

Lawsuit Claims PCBs Found in Fish Oil Supplements

A lawsuit filed in California claims that 10 types of fish oil supplements tested contain polychlorinated biphenyl (PCB), a toxic industrial compound, and that manufacturers and sellers need to warn consumers under the state's Proposition 65.

Following news of the lawsuit, industry groups attempted to reassure the public, defending the safety of fish oil products in general. According to Nutrition Business Journal, U.S. consumer sales of fish and animal oil dietary supplements totaled \$739 million, a growth of 18% in 2008.

"We have complete confidence in the safety of the fish oil supplement market, which has been validated through multiple third-party reviews by industry watchdogs on thousands of products," said Adam Ismail, executive director of the Global Organization for EPA and DHA Omega 3s (GOED). "In fact, this industry is among the highest quality and most transparent of all consumer products."

There are multiple resources in the public domain where consumers can get more information on the quality of their products, including the International Fish Oil Standards program (www.ifosprogram.com). Furthermore, a recent report by Frost & Sullivan found that 93% of the refined fish oils on the market in the U.S. are produced from anchovy and sardine oils. However, the plaintiffs only tested one of these types of oils, which actually had PCB content well within the Safe Harbor provisions of Proposition 65, according to Mr. Ismail. "While the plaintiffs raise an important issue, it is unfortunate that they are implying that most fish oils are unsafe and that the industry is hiding information on such vital nutrients," he said.

Andrew Shao, PhD, senior vice president, scientific and regulatory affairs, Council for Responsible Nutrition (CRN), Washington, D.C., said it is important to put the issues in context. "PCBs are ubiquitous within the environment, which means that all fish—whether fish found in oceans and rivers or fish oil supplements—contain at least trace amounts of PCBs," he said. "In fact, conventional food forms of fish contain higher levels of PCBs than fish oil supplements in part because supplement fish oil products go through a refining process which reduces PCBs and other contaminants."

FDA has established a tolerance level for PCBs in fish, which is 2.0 parts per million (ppm, also expressed as mg/kg) or 2000 parts per billion, he added. In comparison, the Prop 65 daily limit for PCBs for a cancer warning is 90 mg/day, which is significantly lower than what FDA deems safe.

"The lawyers are using California's Prop 65 statute to bring attention to their case by attempting to frame this as a public health concern, when in reality, fish oil has enjoyed decades of safe use," Dr. Shao noted. "The bottom line is that consumers, whether they live in California or elsewhere, should continue to feel confident in the safety and efficacy of their fish oil supplements. This lawsuit does nothing to change the strong science supporting the many health benefits of fish oil, which range from cardiovascular health to cognitive development of infants and young children, and the very low thresholds of PCBs which apparently trigger a labeling requirement in California cannot be extrapolated to demonstrate any actual risks at those levels. The health benefits for fish oil far outweigh any suggested, and unsupported, risks."

According to Mr. Ismail, eight years ago the industry collaborated to develop strict standards to improve quality and ensure consumer safety. This standard, formerly the CRN Voluntary Monograph, is now known as the GOED Voluntary Monograph and has helped the industry grow rapidly and responsibly by pre-emptively addressing quality issues.

GOED members must sign affidavits agreeing to manufacture and market products to the Monograph standards as a condition of membership. Additionally, GOED continues to update the Monograph based on all relevant legislation worldwide, including Proposition 65's No Significant Risk Levels (NSRLs) related to carcinogenic activity and Maximum Allowable Dose Levels (MADLs) related to chemicals causing reproductive toxicity .

"While NSRLs have been set for PCBs in California, MADLs have not," said Mr. Ismail, "This group is actually asserting that since no regulatory body has set a limit related to reproductive toxicity, the default level should be zero." Thus far, toxicological assessments have not supported this position, but due to the unique nature of Proposition 65, the burden of proof is on the defendants in lawsuits to establish Safe Harbor limits.

"In addition, setting a MADL for PCBs appears to be of low-priority to the California Environmental Protection Agency," said Dr. Harry B. Rice, GOED's director of regulatory and scientific affairs. "The Office of Environmental Health Hazard Assessment (OEHHA) has assigned its lowest priority to the project, based in part on a lack of need."

