To the Editor:

This is an article from a series of monthly columns by Environmental Law Specialist Dianne Saxe and Jackie Campbell. Dr. Saxe is one of the top 25 environmental lawyers in the world. These articles are available for publishing at no charge, provided Dr. Saxe and Ms. Campbell are cited as the authors. Dr. Saxe can be contacted at (416) 962 5882 or admin@envirolaw.com. For more information, visit http://envirolaw.com.

PCB in my fish oil?

Are fish oil supplements safe? The Mateel Environmental Justice Foundation doesn't think we know enough to tell. In March, the Foundation filed a lawsuit against fish oil supplement manufacturers, distributors and retailers, claiming that they fail to give clear warnings, required by California law, that some of these products expose consumers to high levels of polychlorinated biphenyls (PCBs).[i]

The fundamental issue is that PCB levels in fish oil vary a lot; many are clearly safe, but others are not. And consumers can't know which is which.

Background – Proposition 65

California's *Safe Drinking Water and Toxic Enforcement Act of 1986*, still often known as Proposition 65, requires the state to publish a list of chemicals known to cause cancer or reproductive toxicity.[ii] There are nearly 900 chemicals on the list.

Companies must give warnings (e.g., via labelling) when significant concentrations of these listed chemicals are present in consumer products they buy or are released to the environment. Companies are excused from giving such warnings only if the chemicals are below "safe harbor" concentrations. These "no significant risk" levels have been published for PCBs and nearly 300 other chemicals. The Proposition 65 "safe harbor" concentration for PCBs is 90 nanograms (ng) [0.09 mcg] per day.[iii]

Mateel test results

Mateel tested 10 fish oil brands and reported too much PCB in 3 of them. That is, if taken according to the recommended labelled dose, three of the ten brands would expose consumers to more than 90 ng/day. None of the three bore Proposition 65 warnings.

(It's hard to know what this means for the brand in your cupboard. Tests of different fish oil brands by other organizations did not find significant levels of PCB's.[iv v])

Mateel's lawsuit asks the Court to compel fish oil vendors to give Proposition 65 warnings to all current and future customers, and even to past customers (by tracking them down individually). Mateel also seeks civil penalties (up to $2500 for each day's exposure of a person to PCB without proper warnings).

What about Canada?

We have nothing comparable to Proposition 65, and both the US Food and Drug Administration and Health Canada are much more tolerant of PCBs in food than California. The FDA's tolerance limit for PCB in fish is 2 parts per million (2 mcg/g or 2 mg/kg);[vi] [vii] Meanwhile, Canada is re-evaluating its tolerance limit for PCB in foods, including fish (there currently is no limit).[viii]

Compared with California's "safe harbor" level of 90 ng, Health Canada's tolerance limit for fish oils is 0.10 mcg/kg of human body weight per day, i.e., 7 mcg/day for the average 70 kg person.[ix] As for the US, it is not within the FDA's jurisdiction to monitor PCB concentration in fish oil supplements.[x] Just to keep the units straight, 7 mcg/day equals 7,000 ng, or 78 times more than California's 90 ng. On the other hand, the California "safe harbor" level only determines what warnings must be given. Health Canada requires that fish oil supplements be tested for PCBs, and will not permit the sale in Canada of fish oil supplements that exceed its tolerance limit.[xi] Fish oil supplements bearing a Natural Product Number (NPN) on the label, should have met Health Canada's regulatory requirements.

Because Health Canada tolerates levels of PCBs that are so much higher than in California, it would not be surprising for most supplements to meet Canadian rules. But this isn't always true. A recent study examined PCB concentrations in thirty fish and seal oil supplements from pharmacies, health food stores and supermarkets in Vancouver, and Internet distributors.[xii] All thirty contained PCBs; median PCB concentrations ranged from 12 ng/g (vegetable and mixed fish oils) to 5260 ng/g (shark oils). The highest PCB concentrations were found in shark, seal and menhaden oils; one shark liver oil supplement contained 10,400 ng/g of PCBs. The estimated daily PCB intake (using the maximum daily dose provided on the label) from these supplements ranged from 0.896-15,700 ng/day (well above Health Canada's tolerance limit). Different lots from the same manufacturer can have wildly different results.

What does it all mean?

Food (and supplements) are our major sources of exposure to PCBs.[xiii] PCBs are highly fat soluble and bioaccumulate, with highest concentrations found at the top of the food chain. [xiv] [xv] Most people consume less than 0.5 mcg/day of PCBs; those who eat a lot of fish, wildlife or sea mammals may get more.[xvi]

Long-term exposure to high levels of PCBs has been linked to liver and kidney cancer. Long-term, low level PCB exposure may affect reproduction and can cause developmental impairment in newborns and young children.[xvii]

These data make us very cautious about fish oil supplements. For one thing, we each weigh less than 70 kg, so 7000 ng/day of PCBs would have a greater impact on us than on Health Canada's "average" person. For another thing, because results are so variable, we can't put much faith in Health Canada's insistence that fish oil supplements have been

tested for PCBs. Maybe one batch was tested, and passed, but there is probably a different lot for sale today. PCB concentrations in fish oils depend on many factors, including fish species, season they were caught, and geographic location, none of which a consumer is told.[xviii] [xix]

For us, the higher levels of PCBs in shark, seal and menhaden oils provide an excellent reason not to take them. We are also very concerned about the environmental impact of fishing out the oceans, and especially about the environmental harm of killing sharks. Sharks are a keystone species, the top predator needed to keep all ocean ecosystems in balance, and we have wiped most of them out in a generation.

Bottom line

All things considered, we think our mothers were right: it is better to eat fish than to take supplements: it's high in protein, low in saturated fat, and contains vitamins, minerals, and other fats and substances that may promote heart and overall health.[xx] And we need to do much more to protect the oceans - everything is connected.

Health Canada will eventually let us know whether it is tightening its tolerance for PCBs in food, but meanwhile we are going to do what we can to avoid it. As to Mateel's lawsuit, it's a long shot, based on a small sample size. But if it provokes better testing of contaminants in supplements, it will have done some good.

[i] The Statement of Claim is posted at https://org2.democracyinaction.org/o/6491/images/Fish%20Oil%20Complaint.pdf

[ii] California's Office of Environmental Health Hazard Assessment, "Proposition 65 in plain language!" at http://www.oehha.org/prop65/background/p65plain.html . This page includes links to listed chemicals. See also California Environmental Protection Agency. No significant risk levels for carcinogens and maximum allowable dose levels for chemicals causing reproductive toxicity. February 2009. At http://www.oehha.ca.gov/prop65/pdf/2009FebruaryStat.pdf

[iii] Reproductive and Cancer Hazard Assessment Branch – Office of Environmental Health Hazard Assessment, California Environmental Protection Agency. Proposition 65 safe harbor levels: No significant risk levels for carcinogens and maximum allowable dose levels for chemicals causing reproductive toxicity. February 2009 http://www.oehha.org/prop65/pdf/2009FebruaryStat.pdf

[iv] Anon. what you need to know about fish oil pills. UC Berkeley Wellness Letter. 2009 Feb; 25(5):4-5

[v] Consumerlab.com. Product review: fish oil/omega-3 supplements and EPA/DHA fortified foods & beverages. Summary of results published at https://www.consumerlab.com/reviews/Omega-3_Fatty_Acids_EPA_and_DHA_from_Fish_Marine_Oils/omega3/

[vi] NSSP 2007 Section IV Chapter II .04 Action Levels, Tolerances And Guidance levels for Poisonous or Deleterious Substances in Seafood. http://www.fda.gov/Food/FoodSafety/Product-SpecificInformation/Seafood/FederalStatePrograms/NationalShellfishSanitationProgram/UCM053987 . See also 21 C.F.R. § 109.30 Tolerances for polychlorinated biphenyls (PCB's) at http://law.justia.com/us/cfr/title21/21-2.0.1.1.9.2.1.1.html

[vii] To convert ppm to mcg/g, see New York State – Glossary of Environmental Health Terms – revised May 2006. At http://www.health.state.ny.us/environmental/glossary/

[viii] Health Canada. Canadian Standards ("Maximum Limits") for Various Chemical Contaminants in Foods. Modified July 9 2007. At http://www.hc-sc.gc.ca/fn-an/securit/chem-chim/contaminants-guidelines-directives-eng.php

[ix] Health Canada. Fish oil. June 22, 2009. http://www.hc-sc.gc.ca/dhp-mps/alt_formats/hpfb-dgpsa/pdf/prodnatur/applications/licen-prod/monograph/mono_fish_oil_huile_poisson-eng.pdf

[x] US EPA. Polychlorinated biphenyls. Toxicity & exposure assessment for children's health. Last revised August 8 2009.At http://www.epa.gov/teach/chem_summ/PCB_summary100809.pdf

[xi] Personal email communication. Natural Health Products Directorate March 10 2010.

[xii] Rawn DF, Breakell K, Verigin V, Nicolidakis H, Sit D, Feeley M. Persistent organic pollutants in fish oil supplements on the Canadian market: polychlorinated biphenyls and organochlorine insecticides. J Food Sci. 2008 Jan;74(1):T14-9

[xiii] Health Canada. PCBs. 2001 November; updated 2005 October. At http://www.hc-sc.gc.ca/hl-vs/alt_formats/pacrb-dgapcr/pdf/iyh-vsv/environ/pcb-bpc-eng.pdf

[xiv] US Environmental Protection Agency. Fact Sheet - Polychlorinated Biphenyls (PCBs) Update: Impact on Fish Advisories. September 1999. At

http://www.epa.gov/waterscience/fish/files/pcbs.pdf

[xv] Rawn DF, Breakell K, Verigin V, Nicolidakis H, Sit D, Feeley M. Persistent organic pollutants in fish oil supplements on the Canadian market: polychlorinated biphenyls and organochlorine insecticides. J Food Sci. 2008 Jan;74(1):T14-9

[xvi] Health Canada. PCBs. 2001 November; updated 2005 October. At http://www.hc-sc.gc.ca/hl-vs/alt_formats/pacrb-dgapcr/pdf/iyh-vsv/environ/pcb-bpc-eng.pdf

[xvii] Moreau CM. Review of Existing Literature on Quantifying and Valuing Human Health Risks Associated with Low Level Exposure to PCBs. Revised May 27, 2007. At http://hc-sc.gc.ca/ewh-semt/alt_formats/hecs-sesc/pdf/pubs/contaminants/pcb/07-pcb-eng.pdf

[xviii] Rawn DF, Breakell K, Verigin V, Nicolidakis H, Sit D, Feeley M. Persistent organic pollutants in fish oil supplements on the Canadian market: polychlorinated biphenyls and organochlorine insecticides. J Food Sci. 2008 Jan;74(1):T14-9

[xix] Anon. what you need to know about fish oil pills. UC Berkeley Wellness Letter. 2009 Feb; 25(5):4-5

[xx] Anon. what you need to know about fish oil pills. UC Berkeley Wellness Letter. 2009 Feb; 25(5):4-5