and Tissue by HRGC-HRMS. Testing of fish oil samples for dioxins and furans shall be performed utilizing a high resolution gas chromatography-high resolution mass spectrometry (HRGC-HRMS) method, EPA Method 1613, Revision B: Tetra- through Octa-Chlorinated Dioxins and Furans by Isotope Dilution HRGC-HRMS. The preparation steps for these methods are applicable to water, soil, fish tissue and other environmental samples. For the analysis of fish oil, for both methods, the preparation of the sample involves dissolution in hexane followed by column based sample clean-up steps prior to the described instrumental analysis.

Manufacturers shall meet this testing requirement by one of the following routes;

- through the use of compliant ingredients as demonstrated by third party testing; or
- performing testing utilizing a laboratory accredited for PCBs, Dioxin and Furans under ISO 17025 and providing the sample results, data, and quality control results, for review to support compliance

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