



GLOBAL ORGANIZATION FOR EPA AND DHA OMEGA-3S

**TO:** Binu Koshy c/o USP-NF

**FROM:** Global Organization for EPA and DHA Omega-3s (GOED)

**RE:** Request for early input on new proposed chapter on Impurities in Ingredients and Dietary Supplements

**DATE:** October 20, 2021

GOED, the Global Organization for EPA and DHA Omega-3s (<https://www.goedomega3.com/>), likes to provide comments to your request for early input from stakeholders on a newly proposed informational General Chapter <2760> *Impurities in Dietary Ingredients and Dietary Supplements*, as announced on September 24, 2021 in the USP-NF Compendial Update ([link](#)). GOED represents the worldwide EPA and DHA omega-3 industry, with a mission to increase consumption of EPA and DHA omega-3s around the world. The membership is built on a quality standard unparalleled in the market and members must comply with quality and ethics guidelines that ensure members produce quality products that consumers can trust. Our 170+ members represent the entire supply chain of EPA and DHA omega-3s, from fisheries and crude oil suppliers to refiners, concentrators and finished product brands.

Contaminants to control in omega-3 EPA/DHA ingredient oils and retail products

Note that the indicated maximum limits are the internal limits GOED sets for its members, as stipulated in the GOED Voluntary Monograph ([link](#)), and are typically as strict or stricter than the applicable international and country-based quality limits (including for the USA).

Parameter	Maximum limit	Recommended methods	Note
<i>Persistent organic pollutants:</i>			
PCBs	90 ng/g oil (based on sum of all 209 congeners)	EPA Method 1668	1. Only EPA Method 1668 covers all 209 PCB isomers. GMP laboratories apply the method according to USP, and the original EPA method is adapted and validated for fish oils and related products, using HRGC/HRMS systems and matrices not disclosed in the original US EPA method. Note: USP



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			<p>refers to revision A. Revision C is the latest one.</p> <p>2. For compliance with California's Proposition 65, omega-3 retail products should also ensure they do not contain more than 90 ng of PCBs per labeled daily serving</p>
Dioxins and furans (PCDDs and PCDFs)	1.75 pg WHO PCCD/F-TEQ/g	<p>a. EPA Method 1613 revision B: "Tetra-through octa-chlorinated dioxins and furans by isotope dilution HRGC/HRMS" (Identification and quantitation of PCDD and PCDF congeners)</p> <p>b. GLS DF-100 : „Bestimmung von Polychlorierten Dibenzodioxinen (PCDD), polychlorierten Dibenzofuranen (PCDF) und polychlorierten Biphenylen (PCB) inkl. aller 209 PCB Kongenere in Lebens- und Futtermittel sowie anderen Proben mittels Gaschromatographie mit massenspektrometrischer Detektion“.</p>	<p>a. GMP laboratories apply the method according to USP, and the original EPA method is adapted and validated for fish oils and related products using HRGC/HRMS systems and matrices not disclosed in the original US EPA method)</p> <p>b. Method used by an ISO-laboratory, corresponding to an in-house method based both upon European legislation and US EPA methods. The ISO method is accredited by the German Accreditation Body (DAkKS) according to DIN EN ISO/IEC 17025:2005</p>
Dioxin-like PCBs	3 pg WHO-TEQ/g	<p>a. EPA Method 1668</p> <p>b. GLS DF-100 : "Bestimmung von Polychlorierten</p>	<p>a. EPA Method 1668 can also be used only for dioxin-like PCBs. The USP refers to EPA 1668A.</p>



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		Dibenzodioxinen (PCDD), polychlorierten Dibenzofuranen (PCDF) und polychlorierten Biphenylen (PCB) inkl. aller 209 PCBKongenere in Lebens- und Futtermittelsowie anderen Proben mittels Gaschromatographie mit massenspektrometrischer Detektion."	b. Method used by an ISO-laboratory, corresponding to an in-house method based both upon European legislation and US EPA methods. The ISO method is accredited by the German Accreditation Body (DAKKS) according to DIN EN ISO/IEC 17025:2005
Total dioxins, furans and dioxin-like PCBs	3 pg WHO-TEQ/g	a. EPA Method 1613B for the dioxins, and EPA Method 1668 for the PCBs as required by USP.  b. GLS DF-100 : "Bestimmung von Polychlorierten Dibenzodioxinen (PCDD), polychlorierten Dibenzofuranen (PCDF) und polychlorierten Biphenylen (PCB) inkl. aller 209 PCB Kongenere in Lebens- und Futtermittel sowie anderen Proben mittels Gaschromatographie mit massenspektrometrischer Detektion."	b. Method used by an ISO-laboratory, corresponding to an in-house method based both upon European legislation and US EPA methods. The ISO method is accredited by the German Accreditation Body (DAKKS) according to DIN EN ISO/IEC 17025:2005
<i>Heavy metals:</i>			
Lead	0.05 mg/kg	a. USP Method 233  b. §64 LFGB L00.00-19/3 (by AAS)	



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		c. EN 15763:2009 (by ICP-MS)	
Cadmium	0.1 mg/kg	a. USP Method 233 b. §64 LFGB L00.00-19/3 (by AAS) c. EN 15763:2009 (by ICP-MS)	
Mercury	0.1 mg/kg	a. USP Method 233 b. §64 LFGB L00.00-19/4 (by cold vapor AAS) c. EN 15763:2009 (by ICP-MS)	
Inorganic arsenic	0.1 mg/kg	a. USP Method 233 b. §64 LFGB 25.06 (by Hg-AAS) (note: only for fish oil)	
			<p>For the reporting of heavy metal concentrations, it is recommended to add information on the detection limit:</p> <p>The Detection Limit is equal to three times the standard deviation of the mean of blank determinations.</p> <p>The determination of the detection limit (DL) and quantitation limit (QL) for heavy metals are described in EU commission regulation No- 333/2007. Results below the DL are suggested to be reported as the actual values of the measured detection limit, and results between the DL and QL are suggested to be reported as actual values.</p>



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We hope this information is useful to USP-NF.

Thank you for your consideration,

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