SUPERIOR COURT OF THE STATE OF CALIFORNIA

CITY AND COUNTY OF SAN FRANCISCO

DECISION

PEOPLE OF THE STATE OF CALIFORNIA, ex rel. BILL LOCKYER, Attorney General of the State of California,

Plaintiff,

vs.

TRI-UNION SEAFOODS, LLC; DEL MONTE CORPORATION; BUMBLE BEE SEAFOODS, LLC; and DOES 1 through 100,

Defendants.

Consolidated ~~Case~~ Nos. CGC-01-402975 and CGC-04-432394

Complaint Filed: June 21, 2004

[~~PROPOSED~~] FINDINGS OF FACT AND CONCLUSIONS OF LAW RE: PREEMPTION, MADL, and NATURALLY OCCURRING

Date: April 17, 2006
Time: 9:00 a.m.
Dept.: 206
Judge: Hon. Robert L. Dondero

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The State of California filed this action to challenge the Tuna Canners' refusal to comply with California's Proposition 65 warning requirements according to Health & Safety Code section 25249.5 et seq. The State argues that the Tuna Canners are required to place a Proposition 65 compliant health warning on defendants' tuna cans because of the potential health risks of methylmercury in canned tuna. This Decision is structured in four parts: (1) Issues Presented; (2) Findings of Fact; (3) Conclusions of Law; and (4) Court Order.

I.

ISSUES PRESENTED

This case contains three central issues: (1) Federal Preemption; (2) Maximum Allowable Dosage Level ("MADL") for methylmercury in canned tuna according to Proposition 65; and (3) Naturally Occurring Exception to Proposition 65 under 22 CCR §12501. This Court finds in favor of the Tuna Canners on all of the three central issues.

PREEMPTION

This Court is asked to decide whether federal law preempts Proposition 65 consumer warning requirements for canned tuna products. This Court concludes that federal law and the policy promulgated by the Food and Drug Administration ("FDA") preempts Proposition 65 warnings for canned tuna products.

MADL

This Court is asked to decide whether the Tuna Canners have met their burden of proving that the Maximum Allowable Dose Level ("MADL") for methylmercury under Health & Safety Code section 25249.5 et seq. ("Proposition 65") is 0.3 micrograms per day. This Court is also asked to determine whether the Tuna Canners have met their burden of

proving that the exposure of methylmercury in the Tuna Canners' food products is below the MADL, therefore exempting the defendants from Proposition 65's warning requirements.

After hearing extensive expert testimony from both sides and evaluating the persuasiveness and credibility of several peer-reviewed scientific studies, this Court finds that the Tuna Canners have met their burden of proving that the appropriate MADL for methylmercury under Proposition 65 is 0.3 micrograms per day based on the 1980 Bornhausen study involving methylmercury in rats. Furthermore, this Court finds that the Tuna Canners' exposure model shows that the level of methylmercury exposure in the Tuna Canners' food products is between 0.26-0.28 micrograms of methylmercury per day, which is below the approved MADL. Therefore, the Tuna Canners' products are exempt from Proposition 65's warning requirements.

NATURALLY OCCURRING

Lastly, this Court is asked to determine whether methylmercury in tuna is "naturally occurring" within the meaning of 22 CCR §12501. This Court is persuaded on balance that virtually all of the methylmercury in tuna originates from natural sources, while a small amount may be attributable to human activity. After undergoing traditional statutory construction analysis, this Court concludes that methylmercury in tuna fits within the "naturally occurring" exception to Proposition 65, in large part because the Tuna Canners have no way to control the level of methylmercury in their canned tuna products.

II.

FINDINGS OF FACT

PREEMPTION

I. FDA'S AUTHORITY AND ACTIONS CONCERNING WARNINGS FOR METHYLMERCURY IN CANNED TUNA

1. The United States Food and Drug Administration ("FDA") is an agency within the United States Department of Health and Human Services ("HHS"). Sullivan, Volume 14 Transcript ("14 Tr.") 1689:12-13, 19-21. FDA is entrusted to protect the safety of food, including seafood, in the United States through the administration of the Food, Drug and Cosmetic Act ("FDCA") (21 U.S.C. §§ 301 *et seq.*). Trial Exhibit ("TX 727"), p. 1-2. The FDCA prohibits the transmission in interstate commerce of food, including seafood, which is adulterated or misbranded. *Id.*; 21 U.S.C. §§ 343(a)(1) and 321(n). FDA also has broad statutory authority under the FDCA to regulate food labeling. TX 727, p. 2 (21 U.S.C. §§ 343 *et seq.*)

A. FDA Established a Methylmercury Action Level to Protect Against Adulterated Seafood

2. FDA generally controls food safety risks by prohibiting the marketing of foods that may pose health risks or by limiting the amount of potentially dangerous substances in foods by developing tolerance and action levels. *See, e.g.*, 42 Fed. Reg. 52814 (Sept. 30, 1977) (rejecting a suggestion that warnings should be required on foods containing low levels of carcinogenic substances as "unnecessary and inappropriate" because "tolerances and action levels will be established at levels intended to ensure that food marketed is not hazardous to health"). FDA's enforcement of "action levels" regarding the existence of contaminants in seafood guides the determination of "adulteration" under the FDCA. In 1979, FDA determined that a methylmercury action level of 1.0 part per million

is safe for seafood. 44 Fed. Reg. 3990, 3992 (January 19, 1979). Since then, FDA has maintained a rigorous monitoring and evaluation program but has found no need to adjust the methylmercury action levels in seafood. *See id.*

B. Tuna Is a Healthy Product that the Federal Government Encourages Americans to Eat

3. The Court heard the testimony of Dr. Louis Sullivan, the former Secretary of Health and Human Services ("HHS") from 1989 to 1993, regarding FDA's food labeling policy. Sullivan, 14 Tr. 1689:12-16; TX 836, p. 2. Dr. Sullivan has practiced medicine since 1958, held numerous teaching and academic positions, and is the founding dean of the Morehouse College School of Medicine. Sullivan, 14 Tr. 1693:28-1694:13; TX 836, pp. 1-2.

4. According to Dr. Sullivan, it is generally accepted in the medical community that fish consumption benefits health and that Americans would be better off eating more fish. Sullivan, 14 Tr. 1720:19-21; 14 Tr. 1721:4-7. For example, fish, including tuna, is a low-calorie source of protein and omega-3 fatty acids. Sullivan, 14 Tr. 1720:22-1721:3; Beard, 17 Tr. 2073:19-22; 17 Tr. 2073:25-2074:1; 17 Tr. 2074:11-24. Omega-3 fatty acids are important in enhancing the growth and development of infants prior to birth, and aid in the development the brain, nerves and eyes. Beard, 17 Tr. 2072:13-19; TX 501.

5. The Court also heard testimony about the health benefits of tuna from Dr. Lillian Beard, an expert witness proffered by the Tuna Canners who is a practicing physician with over thirty years of experience. TX 500, p. 1. Dr. Beard's practice specialty is pediatrics and adolescent medicine. Beard, 17 Tr. 2059:5-8. Dr. Beard is a Board-certified pediatric specialist and Diplomate for the National Board of Medical Examiners. Beard, 17 Tr. 2060:4-21; TX 500, p. 1. She is a spokesperson for the American Academy of Pediatrics and is an advocate for children. Beard, 17 Tr. 2067:26-2068:20; 17 Tr. 2070:18-21; TX 500, p. 5. Dr. Beard has been honored for her work improving the health of infants. Beard, 17 Tr. 2061:2-11; TX 500, p. 2.

6. Dr. Sullivan explained that pregnant women who consume less fish have a higher incidence of low birth weight preterm babies and babies born with complications.

Sullivan, 14 Tr. 1723:1-1724:1; TX 705. Interestingly, preterm birth is considered a developmental harm, which is the harm Proposition 65 warnings are supposed to communicate. Sullivan, 14 Tr. 1724:12-18; TX 2, p. 196 (22 CCR § 12601). Moreover, consumption of canned tuna, which is a low-cost, low-calorie food, is vital to American health because there is such a high incidence of obesity, especially among the poor. Sullivan, 14 Tr. 1696:4-27; Beard, 17 Tr. 2074:20-24; 17 Tr. 2075:7-21.

7. It is Dr. Beard's expert testimony that if people stop eating canned tuna, they will substitute other low-cost foods that are higher in fat, calories and cholesterol, such as processed meat or cheese. Beard, 17 Tr. 2077:17-2078:13; TX 501. For many people, substituting other fish for canned tuna is not practical because of the higher cost and increased difficulty in preparing the meal. Beard, 17 Tr. 2129:12-19.

8. The United States Food and Drug Administration ("FDA") and Environmental Protection Agency ("EPA") recommend in their 2004 Advisory ("FDA/EPA Advisory") that women who may become pregnant, pregnant women, nursing mothers, and young children eat up to 12 ounces (2 average meals) a week of fish and shellfish that are lower in mercury, including canned light tuna. TX 706. The FDA and EPA advise the same group that they may eat up to 6 ounces (one average meal) of albacore tuna per week. TX 706. According to FDA and EPA, fish and shellfish can contribute to heart health and children's proper growth and development. TX 706.

C. FDA Is Uniquely Qualified to Determine How to Convey Information to Consumers About Food and Health Issues

9. Dr. Sullivan is a well-known food-labeling expert who has advised and monitored the administration of food labeling in the United States for many years. TX 837, p. 2; Sullivan, 14 Tr. 1707:16-1710:24. During his tenure as HHS Secretary, Dr. Sullivan was responsible for overseeing the fourth largest budget in the world. Sullivan, 14 Tr. 1706:16-20. As HHS Secretary, Dr. Sullivan provided leadership and oversight of several agencies, including the Public Health Service, Social Security Administration and FDA. Sullivan, 14 Tr. 1705:16-1706:2.

10. Dr. Sullivan directed the amendment of FDA's food labeling regulations to make food labels more useful and understandable to consumers. Sullivan, 14 Tr. 1707:16-1708:6; TX 837, p. 2. Dr. Sullivan testified that he led this effort because of the concern that the information that was then on food labels was not in a form that was readily understood or usable by consumers. Sullivan, 14 Tr. 1708:7-18. The revised labels translate nutritional information, such as serving sizes, into a frame of reference that people use. Sullivan, 14 Tr. 1712:1-4; TX 838 (labels showing that one 2-ounce serving of canned tuna contains one percent of the daily value of total fat and twenty-three percent of the daily value of protein).

11. According to Dr. Sullivan, the process to amend FDA's food labeling regulations took more than two years to complete and involved a multi-disciplinary approach including consultation with scientists, consumer signage experts, survey experts, and other professionals and experts. Sullivan, 14 Tr. 1710:8-24; 14 Tr. 1781:5-14.

12. Consistent with its mission and practice, FDA has studied carefully the issue of methylmercury in fish for more than twenty-five years and has developed substantial expertise in analyzing both the scientific and consumer education aspects of the issue. TX 727, p. 2; 42 Fed. Reg. 52814. Accordingly, FDA is uniquely qualified to determine how to advise consumers on the issue of methylmercury in fish. *Id.*

D. Targeted Consumer Advisory Notices are the Preferred Method of Communicating Health Information Respecting Methylmercury in Fish

1. FDA's Consistent Policy Against Warnings on Food

13. FDA's policy on warning labels on food has been to implement a nuanced approach, where ingredient and nutrition information is disclosed, and warnings are required only under exceptional circumstances,[1] such as when food has been adulterated or

[1] *See, e.g.*, the regulations governing: aspartame (TX 839 (21 C.F.R. 172.804)); high protein products used for weight loss (TX 840 (21 C.F.R. 101.17(d))); and unpastuerized juice (TX 840 (21 C.F.R. 101.17(g))).

misbranded. Sullivan, 14 Tr. 1713:23-1714:1; 14 Tr. 1714:15-1715:6; 14 Tr. 1719:13-15; TX 727, p. 2; TX 837, p. 34; TX 839; TX 840. It is FDA's position that warning overexposure could lead consumers to ignore all warnings, which could create an even greater public health problem. *Id.*

14. FDA's policy against warnings concerning mercury is likewise reflected in a formal response to a 2003 petition requesting an extension of the Omega-3 fatty acids and coronary heart disease qualified health claims. TX 727, p. 4-5. FDA considered the petitioner's argument that the presence of mercury in seafood needed to be addressed in the health claim because Omega-3 fatty acids are contained primarily in oily fish. *Id.* FDA rejected this argument after extensive scientific review and deliberation, stating that:

> FDA has been addressing the issue of reducing the exposure to the harmful effects of mercury by communicating with this target population (pregnant women, women who might become pregnant, nursing mothers, and parents of young children) through the use of consumer advisories.

TX 727, p. 5. FDA concluded that the 2004 FDA/EPA Advisory provides the required information and ruled that "it is preferable not to use a label statement about mercury." TX 727, pp. 4-6.

2. FDA's Mandate for a Targeted, Balanced Message and Development of the Advisories

15. FDA's concern with warnings is the risk of overexposing consumers. Sullivan, 14 Tr. 1714:26-1715:6; 14 Tr. 1780:4-11. FDA also expresses this concern in its letter to Attorney General Lockyer describing why Proposition 65 is preempted as it applies to canned tuna. TX 727.[2]

[2] FDA recently reiterated that state warnings on medications can frustrate FDA policy by: (1) overwarning, which causes consumers to ignore important warnings; (2) discouraging consumption of healthy products; and (3) threatening FDA's role as the expert agency responsible for evaluating and balancing benefits and risks. See Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3921, 3922, 3925 (January 24, 2006).

16. Dr. Sullivan testified that there is a negative relationship between warnings about fish and fish consumption. Sullivan, 14 Tr. 1722:6-15; 14 Tr. 1725:8-10. This opinion is supported by a study that found there was a decrease in fish consumption among pregnant women caused by negative press reports of chemicals in fish. TX 704; Sullivan, 14 Tr. 1722:5-15. This decrease in fish consumption could have adverse health consequences. *Id.* Dr. Sullivan stressed that, prior to imposing warnings, it is necessary to ensure that more harm is not caused by changing people's dietary habits inappropriately so that their diets are actually less healthy as a result. Sullivan, 14 Tr. 1734:13-21.

17. Following FDA's careful and long-term consideration of the issue, FDA concluded that a consumer advisory is the best method to educate the target population about mercury in fish for several reasons. TX 727, pp. 2-3. First, consumer advisories are communicated to the target audience directly. *Id.* Second, a consumer advisory approach is more effective than a label statement in communicating the complex messages about mercury in seafood. *Id.* Third, a label statement that reaches the general public can have unintended adverse public health consequences, such as reduced consumption. *Id.* FDA's policy approach in the FDA/EPA Advisory specifically avoids warning all consumers in favor of a more comprehensive and targeted approach. TX 727, pp. 1-2, 6.

18. FDA has issued fish advisories since the mid-1990s. TX 727, p. 3. In March 2001, FDA revised and changed the emphasis of its advisory to balance the relative benefits and possible risks of eating seafood. TX 727, p. 3; TX 507. In the March 2004 advisory, FDA presented the benefits of fish consumption first, followed by the risks of methylmercury exposure. TX 507, p. 1.

19. The FDA/EPA Advisory released in 2004 is the latest advisory in the evolution of FDA's nuanced and balanced approach to communicating the benefits and risks of fish consumption. TX 706. As FDA explained in its *Backgrounder for the 2004 FDA/EPA Consumer Advisory*, the FDA/EPA Advisory emphasizes the positive benefits of eating fish and addresses issues about mercury in fish. TX 762, p. 2; TX 727. The FDA/EPA Advisory was developed over the course of two years, and is based on several

recommendations made by the FDA Food Advisory Committee extensive scientific data and consumer testing through eight focus groups around the country. TX 762, pp. 2-3; TX 109, p. 1; TX 727, p. 3.

20. The objective of the 2004 FDA/EPA Advisory is to inform the target population of women who may become pregnant, pregnant women, nursing mothers, and parents of young children as to how to get the positive health benefits from eating fish and shellfish, while minimizing their exposure to methylmercury. TX 727, pp. 3-4; TX 706, p. 1; TX 762, p. 1. Although the FDA/EPA Advisory may reach people outside these populations, the advisory is targeted to these groups, is very specific that the consumption limitations are just for the target group, and reduces the risk of frightening people who are not at risk. TX 727, p. 1; Beard, 17 Tr. 2112:13-18; 17 Tr. 2115:3-12; Sullivan, 14 Tr. 1777:3-1780:11.

21. The current FDA/EPA Advisory, in contrast to previous advisories, also contains a section that provides a question and answer section about mercury in fish. TX 762, p. 2. The American Academy of Pediatrics concurs with the current FDA/EPA Advisory. Beard, 17 Tr. 2083:4-8.

22. FDA is opposed to warnings that reach the public at large because such warnings can "have unintended adverse public health consequences." TX 727, p. 3; *see,* Sullivan, 14 Tr. 1777:3-6.

23. Dr. Sullivan and Dr. Beard agree with FDA that it is important to communicate the balanced message of the benefits of consuming tuna along with the risks, just as the FDA/EPA Advisory now does. Sullivan, 14 Tr. 1746:13-16; Beard, 17 Tr. 2112:19-25.

24. Dr. Sullivan confirmed that, based on his experience overseeing FDA's food labeling amendment process, and his familiarity with current federal food labeling policy, FDA's approach to fish warnings is consistent with the agency's approach to food labels in general. Sullivan, 14 Tr. 1722:16-21; 14 Tr. 1734:11-25.

25. As a practicing physician that specializes in pediatrics and adolescent medicine, Dr. Beard uses the 2004 FDA/EPA Advisory in her practice when working with

patients. Beard, 17 Tr. 2059:8; 17 Tr. 2081. Dr. Beard verified that she receives hundreds of copies of the FDA/EPA Advisory from the FDA. Beard, 17 Tr. 2082:1-9. Dr. Beard places the Question and Answer Section of the Advisory in the waiting room of her office for patients to pick up and read about the benefits and risks of consuming tuna. Beard, 17 Tr. 2082:26-2083:3. When patients do see Dr. Beard, she finds the Question and Answer section of the Advisory as an excellent opportunity to have a dialogue with the patient families about fish and mercury. Beard, 17 Tr. 2082:13-2083:3. Dr. Beard's experiences evidence the FDA's targeted approach.

3. FDA's Information Campaign

26. FDA has undertaken several efforts to inform its targeted audience about fish and shellfish consumption and methylmercury in seafood through a comprehensive education campaign, which includes the publication of a consumer oriented magazine, the development of videos, and the dissemination of information through FDA's Offices of Consumer Affairs and Public Affairs ("CFSAN"). TX 727, p. 4; TX 762, p. 3.

27. FDA has developed and is implementing a comprehensive information plan that includes working with state, local, and tribal health departments to get information out to communities. TX 727, p. 4; TX 762, p. 3. FDA also sends information to physicians, other health professionals and health care associations to distribute through their offices. *Id.*; Beard, 17 Tr. 2082:1-9. CFSAN also operates a toll-free "Seafood Hotline" designed for consumers who have questions about labeling and other related matters. TX 706, pp. 2-3.

28. Dr. Beard testified that she disseminates and uses the FDA/EPA Advisory in her medical practice. Beard, 17 Tr. 2081:3-7. She testified that she receives hundreds of copies of the FDA/EPA Advisory from FDA and EPA for use in her practice in working with patients. Beard, 17 Tr. 2081:3-7. Dr. Beard uses the FDA/EPA Advisory to talk to her patients about their diet, fish consumption, and to have a dialogue about what is not clear concerning mercury in fish. Beard, 17 Tr. 2081:7-9; 17 Tr. 2082:15-2083:3.

29. Dr. Beard believes that it is important as a practicing pediatrician to decipher and distill the information on the FDA/EPA Advisory to her patients. Beard, 17 Tr. 2083:9-16. Dr. Beard opines that it is her role as a physician to explain the benefits of fish consumption and to help her patients understand the risks. Beard, 17 Tr. 2084:2-5.

30. Dr. Beard concurs with FDA's approach in distributing the FDA/EPA Advisory to physicians and healthcare providers to use with patients, and to include the question and answer section. Beard, 17 Tr. 2084:6-17. In her practice, Dr. Beard sees patients who, even after reading the FDA/EPA Advisory, still are confused about the FDA/EPA Advisory, and need to discuss it with her. Beard, 17 Tr. 2085:4-20. Therefore, the FDA/EPA Advisory provides Dr. Beard an opportunity to talk about the importance of fish consumption, and to discuss and explain the import of the advisory. Beard, 17 Tr. 2085:12-20; 17 Tr. 2111:28-2112:2.

E. FDA's Position that Product Label Statements Concerning Methylmercury Intake Are Preempted

31. In its letter to Attorney General Lockyer dated August 12, 2005 ("Preemption Letter")(Attachment A of this opinion), FDA makes clear that Proposition 65 warnings on tuna products are preempted for three reasons: (1) Proposition 65 warnings frustrate FDA's carefully considered and nuanced approach to advising the public concerning the benefits and risks of consuming canned tuna; (2) point of purchase warnings conflict with FDA's longstanding opposition to warning signs in connection with the sale of food; and (3) by singling out a healthy product that the federal government encourages Americans to eat, Proposition 65 warnings on canned tuna would be misleading under section 343 of the FDCA. TX 727, p. 6.

32. The views FDA expressed in its Preemption Letter are consistent with FDA's longstanding policy concerning food labeling and its work over the years concerning mercury and fish. Sullivan, 14 Tr. 1734:1-25.

II. THE STATE'S ATTEMPT TO RECONCILE FEDERAL LAW AND PROPOSITION 65

A. Proposition 65's Core and Mandatory Language

33. 22 CCR Section 12601(a) requires that, for a warning to be clear and reasonable, "the message must clearly communicate that the chemical in question is known to the state to cause birth defects or other reproductive harm." TX 2, p. 196. This is the language the defendant Tuna Canners assert is the core and mandatory language of any Proposition 65 warning sign. Plaintiffs argue that the core and mandatory language is just one way to adhere to Proposition 65's warning requirement. However, no Court ruling in favor of Proposition 65 enforcement has mandated anything other than the core and mandatory language of Proposition 65 codified in 22 CCR §12601.

34. One of the "safe harbor" warnings eliciting this core and mandatory language reads: "WARNING: This product contains a chemical known to the State of California to cause birth defects or other reproductive harm." §12601(b)(4)(B).

35. The Final Statement of Reasons for Section 12601 ("FSOR") explains that there are two parts to any Proposition 65 compliant warning: the manner in which the warning is presented and the message that is communicated. *See* FSOR, p. 2. The FSOR states that the term "clear" "appears to have been intended to refer to the message which the warning must convey." *Id.*, p. 2.

36. The FSOR also states that "the reference to the 'State of California' [in a warning] is intended to lend authority to the warning message and is an important part of it." *Id.*, p. 25.

37. Businesses are allowed to provide additional language to the warning. TX 2, p. 196 (22 CCR § 12601(a)). Section 12601(a) states that nothing in the section "shall be construed to preclude a person from providing warnings other than those specified in subsections (b), (c), and (d) which satisfy the requirements of this subsection, or to require that warnings be provided separately to each exposed individual." TX 2, p. 196.

B. The State Abandoned Proposition 65's Core and Mandatory Language in Order to Avoid Preemption

38. The State acknowledges that the safe-harbor language would be inappropriate in light of the FDA's approach to methylmercury in tuna and its own concern with violating the federal preemption doctrine. The Attorney General responded to the FDA's Preemption Letter on August 30, 2005 ("Lockyer Letter"). TX 728. In the Lockyer Letter, the Attorney General acknowledges that the safe-harbor language "would not be appropriate in these circumstances." *Id.*, p. 1. Rather, the State claimed that its proposed warning (which the Attorney General did not describe) would be consistent with the FDA/EPA Advisory, but be "more concise." *Id.*, p. 2.

III. THE STATE'S PROPOSED WARNINGS

A. Griffin Shelf Sign

39. The State's proposed shelf sign introduced at trial was designed by Dr. Dale Griffin ("Griffin Shelf Sign"). TX 365A. Dr. Griffin is a marketing professor at the University of British Columbia's Sauder School of Business. TX 105, p. 1.

40. Prior to this case, Dr. Griffin had never prepared a warning sign or label and had never prepared a point-of-purchase sign of any kind for any product. Griffin, 5 Tr. 570:28-3; 6 Tr. 673:4-11. Moreover, Dr. Griffin has no expertise concerning shoppers' in-store behaviors. Griffin, 6 Tr. 692:20-22.

41. Prior to developing the Griffin Shelf Sign, the Attorney General's Office did not ask Dr. Griffin to look at either the statute or the regulations. Griffin, 6 Tr. 634:19-22. Dr. Griffin did not look at the regulations until after he completed his signs, and he never read the statute. Griffin, 6 Tr. 634:23-27; 6 Tr. 673:15-20.

42. When Dr. Griffin was developing his sign and label, he happened to review the "safe harbor" Proposition 65 warning language from a "Fish Alert" that Dr. Jerry Wind, one of the Tuna Canners' experts, tested for purposes of settlement (Fiering, 14 Tr. 1672:27-1673:6, 9-13). Griffin, 6 Tr. 716:1-13. When Dr. Griffin asked the Attorney General's

Office whether he should include this language, the Attorney General instructed him not to include it or even work off it as a model. Griffin, 6 Tr. 678:25-679:10; 6 Tr. 682:2-686:28. Dr. Griffin further testified that "I think my instructions were don't think about legal issues, make it clear and reasonable." Griffin, 6 Tr. 634:13-14.

43. Instead, the Attorney General instructed Dr. Griffin to work off the FDA/EPA Advisory to develop his sign. Griffin, 6 Tr. 606:27-607:3; 6 Tr. 677:28-678:7; 6 Tr. 678:25-679:3. Accordingly, Dr. Griffin captured what he thought were the key messages from the FDA/EPA Advisory to put into his sign. Griffin, 6 Tr. 615:28-617:8. The Griffin Shelf Sign is Dr. Griffin's "concise way of telescoping what was important on the FDA site" and to "translate [the FDA/EPA Advisory] into a simpler, clearer sign." Griffin, 5 Tr. 581:4-6; 6 Tr. 617:9-12. According to Dr. Griffin, "clear" means, "it's easy to process and it's easy to find if you're searching for it." Griffin, 6 Tr. 612:18-19.

44. With no experience in developing warning signs, and with no consideration of the requirements of Proposition 65, Dr. Griffin developed his warning sign (and a can label) in just eighteen days, revising and cutting down the message that a team of FDA experts took at least four years to develop. Griffin, 6 Tr. 698:27-699:27; TX 106; TX 108.

45. Dr. Griffin followed the State's directive that he create a condensed version of the FDA/EPA Advisory and changed the FDA/EPA Advisory in several ways. Dr. Griffin's Shelf Sign does not begin with, and indeed excludes, the first paragraph of the FDA/EPA Advisory, which announces, "Fish and shellfish are an important part of a healthy diet." Griffin, 6 Tr. 699:11-27; TX 706; TX 365A. By excluding the lead-off benefits paragraph, Dr. Griffin does not include several of the detailed benefits from eating fish, including its being low in saturated fat and containing Omega-3 fatty acids. Griffin, 6 Tr. 699:14-17; TX 706; TX 365A.

46. Dr. Griffin's Shelf Sign starts with Recommended Limits (rather than benefits), but leaves off the identification of fish that pregnant women should not eat: Shark, Swordfish, King Mackerel and Tilefish. Griffin, 6 Tr. 696:4-9; TX 365A. The Griffin Shelf Sign suggests that women and children in the target groups can safely eat up to twelve

ounces of these fish per week, because no qualification is placed upon the recommended limits other than for canned tuna. TX 365A.

47. Dr. Griffin changes the FDA's recommendation that the target group eat a certain amount of fish and shellfish, including canned light and albacore tuna, to a limiting statement. TX 706; TX 365A.

48. Dr. Griffin changes the FDA/EPA Advisory's language from "Yet, some fish and shellfish contain higher levels of mercury that may harm an unborn baby or young child's developing nervous system" to "Mercury can build up in the body and harm the developing nervous system of an unborn baby or young child." TX 706, p. 1; TX 365A.

49. Dr. Griffin also omits the Frequently Asked Questions contained in the FDA/EPA Advisory. Griffin, 6 Tr. 701:4-7; TX 706, p. 2; TX 365A.

50. Dr. Griffin testified that consumers often stop reading after the first or second point in a message and never get to the third point. Griffin, 6 Tr. 693:5-14. However, Dr. Griffin placed his purported warning language ("Risks") in the third paragraph of the sign, so consumers would be unlikely ever to read the warning part of his point of purchase sign. Griffin, 6 Tr. 609:9-15; 6 Tr. 693:10-27. Because this language is not easy to find, it is not "clear" according to Dr. Griffin's standards. Griffin, 6 Tr. 612:18-19.

51. Additionally, the Griffin Shelf Sign does not contain the core and mandatory language of Proposition 65. *See* 22 CCR § 12601(a). The Griffin Shelf Sign does not include the word "Warning", it does not mention the State of California, and it does not say that methylmercury is known to cause birth defects or reproductive harm. TX 365A.

52. Dr. Griffin targeted nursing mothers and young children in the sign. Griffin, 6 Tr. 688:4-15; TX 365A. However, because methylmercury is listed as a developmental toxicant, and only prenatal exposure is to be considered, the only target audience for any methylmercury warning under Proposition 65 is women of childbearing age. Rice, 2 Tr. 82:6-14; 4 Tr. 353:11-13. Also, the Griffin Shelf Sign refers to fish and shellfish, which would lead not only to a reduction in the consumption of tuna, but also of all seafood. Cohen, 7 Tr. 808:1-809:24; TX 365A.

53. The Griffin Shelf Sign is designed as a point-of-purchase sign to be placed on the shelf where canned tuna is sold. Griffin, 5 Tr. 574:23-27; TX 365A. According to the State's expert Dr. Cohen, any point-of-purchase sign or package label could affect the purchase decisions of all consumers, not just those in the target population. Cohen, 7 Tr. 801:7-19. In fact, the State's penalties theory is based on the premise that a point-of-purchase warning sign would reduce tuna consumption by all consumers by at least eleven percent. Cohen, 7 Tr. 778:2-12. Dr. Cohen used eleven percent as a conservative estimate. Cohen, 7 Tr. 779:1.

B. Griffin Can Label

54. The other warning Dr. Griffin produced, the Griffin Can Label, starts with the word "Warning," which Dr. Griffin testified is a fear-provoking word. Griffin, 6 Tr. 686:8-17; TX 365B. Also, the label contains neither a reference to the State of California nor language about birth defects or reproductive harm. TX 365B.

C. Dr. Griffin's Internet Experiment

55. Dr. Griffin testified that, in his opinion, the shelf sign and can label are "clear and reasonable" warnings about methylmercury in canned tuna. Griffin, 5 Tr. 579:23-580:12. However, Dr. Griffin did not testify what, if any message, was clearly and reasonably conveyed. There is limited support for Dr. Griffin's conclusion in any event. Dr. Griffin's opinion is based on an Internet experiment he conducted where he tested the effect of the Griffin Shelf Sign, Griffin Can Label and Wind Shelf Sign. Griffin, 6 Tr. 635:20-27. Dr. Griffin admitted that the experiment is not generalizable to the California population, was not conducted in an in-store environment, and was conducted without a control group. Griffin, 6 Tr. 638:24-26; 6 Tr. 708:21-26; 6 Tr. 711:21-712:18.

56. Dr. Yoram (Jerry) Wind testified about additional deficiencies in Dr. Griffin's experiment. His background and significant experience is detailed in this Statement of Decision at paragraph 66.

57. Dr. Wind criticized Dr. Griffin for not taking measures to ensure that the experiment's participants were not professional respondents who are paid and want to

answer questions. Wind, 17 Tr. 2170:21-2171:21. Another issue is that Dr. Griffin did not verify his results. Wind, 17 Tr. 2186:25-2187:3; 17 Tr. 2189:10-12. The questions Dr. Griffin asked in his experiment also encouraged respondents to guess if they did not know an answer. Wind, 17 Tr. 2189:19-20. According to Dr. Wind, encouraging such speculation is against industry practice and affects the reliability of the data. Wind, 17 Tr. 2189:23-2190:9.

58. Dr. Griffin's experiment does show that exposure to the Griffin Shelf Sign may lead to decreased tuna consumption. Griffin, 6 Tr. 663:7-20; TX 110, p. 15.

D. PMC Campaign

59. A second plaintiff in the case, Public Media Center ("PMC"), proposed a nebulous education campaign. TX 368. Herb Gunther of PMC testified that this unformed "concept" might include point-of-purchase signage, but had not yet developed the message to be communicated. Gunther, 7 Tr. 748:16-23; 7 Tr. 751:4-12; 7 Tr. 751:21-25. Mr. Gunther did not know if the Attorney General's Office approved of this concept. Gunther, 7 Tr. 748:24-749:5.

MADL

I. THE WITNESSES

60. **F. Jay Murray, Ph.D.**, received his Ph.D. in toxicology from the University of Cincinnati College of Medicine, Institute of Environmental Health in 1974. Murray, Volume 10 Transcript ("10 Tr.") 1143:1-3; 10 Tr. 1147:21-23; Trial Exhibit ("TX") 657, p. 1. Dr. Murray was certified as a toxicologist by the American Board of Toxicology in 1980, and has been recertified every five years thereafter. Murray, 10 Tr. 1148:14-28; TX 657, p. 2. He is a member of the following toxicology associations: American Board of Toxicology, Society of Toxicology, Society of Risk Analysis and Academy of Kettering Fellows. TX 657, p. 2. Dr. Murray has thirty-one years of experience as a toxicologist. TX 657, p. 1. Since 1992, he has been a consulting toxicologist for business, trade and

government agencies, including the United States Environmental Protection Agency and the California Environmental Protection Agency ("California EPA"). Murray, 10 Tr. 1144:21-26; 10 Tr. 1146:1-3; TX 657, p. 2.

61. Dr. Murray has significant credentials as a Proposition 65 toxicologist. He was appointed by the governor of California and served nearly three years as a member of the Proposition 65 Scientific Advisory Panel from 1987-1989. Murray, 10 Tr. 1136:28-1137:1-6; 10 Tr. 1141:1-3; TX 657, p. 2. As a member of the Scientific Advisory Panel he participated in reviewing the State's risk assessments, including MADLs, under Proposition 65 and the regulations. Murray, 10 Tr. 1137:14-17; 10 Tr. 1138:12-15. From 1987-1989, he served on the Reproductive Toxicity Subcommittee for Proposition 65. Murray, 10 Tr. 1137:12-14. Several years later, he was invited to rejoin the successor to the Scientific Advisory Panel, the Developmental and Reproductive Toxicity Committee, but declined for personal and professional reasons. Murray, 10 Tr. 1141:6-9, 11-13. Recently, Dr. Murray was asked to serve as a peer reviewer on the California EPA's internal report evaluating the quality and role of the science in the California EPA. Murray, 10 Tr. 1141:28-1142:13; TX 817.

62. **Dr. Deborah Rice** is a Toxicologist at the Environmental Health Unit, Maine Bureau of Health. She is not Board Certified. Rice, 2 Tr. 70:26-71:5; TX 7, p. 1. Before this case, Dr. Rice had no experience performing a quantitative risk assessment under Proposition 65 and had never calculated an MADL. Rice, 2 Tr. 81:20-82:1; TX 7. The State presented Dr. Rice's testimony both to criticize Dr. Murray and in support of the alternative MADL the State proposes for methylmercury. The Office of Environmental Health Hazard Assessments ("OEHHA"), a division of the California EPA, has never submitted Dr. Rice's MADL for internal review and public comment in accordance with OEHHA's procedures for developing a proposed MADL. Zeise, 16 Tr. 2027:23-2028:12; Rice, 4 Tr. 320:24-27. The State instructed Dr. Rice not to consult with OEHHA in developing her MADL. Rice, 3 Tr. 241:24-242:1. Dr. Rice never asked OEHHA (1) how the agency calculated its MADLs; (2) whether, and under what circumstances, OEHHA had ever used human studies as the

basis for its MADLs; (3) why OEHHA chose the Bornhausen study as the basis for its draft MADL; and (4) whether OEHHA had ever used a benchmark dose ("BMD") analysis as the basis for an MADL. Rice, 3 Tr. 240:27-241:16.

63. **Dr. Mari Golub** is a part-time staff scientist at the Reproductive and Cancer Hazard Assessment Branch of OEHHA. Golub, 4 Tr. 377:21-23. This branch works primarily on Proposition 65 issues, with the bulk of its work devoted to hazard identification and MADL development. Golub, 4 Tr. 378:3-11. Dr. Golub worked on the draft MADL for methylmercury that OEHHA prepared and published beginning in 1993. Golub, 4 Tr. 452:16-18; TX 77.

64. **Dr. Lauren Zeise** has been the Chief of the Reproductive and Cancer Hazard Assessment Branch of OEHHA since 1991. Zeise, 16 Tr. 1960:11-13, 18-21. She has worked for OEHHA on Proposition 65 MADLs since 1988. Zeise, 16 Tr. 1961:10-14. Dr. Zeise was on a team that recommended the final draft MADL for methylmercury in 1993. Zeise, 16 Tr. 1962:11-13.

65. **Dr. Robert Brodberg** is a senior toxicologist at the Pesticide Environmental and Toxicology Branch ("PETS") of OEHHA. Brodberg, 16 Tr. 1929:18-25; 16 Tr. 1930:20-26. Dr. Brodberg has a Ph.D. in biology with an emphasis in genetic toxicology. Brodberg, 16 Tr. 1929:15-17. As part of his job at PETS, Dr. Brodberg issues advisories that are included in fishing regulations published by the California Department of Fish & Game. Brodberg, 16 Tr. 1930:13-16. Dr. Brodberg testified about OEHHA's calculation of permissible methylmercury exposure through fish consumption.

66. **Dr. Yoram (Jerry) Wind** is a tenured professor of marketing at the Wharton School of Business with a Ph.D. in Marketing from Stanford. Wind, 17 Tr. 2137:24-2138:1; 17 Tr. 2138:4-9; TX 734, p. 1. Dr. Wind is a forty-year veteran in the field of market research who has designed and conducted hundreds of surveys of consumer behavior and preference for trials, consulting engagements, and in his lectures at Wharton. Wind, 17 Tr. 2156:4-12. Dr. Wind is a recipient of the four most prestigious awards in marketing: the Charles Coolidge Parlin Award, the Irwin Award, the Paul D. Converse Award, and the

Elsevier Science Distinguished Scholar Award. Wind, 17 Tr. 2150:27-2151:21; TX 734, p. 1. He is a member of the Attitude Research Hall of Fame, and in 2001 was selected as one of the ten *Grand Auteurs* in Marketing. Wind, 17 Tr. 2151:22-25; TX 734, p. 1. Dr. Wind has consulted to the United States and Canadian governments, and to the Israeli Defense Ministry. He is currently consulting an agency of the Treasury Department on methods of identifying terrorist financing. Wind, 18 Tr. 2213:15-2214:6; TX 734, p. 33. Dr. Wind has been a member of the editorial boards of a number of leading marketing journals. Wind, 17 Tr. 2159:17-28; TX 734, pp. 40-41. Among Dr. Wind's publications (21 books and more than 250 papers, articles and monographs), Dr. Wind authored "Statistics in Marketing" in the Encyclopedia of the Statistical Sciences. Wind, 17 Tr. 2151:27-2152:12; TX 734 passim and p. 19. Dr. Wind testified about the survey he prepared and conducted in order to determine the average frequency of consumption of canned tuna by women of childbearing age in California.

67. **Dr. Dale Griffin** is a professor at the Sauder School of Business at the University of British Columbia. Griffin, 19 Tr. 2370:14-17. The State offered Dr. Griffin's testimony on the meaning of the word "average."

68. **Dr. Sander Greenland** is a professor of epidemiology and professor of statistics at the University of California Los Angeles. Greenland, 20 Tr. 2606:9-11. He received a Bachelor's and Master's in mathematics from the University of California at Berkeley in the early 1970s. Greenland, 20 Tr. 2606:24-27. The State offered Dr. Greenland's testimony on the meaning of the word "average."

II. TUNA CANNERS' IDENTIFICATION OF THE APPROPRIATE MADL UNDER SECTION 12803

69. Under Proposition 65, "no person in the course of doing business shall knowingly and intentionally expose any individual to a chemical known to the state to cause ... reproductive toxicity without first giving clear and reasonable warning to such individual...." TX 1 p. 1. The Regulations provide that if a person can show that the

exposure will have no observable effect assuming exposure at one thousand (1,000) times the level in question for substances known to the state to cause reproductive toxicity, a warning is not required. This exposure is termed the maximum allowable dose level, or MADL. TX 2, § 12801, pp. 200.4-200.5; Murray, 10 Tr. 1147:6-7.

70. Regulations governing Proposition 65 outline the procedures for identifying the level at which a chemical has no observable effect (the "NOEL") and calculating whether the level of exposure to the chemical is at or below the NOEL. TX 2, pp. 200.5-200.6.[3] A risk assessor calculating a MADL under section 12803 is required to select the study producing the lowest NOEL from the most sensitive study deemed to be of sufficient quality. Murray, 10 Tr. 1172:25-1173:12; TX 2, p. 200.5.

A. Dr. Murray's Reliance on the Bornhausen Study as the Most Appropriate Study Under Section 12803

71. To prepare his risk assessment under section 12803, Dr. Murray reviewed more than thirty epidemiological and animal studies to determine the most appropriate study upon which to base a Proposition 65 MADL for methylmercury. Murray, 10 Tr. 1183:6-9.

72. Dr. Murray concluded that the Bornhausen study represented the best quality study that yielded the lowest NOEL – 0.005 milligrams per kilogram – out of all the studies he evaluated. Murray, 10 Tr. 1181:2-4; 10 Tr. 1183:21-24; 10 Tr. 1184:4-6.[4] The Bornhausen study was performed by a team of doctors in the Department of Radiation Biology, Department of Toxicology, Gesellscheft fur Strahlen-und Umweltfaschung, in Germany. TX 82. The senior author, Dr. Helmut Greim, is a well-known and renowned

[3] Section 12801(a) outlines the general framework for establishing the level at which methylmercury has no observable effects under Proposition 65, and mandates that the NOEL shall be divided by one thousand (1,000) to arrive at a maximum allowable dose level. TX 2, p. 200.4.

[4] The Burbacher study yielded the same NOEL. Murray, 10 Tr. 1197:7-10.

toxicologist, and the recipient of one of the highest awards in the field of toxicology. Murray, 10 Tr. 1182:10-16; TX 82, p. 305. In 1980, the Bornhausen study was published in a prominent peer-reviewed scientific journal, *Toxicology and Applied Pharmacology*, which at the time was the official journal of the Society of Toxicology. Murray, 10 Tr. 1182:17-20; TX 82, p. 305.

73. The Bornhausen study tested the potential effects of prenatal exposure to methylmercury using rats. Murray, 10 Tr. 1183:2-3. Rats have been sufficiently well studied to enable researchers to conclude that the half-life of methylmercury in a rat is fourteen days, and that the normal gestation period is twenty-two days. Murray, 10 Tr. 1183:2-3; 10 Tr. 1186:6-9. A total of sixteen pregnant rats were dosed with varying levels of methylmercury (control, 0.005, 0.01, and 0.05 mg/kg) on the sixth, seventh, eighth, and ninth days of gestation. Murray, 10 Tr. 1186:2-5; TX 82, p. 305. The methylmercury was delivered to the pregnant rats' stomachs directly through a tube inserted into the mouth ("by gavage"). Murray, 10 Tr. 1184:8-23; 10 Tr. 1185:12-15; TX 82, p. 306(2). Because the rats were dosed by gavage, the researchers could control the exposure dose. Murray, 10 Tr. 1184:26-28. Given the fourteen-day half-life of methylmercury and the twenty-two-day gestation period, dosing the pregnant rats through the ninth day guaranteed that the exposure to methylmercury in the fetal rats continued through the period of brain development until birth. Murray, 10 Tr. 1186:1-27. By cross-fostering the rat pups after birth, the Bornhausen study researchers ensured that the pups were not postnatally exposed to methylmercury. Murray, 10 Tr. 1186:28-1187:17.

74. After the pups reached full physical and mental maturity, the researchers examined their growth, survival, and sex ratio. Murray, 10 Tr. 1188:4-6, 21-28. The researchers also administered the Differential Reinforcement of High Rates ("DRH") test to assess the potential effects of prenatal methylmercury exposure on the pups' learning and motor skills. Murray, 10 Tr. 1189:2-4. Initially, each rat was trained to press a lever at a high rate and was rewarded with a food pellet. Murray, 10 Tr. 1189:7-8. The rat was then required to learn that when a light came on, it had to press a lever during a five-minute

period to get a food pellet. Murray, 10 Tr. 1189:7-14. The pattern changed from two bar presses per second, to four bar presses in two seconds, to eight bar presses in four seconds. Murray, 10 Tr. 1189:14-21; TX 82, p. 306. The test was designed specifically to evaluate neurodevelopmental learning deficits. Murray, 10 Tr. 1190:2-10.

75. A total of eighty rats were tested in four dose groups. Murray, 12 Tr. 1458:4-6; TX 82, p. 306. Among the four groups, effects of methylmercury exposure were seen in the pups at 0.05 and 0.01 mg/kg/day but not at 0.005 mg/kg/day. TX 82, p. 308; TX 659, p. 3. Based on these figures, the Bornhausen study concluded that the NOEL for methylmercury in rats is 0.005 mg/kg. Murray, 10 Tr. 1250:25-26; TX 659, p. 3.

B. OEHHA Also Relied on the Bornhausen Study to Prepare the Draft MADL in 1993

76. In 1993, Drs. Mari Golub and Lauren Zeise, together with other scientists at OEHHA, also determined that the Bornhausen study represented the best quality study that yielded the lowest NOEL under section 12803. Golub, 4 Tr. 452:9-18; TX 77, p. 1. OEHHA considered epidemiological data from the Minamata and Iraq poisoning episodes, and a New Zealand human epidemiological study, but concluded that the Bornhausen study was the most sensitive and most scientifically appropriate study on which to base the MADL for methylmercury. Golub, 5 Tr. 493:11-494:4; TX 77, pp. 54-68.

77. From 1993 and continuing throughout the trial, OEHHA published the draft MADL for methylmercury of 0.3 micrograms (ug)/day in OEHHA's Status Report available on the OEHHA Proposition 65 website.[5] Golub, 4 Tr. 465:8-11; TX 548, p. 16; TX 549, p. 16.

[5] Dr. Zeise testified that, based on discussions with the Attorney General's Office and no scientific evidence, shortly before trial, OEHHA noted in an obscure portion of its website that the draft MADL for methylmercury was "obsolete." Zeise, 16 Tr. 1979:21-2009:11.

78. Although OEHHA used the Bornhausen study as the basis for the draft MADL for methylmercury, at trial Dr. Golub questioned whether the rats were exposed to methylmercury during the critical periods of brain development. Golub, 4 Tr. 423:5-23. Because of the fourteen-day half-life of methylmercury, the dosing assured that exposure continued through the period of brain development to birth. Murray, 10 Tr. 1183:2-3, 1186:6-9.

79. Dr. Golub also questioned whether the pups in the Bornhausen study may have been exposed to methylmercury during the postnatal period through their food. Golub, 4 Tr. 421:3-6. Dr. Golub conceded that only Purina formula 5001 and AIN-93G rat chow have been found to have detectable levels of methylmercury. Golub, 5 Tr. 524:14-15. The rats in the Bornhausen study were fed the Altramin standard diet, and no study has ever suggested that this diet was contaminated with methylmercury. Murray, 10 Tr. 1193:16-23. If the rat chow used in the Bornhausen study had contained methylmercury, the NOEL would have been higher because the rats would have actually ingested more methylmercury than accounted for by the study. Murray, 10 Tr. 1194:9-19, 10 Tr. 1195:8-11. The resulting MADL would have been higher, not lower. Murray, 10 Tr. 1195:8-11.

C. Both Dr. Murray and OEHHA Selected Animal Studies Rather Than Human Studies to Calculate an MADL for Methylmercury Under Proposition 65

80. Both Dr. Murray and OEHHA agree that, unlike animal studies, human studies such as the Faroe Islands, Seychelles, and New Zealand studies fail to provide the necessary "reliable ascertainment of exposure" that Proposition 65 requires. Murray, 10 Tr. 1202:18-28; TX 2, p. 200.5; TX 77, p. 2. In his expert report, Dr. Murray stated that "there is no scientifically sound way to derive a LOEL or a NOEL from [the] human epidemiologic studies" conducted in the Faroe Islands, the Seychelles, or New Zealand. TX 659, p. 8.[6]

[6] Section 12803(a)(7) provides that where data in the most sensitive study deemed to be of sufficient quality do not allow for the determination of a NOEL, a NOEL may be derived by dividing the lowest observable effect level ("LOEL") by a factor of 10. TX 2, p. 200.5.

Further, none of these studies distinguished between effects due to pre- rather than postnatal exposure. TX 659, p. 10. Due to the difficulty of controlling all aspects of humans' lives, epidemiological studies are often confounded by exposure to chemicals other than methylmercury, like PCBs, which are known to cause neurodevelopmental harm. Murray, 10 Tr. 1203:1-9; 10 Tr. 1239:16-29; TX 659, pp. 11-12. In contrast, all aspects of the animal's life can be controlled in an animal study, including exposing the animals to the same drinking water, climate, and living conditions. Murray, 10 Tr. 1203:2-5.

81. Dr. Chernoff, an OEHHA scientist who authored a memo explaining OEHHA's reliance on the Bornhausen study for the draft MADL in 1993, mirrored Dr. Murray's concern with using human studies as a basis for calculating an MADL, noting that the human data "was limited in terms of sample size, range of exposure, time of exposure, and actual intake levels of MeHg (methylmercury). Since these variables were well defined in the rat study, the animal NOEL was considered the most appropriate for deriving a Proposition 65 MADL." TX 77, p. 3. Dr. Chernoff declined to rely on the human data from the Iraq poisoning episode[7] because it would produce a MADL of 0.004 ug/day, a number so low that it would be "scientifically difficult to defend." Murray, 11 Tr. 1357:18-27; TX 77, p. 3.

82. Dr. Golub testified that, "all final MADLs that have ever been formulated by OEHHA have been based on animal studies" and "animal studies will always be permitted if they represent the most sensitive study of sufficient quality." Golub, 4 Tr. 385:5-8; 4 Tr. 387:12-25. Consistent with this, OEHHA's Final Statement of Reasons for Proposition 65 (the "Statement of Reasons") recognizes "[t]he difficulty in identifying a NOEL from

[7] In Iraq, individuals consumed bread over a period of several months that was made with grain treated with a fungicide containing methylmercury, resulting in severe mercury poisoning. Rice, 2 Tr. 124:1-20.

reproductive toxicants when the effects of concern are based upon human experience rather than animal bioassays" because "there is often no precise data predicting what levels will produce no observable effect." TX 3A, p. 78.

83. The only chemicals for which OEHHA has used and calculated a MADL based on human studies are lead and ethylene oxide. Murray, 11 Tr. 1344; Zeise, 16 Tr. 1975:8-27. For each of these chemicals, OEHHA relied on the federal Occupational Safety & Health Administration ("OSHA") Permissible Exposure Levels (a "PEL") as surrogates for the NOEL. Murray, 12 Tr. 1456-1457. OSHA PELs pinpoint the level of exposure to a particular chemical that will not cause reproductive harm based on "experience derived from the occupational exposures..." TX 3, p. 78.

D. Currently Available Epidemiological Data on Methylmercury Is Not Suitable for Use Under Proposition 65

84. Dr. Murray properly concluded that the Faroe Islands, Seychelles and New Zealand studies were unsuitable as a basis for a quantitative risk assessment under § 12803(a)(2) of the California Code of Regulations. TX 2, p. 200.5; Murray, 10 Tr. 1202:18-28.

1. Faroe Islands

85. The Faroe Islands study is a human epidemiologic study involving 900 children in the Faroe Islands beginning in 1986 (the "Faroe Islands study"). Rice, 2 Tr. 126:5-127:5; TX 34, p. 1. A team of researchers from the Harvard School of Public Health and a team of government-employed scientists in the Faroe Islands conducted the Faroe Islands study. TX 38, p. 1. The Faroe Islands study researchers sought to analyze the effects of prenatal exposure to methylmercury. The Faroese's primary exposure to methylmercury comes from eating pilot whale. Murray, 10 Tr. 1214:19-22; TX 34, p. 418. To measure exposure to methylmercury, researchers examined maternal hair and umbilical cord blood

and tissue.[8] Rice, 2 Tr. 126:17-21. Levels of mercury detected in the hair and cord blood were then correlated with a variety of endpoints, including motor skills, sensory, hearing, vision, balance, and neuropsychological development tests. Golub, 4 Tr. 402:20-25.

86. The Faroe Islands study does not meet the requirements of § 12803(a)(2) because it fails to have both an exposed and a reference group, fails to have reliable ascertainment of exposure, has incomplete follow-up, and fails to identify or quantify all biases and confounding factors.[9] Murray, 10 Tr. 1164:14-23; TX 2, 200.5. Additionally, the exposure in the Faroe Islands population was not limited to the prenatal period. Murray, 11 Tr. 1376:81-14.

2. New Zealand

87. The New Zealand study was designed as a case control study.[10] Rice, 2 Tr. 129:3. The principal exposure to mercury in New Zealand is through the popular meal of fish and chips, which is made from shark meat. Rice, 3 Tr. 267:1-268:13; TX 91, 1691. After delivering a baby, women were surveyed about their pregnancy diet, specifically how many fish meals they ate per week during their pregnancy. TX 4A, p. 134.

88. Dr. Murray testified he did not believe that the New Zealand study was appropriate to use in developing a Proposition 65 MADL because the size of the study was very small. Murray, 10 Tr. 1242:4-9. The analysis was based on approximately 38 mother-child pairs found to have high mercury levels. Murray, 10 Tr. 1242:9-11. OEHHA also

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[8] Cord blood levels will show mercury ingestion during the last trimester of pregnancy. Rice, 3 Tr. 258:21-24. Maternal hair will show mercury ingestion only during the second trimester of pregnancy. Murray, 10 Tr. 1212:16-1213:6.

[9] A confounding factor is "a factor that is associated both with the chemical that is being studied and the endpoint that is being studied ... it's something that can explain the results of the study other than the chemical that was originally being studied." Murray, 10 Tr. 1171:8-13.

[10] A potential strength of the New Zealand study was that it grouped the data according to hair mercury levels and frequency of fish consumption. Rice, 2 Tr. 129:3-8; TX 77, p. 59. However, the size of the study was too small to be meaningful. TX 77, p. 60.

rejected the New Zealand study because it was too small, making it impossible to predict a threshold dose or the probability of a response at a given dose. TX 77, pp. 2-4; TX 77, p. 60; Zeise, 16 Tr. 1972:9-1973:3.[11]

89. Furthermore, the New Zealand data was not published in the peer-reviewed literature. Murray, 10 Tr. 1242:13-15. The New Zealand study documents in evidence are copies of reports issued by the Swedish government. TX 45 & 46; Rice, 2 Tr. 100:12-15. These reports are not peer-reviewed and no copies of subsequent analysis of the study in a peer-reviewed journal were placed in evidence. TX 45; TX 46.

3. The Seychelles Study

90. The Seychelles study is a large epidemiologic study examining the effects of methylmercury on more than 700 children. Rice, 2 Tr. 130:11-13. Unlike the Faroe Islands, the Seychelles is an island nation where the primary source of methylmercury is from ocean fish, which are consumed on average twelve times per week. Murray, 10 Tr. 1243:1-10; TX 91, p. 1. Methylmercury exposure in the Seychelles was measured in maternal hair. TX 91, p. 1. Although the maternal hair mercury levels in the Seychelles were actually higher than those recorded in the Faroe Islands, no adverse effects from methylmercury exposure to the neurological performance of children have been noted in the Seychelles study. Rice, 2 Tr. 130:16-17; Murray, 10 Tr. 1249:14-15; TX 91, p. 1. Notably, the ocean fish consumed in the Seychelles have undetectable levels of PCBs. Murray, 10 Tr. 1244:1-28; TX 33, p. 703.

E. Dr. Murray's MADL Calculation Is Based on the Bornhausen Study

91. Health and Safety Code section 25249.10(c) provides that businesses are exempt from the Proposition 65 warning requirements if an exposure "will have no observable effect assuming exposure at one thousand (1,000) times the level in question for substances known to the state to cause reproductive toxicity, based on evidence and

[11] Dr. Rice stated that the New Zealand authors did not address whether the exposure was limited exclusively to prenatal exposure. Rice, 3 Tr. 192:9-12.

standards which form the scientific basis for the listing of such chemical pursuant to subdivision (a) of Section 25249.8." TX 1, p. 4.

92. Dr. Murray calculated his MADL by multiplying the NOEL from the Bornhausen study by 58 kg, the statutorily defined weight of the average woman, and dividing this number by 1,000 to reach a Proposition 65 MADL of 0.00029 mg/day, which he rounded to 0.3 micrograms (ug)/day. Murray, 10 Tr. 1250:18-1251:2; TX 659, p. 3. Dr. Murray's method for deriving the MADL was identical to the calculation OEHHA used in 1993 to develop the draft MADL for methylmercury. Murray, 10 Tr. 1251:4-6; TX 77, pp. 1-2.

93. Dr. Rice contended that a methylmercury MADL of 0.3 ug/day is inappropriate because "actual clinical effects" have been seen at levels less than 300 ug, which is 1,000 times the Tuna Canners' MADL. Rice, 2 Tr. 157:17-23. Dr. Rice claimed that the Iraq study noted clinical effects at exposures of 200 and at 50 micrograms/day. Rice, 2 Tr. 157:17-23; TX 786, p. 2. Dr. Rice claimed that the World Health Organization ("WHO") had "observed" paresthesia in persons poisoned in the Iraqi grain episode at a daily dose of 50 and 200 micrograms.[12] She was specifically asked, and testified under penalty of perjury that the paresthesias were "observed not modeled." Rice, 25 Tr. 3152:10-15. When, however, Dr. Rice reviewed the WHO Report, she admitted that the 50-ug/day "impairment" and the "impairment" of 200 ug/day and below were modeled "extrapolations beyond the observed data." Rice, 25 Tr. 3154:10-3156:11.

94. Dr. Murray compared the MADL derived from the Bornhausen study with a study evaluating spatial vision in monkeys exposed prenatally to methylmercury (the "Burbacher study"). Murray, 10 Tr. 1196:14-16; TX 48. As with the Bornhausen study, the Burbacher study's experimental design included a control group and three dosed groups.

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[12] Dr. Rice wrote that an intake of 50 ug/day would result in a 0.3 percent risk of paresthesia, while an intake of 200 ug/day would involve a paresthesia risk of approximately 6-8 percent. TX 786, p. 2. Parethesia is not a developmental effect. Murray, 11 Tr. 1371:6-7; 1372:7-8.

Murray, 10 Tr. 1197:4-5; TX 48, p. 2. The Burbacher study identified a LOEL of 50ug/kg/day and a NOEL for methylmercury of 5ug/kg/day. Murray, 10 Tr. 1198:18. The NOEL calculated from the Burbacher study is identical to the NOEL identified in the Bornhausen study. Murray, 10 Tr. 1197:7-10. To calculate an MADL from the Burbacher study, Dr. Murray multiplied the NOEL by 58 kilograms and divided by 1,000 to reach an MADL of .3ug/day, as required by §§ 12801(b)(1), 12803(b). TX 820; Murray, 10 Tr. 1198:9-1199:7; TX 2, pp. 200.4-200.5. [13]

95. The State's expert, Dr. Rice, endorsed the Burbacher study as an appropriate study from which to derive the MADL, but performed an additional calculation designed to adjust the monkey NOEL to a human NOEL to account for pharmacokinetics. TX 786, p. 1; Murray, 10 Tr. 1199:22-28. Section 12803 does not require adjustments to NOELs derived from animal studies, nor are there any regulations that dictate how to adjust an animal NOEL to a human NOEL.[14] Murray, 10 Tr. 1200:5-16; Golub, 5 Tr. 491:11-15; Murray, 12 Tr. 1464-1465; TX 2, p. 200.5. Significantly, as discussed above, OEHHA has used animal studies for every published MADL except for lead and ethylene oxide, and has never adjusted an animal LOEL or NOEL to a human NOEL. Murray, 12 Tr. 1464:15-20; 11 Tr. 1464:25-1465:1; Golub, 5 Tr. 491:9-10. It mystifies this Court why Dr. Rice felt compelled to go against traditional scientific norms and adjust the NOEL derived from animal studies

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[13] Dr. Murray testified that he initially rejected the Burbacher study because the only information that was available about the study when he prepared his report was a 1999 abstract. Murray, 10 Tr. 1197:13-14. The abstract did not eliminate the possibility that the baby monkeys were postnatally exposed to methylmercury through their mothers' milk. Murray, 10 Tr. 1201:17-20. The full article published in 2005, however, does not state that the animals were cross-fostered. TX 48. Dr. Rice, one of the authors of the Burbacher study, testified that the baby monkeys were isolated from their mothers and raised in a primate nursery, where they were bottle fed, thus alleviating Dr. Murray's only concern regarding the Burbacher study. TX 48; Rice, 25 Tr. 3172:20-3173:5; 3073:16-23.

[14] Dr. Murray testified that while section 12803(a)(6) does not allow the mathematical conversion proposed by the State, it does permit a scientist to use certain factors like pharmacokinetics in their reasoning as to whether or not a study is appropriate for use under section 12803. Murray, 11 Tr. 1385:22-1388:5. The statement of reasons for 12803(a)(6) and OEHHA's practice support Dr. Murray's interpretation of the regulations. TX 3A, p. 76; TX 77, pp. 1-2.

when the statute does not call for any such adjustment nor do historical practices of OEHAA make such corrections.

III. THE STATE'S PROPOSED MADL

96. In this case, the State proposes that the Court accept the MADL that its expert, Dr. Deborah Rice, calculated. As noted above, OEHHA has not adopted or proposed Dr. Rice's MADL, and Dr. Rice did nothing to ensure that her MADL was calculated consistently with MADLs that OEHHA has adopted. Rice, 3 Tr. 240:27-241:16.

97. Dr. Rice based her MADL on the Faroe Islands study. Rice 2 Tr. 126:5-127:5. The principal neuropsychological development test in the Faroe Islands study that showed an effect upon the children was the Boston Naming Test, which is a test of both language processing and expressive language. Rice, 2 Tr. 149:24-150:1. The children's performance on the Boston Naming Test at age seven was correlated to the mercury level in cord blood drawn at the time of birth. TX 4A, p. 300.

A. Deficiencies of the Faroe Islands Study

98. An epidemiological study may form the basis of a risk assessment under section 12803(a)(2) if the study has features such as: selection of the exposed and reference group, reliable ascertainment of exposure, completeness of follow-up, and both identification and quantification of biases and confounding factors. Murray, 10 Tr. 1164:14-23; TX 2, p. 200.5. Further narrowing the range of appropriate Proposition 65 studies is the requirement that a study evaluate pre-, rather than postnatal, exposures.[15] Murray, 10 Tr. 1376:8-14.

[15] The parties agreed that because Proposition 65 evaluates chemicals that cause reproductive toxicity, a study that forms the basis for a risk assessment under section 12803 must evaluate prenatal exposure to methylmercury. Murray, 11 Tr. 1376:8-14; Rice, 2 Tr. 95:28-96:8; TX 659, p. 10.

99. Few human epidemiologic studies can meet the strict requirements Proposition 65 imposes.[16] As discussed above, OEHHA has never authored a published MADL based on human epidemiologic data. Murray, 10 Tr. 1164:5-10. Ignoring the heightened requirements Proposition 65 imposes, Dr. Rice mistakenly assumed that suitable epidemiological studies under section 12803 are the same as for any other type of risk assessment. Rice, 2 Tr. 96:9-14. Contrary to Dr. Rice's assumptions, the Faroe Islands study is not of sufficient "quality and suitability" under section 12803(a)(2) to derive a NOEL under Proposition 65.

1. The Faroe Islands Study Has No Exposed or Reference Groups

100. Appropriate Proposition 65 epidemiological studies will have grouped data including an exposed group and a reference or control group. Murray, 10 Tr. 1164:14-20; 10 Tr. 1165:1-8; TX 2, p. 200.5. The Faroe Islands study had no groups because all islanders were exposed to an unknown amount of methylmercury primarily through eating pilot whale. Murray, 10 Tr. 1209:21-22, 1214:19-22; Golub, 4 Tr. 441:11-15; TX 34, p. 418. According to the Faroe Islands study investigators; the average Faroese adult eats 12 grams of pilot whale muscle and 7 grams of pilot whale blubber per day. Pilot whale contains an average mercury concentration of 3.3 ug/g. TX 80, p. 141. Whale blubber contains large amounts of DDT – about 20 ug/g. TX 80, p. 145. Additionally, the blubber contains substantial amounts of PCB's, which acted as a significant confounding factor to the epidemiological study. See discussion, *infra,* at III (A)(4). Without a control group, investigators were unable to compare the effects on exposed groups to non-exposed groups. Murray, 10 Tr. 1165:6-28, 1223:15-27.

[16] OEHHA proposed that human epidemiological data form the basis for the MADL for arsenic, but a public comment critical of the study sent the proposed arsenic MADL back to the drafters. Murray, 12 Tr. 1454:13-1455:6.

2. The Faroe Islands Study Lacks a Reliable Ascertainment of Exposure

101. Proposition 65 also requires epidemiological studies to have a reasonable ascertainment of exposure. Murray, 10 Tr. 1166:1-8; TX 2, p. 200.5. For all published final MADLs, OEHHA has known the amount of exposure to the chemical. Golub, 5 Tr. 496:27-497:5. One way that investigators can reliably ascertain exposure to methylmercury (or another chemical) in an epidemiological study would be to require participants to maintain a food diary. Murray, 10 Tr. 1166:1-10. The Faroe Islands investigators, however, did not have the mothers keep a food diary and do not know how much mercury was ingested by any of the women in the study. Golub, 5 Tr. 489:15-24; Murray, 10 Tr. 1211:8-10.

102. Cord blood is not a reliable indicator of the actual dose of methylmercury ingested during pregnancy because cord blood primarily reflects mercury exposure during the third trimester only, which "might not correspond to the periods of greatest fetal sensitivity to MeHg neurotoxicity." TX 4A, p. 137. Dr. Golub narrowed the period of exposure even further, testifying that cord blood reflects exposure only during a two to three week time period late in the pregnancy. Golub, 4 Tr. 454:7-11.

103. Reliable ascertainments of exposure also cannot be pinpointed through the use of a benchmark dose analysis ("BMD"), which uses mathematical modeling to predict the likely exposure to a chemical over time based on the known chemical level in the blood (a biomarker) on a particular day. Murray, 10 Tr. 1267:1-10; 10 Tr. 1207:1-8. OEHHA's Status Reports have never included a final or draft MADL based on a BMD analysis, nor has OEHHA issued a draft or a final MADL in which a BMD was used as a surrogate for a LOEL. Golub, 4 Tr. 438:21-27-439:1. For all previous MADLs the actual dose of the chemical exposure was known. Golub, 4 Tr. 441:7-10.

3. The Faroe Islands Study Suffers from Incomplete Follow-Up

104. Proposition 65 mandates that an appropriate epidemiologic study have complete follow-up of the subjects enrolled in the study. Murray, 10 Tr. 1167:16-18; TX 2,

p. 200.5. The Faroe Islands study suffered from incomplete follow-up by: (1) failing to collect prenatal PCBs and DDT from umbilical cord blood, (2) failing to test for postnatal exposure to methylmercury, PCBs, and DDT, and (3) failing to publish neuropsychological data from the 14-year-old cohort. Murray, 10 Tr. 1167:16-1168:15; 10 Tr. 1228:22-28; 10 Tr. 1239:24-1231:1.

105. The average daily exposure to PCBs among Faroese women exceeds the United States reference dose ("RfD") for PCBs by 172 times, and the average daily exposure to methylmercury exceeds the RfD for methylmercury by four times. Murray, 10 Tr. 1216:21-1218:27; 10 Tr. 1221:1-11; TX 821. Despite these higher exposure levels, the Faroe Islands researchers never measured the prenatal PCB exposure for approximately half of the children. Murray, 10 Tr. 1228:22-25; TX 796, p. 3. The Faroe investigators also failed to document and analyze the amount of methylmercury, PCBs, and DDT that the children were exposed to postnatally by either their mother's milk or by eating whale after they were weaned. Murray, 10 Tr. 1169:18-1170:2; 10 Tr. 1223:20-23; 10 Tr. 1241:15-25. If a child is exposed prenatally to both methylmercury and PCBs, and proper exposure measurements are not made of both chemicals, it is impossible to determine what chemical caused the poor results on the Boston Naming Test. Murray, 10 Tr. 1228:2-10; TX 796, p. 3.

4. The Faroe Islands Study Does Not Adequately Identify or Quantify Biases and Confounding Factors

106. An appropriate epidemiologic study for use under Proposition 65 must identify and quantify all biases and confounding factors. Murray, 10 Tr. 1168:16-1169:3; TX 2, p. 200.5. A bias is any factor that consistently changes the results in one direction of the study. Murray, 10 Tr. 1170:4-7. A confounding factor is "a factor that is associated both with the chemical that is being studied and the endpoint that is being studied ... it's something that can explain the results of the study other than the chemical that was originally being studied." Murray, 10 Tr. 1171:8-13. The Faroe investigators failed to identify and quantify the bias and confounding factors that could overestimate the effects of methylmercury mercury in their data.

107. PCBs are a confounding factor in the Faroe Islands study. Murray, 10 Tr. 1233:19-1234:5. Like methylmercury, PCBs are an established neurotoxicant. Murray, 10 Tr. 1228:2-10; TX 796, p. 3. Prenatal exposure to PCBs was documented to be a confounding factor on the children's performance on the Boston Naming Test in the seven-year-old cohort for whom PCB exposure was measured. Murray, 10 Tr. 1223:26-28; Golub, 4 Tr. 408:1-9; TX 34, p. 425; TX 98. Although the initial report from the Faroe Islands study found a correlation between neuropsychological developmental defects and methylmercury exposure as measured by the Boston Naming Test, when the investigators controlled for concurrent PCB exposure, they found that the *correlation* between methylmercury exposure and performance deficits on the Boston Naming Test was not significant. Golub, 4 Tr. 408:1-9; Tx 34, p. 425; Tx 98. In other words, the Faroe Study investigators raised doubts about the statistical significance of the methylmercury exposure in the Boston Naming Test because of the PCB confounding factor. Golub, 4 Tr. 408:1-23; Tx. 34, p. 425; Tx 98. Dr. Rice ignored the confounding effects of PCBs, and did not quantify the effects that PCBs had on the Boston Naming test in her proposed MADL. Rice, 3 Tr. 213:9-13; TX 8.

108. The incomplete PCB data introduced bias, which was not adequately quantified into the results of the Faroe Islands study. Murray, 10 Tr. 1235:2-10; TX 796, p. 1. In the Faroe Islands study the PCB measurements were collected from cord tissue rather than cord blood, the way PCBs are usually measured. Golub, 5 Tr. 529:6-9; TX 34, p. 420. The authors theorized that about half of the PCBs were recovered from the cord tissue and made estimations of exposure based on this assumption. Golub, 5 Tr. 528:16-25; TX 363, p. 307. In a recent attempt to quantify the influence PCBs had on the study endpoints, the Faroe investigators acknowledge that if the error in measurement of the PCBs exceeds 46%, the effects seen in the Faroe Islands are not due to methylmercury at all. Murray, 10 Tr. 1226:28-1227:11; TX 796, p. 16. The investigators' failure to quantify error can cause an overestimate of the mercury effect in the Faroe Islands. Golub, 5 Tr. 515:24-27; Murray, 10 Tr. 1227:2-11; TX 796, p. 16. The authors admit that they assumed an error

rate of zero, even though the error rate for the measurement of PCBs is definitely greater than zero. Murray, 10 Tr. 1227:22-1228:1; TX 796, p. 16.

109. Another confounding factor in the Faroe Islands study was the fact that rural and urban populations had different availability of food. Whale meat was not available in Tvan, a city on the Faroe Islands where some of the mothers in the study lived while they were pregnant. Murray, 10 Tr. 1229:6-23; TX 796, p. 3. Although the authors noted that the city children had higher scores on the Boston Naming Test than their rural counterparts (where whale meat was available), they did not consider whether the difference was attributable to the lower levels of PCBs and DDT in the city mothers' diets compared to the rural dwelling mothers, a possible explanation for the difference. Murray, 10 Tr. 1229:6-1231:5; TX 796, p. 3.

5. The Faroe Islands Study Does Not Adequately Separate Prenatal from Postnatal Effects

110. The Faroe Islands investigators recognized that one of the "shortcomings" of the study was its failure to separate the effects caused by pre- versus postnatal methylmercury exposure. Murray, 10 Tr. 1209:23-25; TX 38, p. AGO 01712. This is a unique requirement under Proposition 65 because most agencies do not separately regulate prenatal and postnatal exposure. Rice, 2 Tr. 96:4-8.

111. Children were exposed to methylmercury, PCBs, and DDT prenatally during gestation and postnatally through breast milk and subsequently through their own diet. Murray, 10 Tr. 1169:18-1170:2; 10 Tr. 1222:12-24; 10 Tr. 1223:20-23; 10 Tr. 1241:15-25. The authors made no attempt to quantify the level of mercury in the breast milk and to determine what, if any, effect the postnatal methylmercury exposure had on the children. Murray, 10 Tr. 1222:14-20; TX 34, p. 420. The authors also did not measure postnatal exposure to PCBs through breast milk, even though the authors noted in an earlier paper that an "infant's total intake of PCBs during the nursing period may average up to five percent of the total lifetime exposure and increased susceptibility may augment the risk." Murray,

10 Tr. 1222:25-1223:8; TX 80, p. 145. The authors also did not measure pre- or postnatal exposure to DDT. Murray, 10 Tr. 1223:20-23.

112. In a paper published after the NRC report,[17] the Faroe investigators examined maternal serum, breast milk, and cord blood for 28 individual PCB congeners[18] and 18 types of pesticide and pesticide metabolites.[19] Murray, 10 Tr. 1221:21-1222:7; TX 791, p. 13. In a cohort established solely to study the effect of PCB exposure, the Faroe Islands investigators noted that the milk of the Faroese mothers has some of the highest concentrations of PCBs found in the world. TX 823, pp. 1-2. The nursing children in the Faroe Islands are therefore exposed to high levels of PCBs, a known neurotoxicant, during an important time of human brain development and in the postnatal period. Murray, 10 Tr. 1239:16-27. Failure to identify and quantify PCB exposure through breast milk disqualifies the Faroe Islands study for use under Proposition 65 because there is no way to separate out prenatal versus postnatal exposures to neurotoxicants. Murray, 10 Tr. 1241:12-14; TX 659, p. 10.

6. The NRC Report, Which Endorsed Reliance on the Faroe Islands Study, Was Published in 2000, Before a Series of Articles Focused on PCBs in the Faroes

113. The State relies heavily on the 2000 NRC Report, which concludes that the Boston Naming Test results of the Faroe Islands study are an appropriate basis for a reference dose ("RfD"). TX 4A, p. 317. The NRC failed to cite a critical paper in which the Faroe Islands authors state that a new cohort was being formed in the Faroe Islands to study the role of PCBs. Murray, 11 Tr. 1269:20-1270:11; TX 4A; TX 80.[20] Following the

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[17] Toxicological Effects of Methylmercuy, National Research Council (2000).

[18] Cogener is defined as (1) a member of the same taxonomic genus as another plant or animal; (2) a chemical substance related to another. Merriam-Webster's Medical Dictionary (2002).

[19] Metabolite is defined as a substance essential to the metabolism of a particular organism or to a particular metabolic process. Merriam-Webster's Medical Dictionary (2002).

[20] In 1998 the health authority in the Faroe Islands issued the following advisory – "The best way to protect fetuses against the harmful effects of PCBs is if girls do not eat blubber until after they have given birth to their children" but the NRC failed to mention this in their report. Murray, 10 Tr. 1237:23-1238:3; TX 822, p. 899.

publication of the NRC report, four papers have been published discussing the high levels of PCBs in the Faroe Islands. Murray, 11 Tr. 1270:12-1272:10; TX 796; TX 822; TX 791; TX 823. [21]

B. The Boston Naming Test Has No Statistically Significant Relationship to Methylmercury Exposure

114. Dr. Rice based her MADL on a single endpoint, the Boston Naming Test, which tests language-processing skills. Rice, 2 Tr. 149:20-150:1. The initial report from the Faroe Islands study correlated neuropsychological developmental defects and methylmercury exposure reflected in the Boston Naming Test results. TX 34, p. 1. When investigators controlled for concurrent PCB exposure, there was no statistically significant correlation between methylmercury exposure and performance deficits on the Boston Naming Test. Golub, 4 Tr. 408:1-9; TX 791, p. 12. The authors of the Faroe Islands study recognized the impact of PCBs rather than methylmercury on the results of the Boston Naming Test, noting that "especially for the Boston Naming Test, the PCB concentration appeared to be an important predictor" of the children's performance. TX 34, p. 425. Consequently, the EPA peer review of the methylmercury Reference Dose advised against relying on the Boston Naming Test without an adjustment for PCB exposure. TX 362, p. 5. Dr. Rice herself listed PCB exposure as causing deficits on the Boston Naming Test. TX 791, p. 18.

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[21] While the NRC (National Research Council) is a part of the National Academy of Sciences and a respected professional group, this Court has on at least one prior instance dealt with a series of reports by the NRC that created controversy. In 1992, the NRC published *DNA Technology in Forensic Science.* The report addressed DNA evidence in the courtroom, and suggested serious controls on its use. A number of groups, led by the FBI Laboratory, challenged the 1992 NRC Report. The tumult triggered a new, more embracing assessment of forensic DNA. That new report was *The Evaluation of Forensic DNA Evidence,* published in 1996 by the NRC. This 1996 rejected certain findings in the 1992 Report.

C. Benchmark Dose Has Never Been Used by OEHHA and Is Not a Reliable Method for Determining the MADL

115. Dr. Rice used a benchmark dose ("BMD") analysis to derive her MADL. Using data generated from the Boston Naming Test in the Faroe Islands study, Dr. Rice chose a number that she describes as the benchmark dose level ("BMDL") corresponding to a 5% likelihood of an effect due to methylmercury on the Boston Naming Test as the starting point for her MADL calculation. Rice, 3 Tr. 184:21-185:21; TX 360X. There are sixteen different models that can be used to produce a BMD analysis, and each would yield a different result. Murray, 10 Tr. 1207:9-14.

116. A BMD is not the same as a NOEL or LOEL. Murray, 10 Tr. 1205:21-24; Rice, 3 Tr. 245:25-246:3; TX 95, p. 110. Section 12803(a)(1) of the regulation requires that the risk assessor arrive at a NOEL in order to calculate a Proposition 65 MADL. TX 2, p. 200.5. In a 2003 article, Dr. Rice recognized that values derived from a BMD analysis do not represent a threshold, nor are they comparable to a NOAEL or LOEAL as typically derived from animal studies. TX 95, p. 110.[22] The NRC cautioned that "cord blood is not a reliable indicator of the actual dose of methylmercury ingested." TX 4A, p. 137. Nevertheless, to calculate her MADL, Dr. Rice used a BMD as a substitute for a LOEL. Rice, 3 Tr. 244:5-12.

117. OEHHA has never used a BMD analysis to calculate a MADL. Golub, 4 Tr. 438:21-26. Dr. Golub testified that OEHHA has never used a BMD analysis for a final MADL and none of the final or draft MADLs that have been published in the status report are based on BMD analysis. Golub, 4 Tr. 438:21-26. OEHHA has never issued a draft or a final MADL in which a BMD analysis was used as a surrogate for a LOEL. Golub, 4 Tr. 438:27-439:1. For all previous MADLs, the actual dose of the chemical exposure was known. Golub, 5 Tr. 496:27-497:5.

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[22] Dr. Rice testified that a NOAEL and a LOAEL are virtually indistinguishable from a NOEL and a LOEL. Rice, 3 Tr. 243:27-244:4.

118. Using her BMD analysis, Dr. Rice calculated virtually the same MADL from the Faroe Islands study and from the Seychelles study, which showed no adverse effects of methylmercury. Murray, 10 Tr. 1243:1-5; Rice, 3 Tr. 288:2-25; TX 91, p. 1; 360T. According to Dr. Golub, because no adverse effect was seen in the Seychelles, this study cannot be used to derive a LOEL or a MADL. Golub, 4 Tr. 451:16-452:1. Dr. Rice testified that she based her methodology on the NRC report; however, the NRC committee did not say that the BMDL analysis was analogous to a LOEL, nor did it endorse using it to find a NOEL. Rice, 2 Tr. 168:2-9; TX 4A: 272-273.

119. Dr. Rice testified that to create her MADL, she took the BMD and called it a LOEL. Rice, 3 Tr. 244:5-16. The BMDL in the NRC Report is 58. TX 4A, p. 327. If that is a LOEL, under the Regulations, one would divide it by 10, multiply by 58 and divide by 1,000. TX 2, p. 200.5. This would give a MADL of 0.3. Instead, Rice derived a much lower MADL by transforming the BMDL to a much lower number, 0.8, based on an article entitled "A Revised Probabilistic Estimate of the Maternal Methyl Mercury Intake Dose Corresponding to a Measured Cord Blood Mercury Concentration," authored by Dr. Alan H. Stern. TX 42. Among other things, Dr. Stern postulated that the maternal to fetal blood ratio for methylmercury is 1.0:1.7, meaning that the fetus has a 70% higher concentration of methylmercury circulating in its blood than the mother. Rice, 3 Tr. 222:22-24; TX 42. Dr. Stern's 1.0:1.7 ratio has not been factored into the risk assessment performed by the EPA/FDA Advisory authors or by OEHHA's fish advisory group. Rice, 4 Tr. 345:11-13; Murray, 11 Tr. 1277:24-27; Brodberg, 16 Tr. 1939:24-1940:2; TX 514, p. 7. According to Dr. Murray, there is no scientific consensus that the ratio is 1.0:1.7, or that it is anything other than 1:1; therefore, it is not appropriate to incorporate this calculation into a Proposition 65 risk assessment. Murray, 11 Tr. 1277:12-27; TX 360E; TX 825.

D. Problems with Dr. Rice's Credibility

120. Dr. Rice neglected to quantify the effect of PCBs on the Boston Naming Test for her MADL calculation even though in 2003 she published a paper entitled "Effects of PCB Exposure on Neuropsychological Function in Children," which concluded that PCBs

caused the performance deficiencies measured by the Boston Naming Test. TX 791, p. 18. Dr. Rice's paper reports that a number of endpoints in the Faroe Islands study, including the Boston Naming Test, were negatively associated with methylmercury until the authors controlled for the effects of PCBs. TX 791, p. 12. After the researchers controlled for PCBs, there was no statistically significant correlation between methylmercury and the Boston Naming test or any neuropsychological endpoint other than the continuous performance test. *Id.* A more detailed analysis of the data "confirmed a relationship between umbilical cord PCB concentrations and poorer performance on the Boston Naming Test." TX 791, p. 13. When asked about this article, Dr. Rice initially denied that she had ever written a paper stating that PCB exposure caused deficits on the Boston Naming Test. Rice, 3 Tr. 275:27-276:10. Then, when she was shown her article stating this precise conclusion (TX 791, p. 18), she first tried to distance herself from its authorship, but then admitted to reviewing and approving it, and that the article was published under her name. Rice, 3 Tr. 279:5-13.

121. Dr. Rice provided misleading testimony that a single exposure to methylmercury of the kind at issue in this case can cause adverse effects in humans. Rice, 2 Tr. 115:14-117:1; TX 360E; TX 360F; TX360G. Dr. Rice produced a series of abstracts where animals were exposed to a single dose of methylmercury at levels that likely exceeded the levels of the Minamata poisoning.[23] TX 423; Rice, 25 Tr. 3141:9-3146:28. This level of exposure exceeded the Tuna Canners' proposed MADL by more than a million-fold.[24] Rice, 25 Tr. 3142:22-23; TX 423. Contrary to Dr. Rice's testimony, these studies do not conclude

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[23] The Tuna Canners' counsel confirmed with Dr. Rice at trial that Minamata was a "massive exposure to methylmercury" and then asked whether there is any reason to believe that anyone in Minamata was exposed to 232,000 micrograms of methylmercury. Dr. Rice responded "I would doubt it." Rice, 25 Tr. 3141:1-8. In the Iraq poisoning, people died when exposed to more than 200,000 micrograms of methylmercury. TX 865, p. 54.

[24] Dr. Rice was unable to compare the mercury levels involved in the poisoning episode in Minamata Bay to the levels of mercury consumed in fish in the New Zealand, Seychelles, or the Faroe Islands studies. Rice, 3 Tr. 269:10-11. Dr. Rice was not even sure if the levels of exposure differed by a factor of ten. Rice, 3 Tr. 269:11-12. Data from Iraq demonstrated that the exposure levels in a poisoning episode can exceed a body burden of 200 milligrams (mg) or 200,000 micrograms (ug). TX 865, p. 54. The proposed MADLs in this case are fractions of a microgram. TX 659; TX 8.

that a single serving of canned tuna could contain enough methylmercury to harm the fetal brain. Rice, 2 Tr. 115:14-117:1; Rice, 24 Tr. 3093:3-14; 25 Tr. 3140:26-3146:28.

122. To buttress her misleading testimony that a single exposure to methylmercury at the levels at issue in this case can have harmful effects, Dr. Rice misstated the WHO's analysis of the Iraq poisoning, and testified that the WHO "observed" paresthesia from a single day's exposure to methylmercury at 50 and 200 ug/day. Only when confronted with the WHO report did Dr. Rice acknowledge that the 50 and 200 ug/day levels were modeled, not observed, and were for cumulative exposures over a long period of time, and not single exposures. Rice, 25 Tr. 3154:10-3156:11; 25 Tr. 3149:23-3152:15.

123. The Court finds that Dr. Rice's testimony was unreliable. It was also biased. Under Dr. Rice's MADL, products with methylmercury levels below the level of detection would be required to carry a Proposition 65 warning. Murray, 11 Tr. 1296:23-1297:17. As a result, all servings of fish and shellfish larger than literally a grain of rice would require a warning under Proposition 65. Murray, 11 Tr. 1296:23-25; 11 Tr. 1298:18-1299:5; TX 828. Dr. Rice disagrees with the fish consumption advisories issued by the FDA/EPA, and the advisories put forth by state agencies (including her home state of Maine) regarding safe fish consumption for pregnant women and women of childbearing age. Rice, 4 Tr. 361:15-368:27; TX 706; TX 347; TX 348; TX 349; TX 350; TX 351; TX 764. Specifically, Dr. Rice does not believe that women and young children should eat up to 12 ounces of canned light tuna per week and 6 ounces of canned albacore per week. Rice, 3 Tr. 237:15-238:3.[25]

E. Dr. Golub's Cursory Review and Endorsement of the Rice MADL

124. The State also presented testimony from OEHHA scientist Dr. Mari Golub to endorse the appropriateness of Dr. Rice's MADL under Proposition 65. Although Dr. Golub

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[25] Dr. Rice did not include a section in her report on the application of the MADL in terms of exposure. TX 8. Dr. Rice was not sure how many grams or ounces of canned tuna her MADL would allow a person to eat without issuing the warning. Rice, 3 Tr. 300:3-7. Dr. Rice did not compare her MADL to other commercial seafood. Rice, 3 Tr. 301:8-11.

reviewed Dr. Rice's report and endorsed her MADL, she did not conduct an independent analysis of the reliability of the studies that Dr. Rice relied on to evaluate, for example, whether in the Faroes Islands study, confounding factors had been adequately identified and quantified.[26] Golub, 4 Tr. 450:10-451:7; TX 74. Dr. Golub's unfamiliarity with the Faroe Islands study is reflected in her mistaken belief that PCBs were a main focus of the Faroe Islands study and the analysis performed by the NRC. Golub, 4 Tr. 404:22-26.

IV. CALCULATING LEVEL OF EXPOSURE TO METHYLMERCURY IN TUNA CANNERS' PRODUCTS

125. California Code of Regulations section 12821 outlines the exposure guidelines for determining whether the level of exposure to methylmercury in canned tuna exceeds the MADL for methylmercury.

A. Dr. Murray's Formula for Calculating Exposure to Methylmercury

126. Dr. Murray testified that the level of exposure to methylmercury in canned tuna is below the MADL for methylmercury. Murray, 11 Tr. 1289:6-1293:21; TX 659, p. 18; TX 827 A-C. He used the following formula to calculate the average daily intake of methylmercury from canned tuna: S x F x C, where "S" is the serving size of canned tuna, "F" is the frequency of consumption of canned tuna among women of childbearing age in California, and "C" is the average concentration of methylmercury in canned tuna. Murray, 10 Tr. 1254:15-19; TX 659, pp. 15-16. Dr. Murray testified that this formula was consistent with section 12821 exposure guidelines. Murray, 10 Tr. 1253:15-18; TX 2, p. 200.6.

127. The parties stipulated that the average serving size of canned tuna ("S") is 2.3 ounces (64.4 grams). Murray, 10 Tr. 1254:20-1255:25; TX 824.

1. Average Concentration of Methylmercury in Canned Tuna

128. To determine the average concentration of methylmercury in a can of tuna

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[26] Neither Dr. Golub nor Dr. Rice noticed that Dr. Rice had made a serious mathematical error of an order of magnitude (a factor of ten) on the first four drafts of her report. Rice, 2 Tr. 101:10-19; TX 74.

("C"), and the frequency with which women of childbearing age in California consume canned tuna ("F"), Dr. Murray relied on survey data collected by Dr. Wind (the "Frequency of Consumption Survey" or the "Frequency Survey"). Murray, 10 Tr. 1256:9-11. The Frequency Survey targeted women in California between the ages of fifteen and forty-four who were asked to identify the last two times they ate canned tuna.[27] Wind, 17 Tr. 2165:18-2167:22; 17 Tr. 2191:6-2192:17. The time difference between the two eating occasions was calculated arithmetically by subtracting the number of days since the most recent canned tuna consumption from the number of days since the prior canned tuna consumption. Wind, 17 Tr. 2201:18-2203:20; TX 732A. To validate the study, respondents were also asked if this was a typical amount of time between canned tuna consumptions. Wind, 17 Tr. 2197:1-26. Seventy percent (70%) of respondents verified that the reported frequency was typical for their consumption of canned tuna. Wind, 17 Tr. 2197:22-26; TX 732A. Respondents were also asked to identify the percentage of canned light tuna versus canned albacore tuna that they consumed. Wind, 17 Tr. 2198:28-2200:5.

129. Dr. Wind personally designed every aspect of the Frequency Survey, including the targeted population, the research design, the questions, and the data collection method. Wind, 18 Tr. 2269:20-2270:24; TX 732A. Drawing on his forty years of experience in market research, Dr. Wind framed the Frequency Survey questionnaire as a perception study in a clear, open-ended, leading, and unbiased manner that was designed to trigger the respondent's memory of her canned tuna eating habits. Wind, 17 Tr. 2156:4-12; 17 Tr. 2192:15-2194:25. The Frequency Survey was "double blind," meaning that neither

[27] Dr. Wind obtained the database of telephone numbers from Survey Sampling, Inc. and Data Development Worldwide, which conducted the Frequency Survey. TX 732A; Wind, 17 Tr. 2168:9-13; 17 Tr. 2176:13-16. Telephone surveys are generally preferable to other survey techniques because they ensure that all persons in the population have an equal chance of being included. Wind, 17 Tr. 2163:1-2165:16. To obtain a representative sample of California women of childbearing age from the database of telephone numbers, Dr. Wind used the random digit dialing technique, which generates random telephone numbers from every county in the state. Wind, 17 Tr. 2168:14-2169:13; TX 732A.

the interviewer nor the respondent knew the name of the sponsor of the survey. Wind, 17 Tr. 2176:24-2177:6.

130. The State's expert witness, Dr. Griffin, offered statistical theoretical critiques of the methods and results of the Frequency Survey, but did not proffer any independent survey data to undermine the Frequency Survey results. Griffin, 19 Tr. 2383:8-2395:25.

131. The Frequency Survey data represents the responses of 401 non-pregnant women of childbearing age and 115 pregnant women in California. Wind, 17 Tr. 2167:20-22. The data establishes that the average non-pregnant woman of childbearing age in California eats canned tuna once every 61.5 days, and the average pregnant woman eats canned tuna once every 60 days. Wind, 18 Tr. 2223:1-3; TX 732A. Among non-pregnant women of childbearing age in California, 59.7% eat canned albacore tuna and 40.3% eat canned light tuna. Wind, 18 Tr. 2245:9-11; TX 732A. For pregnant women in California, 51.6% eat canned albacore tuna and 48.4% eat canned light tuna. Wind, 18 Tr. 2245:11-12; TX 732A. Taken together, the Frequency Survey data reflects that among women of childbearing age in California, 51.6-59.7% eat canned albacore tuna and 40.3-48.4% eat canned light tuna. Murray, 10 Tr. 1257:20-25; TX 659, p. 17.

132. The FDA has determined that the average concentration of methylmercury in canned light tuna is 0.12 ppm, and the average concentration for canned albacore is 0.35 ppm. Murray, 10 Tr. 1256:15-1257:3; TX 53.[28]

133. Assuming that 51.6 to 59.7% of women of childbearing age eat canned albacore, that 40.3 to 48.4% of women of childbearing age eat canned light tuna, and that the

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[28] The FDA's "Mercury Levels in Commercial Fish and Shellfish" provides the mean, median, and minimum and maximum levels of methylmercury in canned light tuna and canned albacore. TX 53, pp. 3-5. Dr. Murray relied on the average, or mean, methylmercury level to calculate the average exposure to methylmercury. Murray, 12 Tr. 1471:6-20. The State challenged Dr. Murray's reliance on the mean, rather than the maximum, levels of mercury. Murray, 11 Tr. 1312:6-1314:5. Dr. Murray explained that the regulations required that he use the average. Murray, 12 Tr. 1471:6-7. Dr. Murray did not use the median or the lowest levels of detection, which would have yielded lower levels of exposure because he did not believe that the regulations allowed him to consider anything other than the average, or mean, concentration. Murray, 12 Tr. 1471:1-20.

FDA's average methylmercury concentration for canned light tuna is 0.12 ppm and 0.35 ppm for canned albacore, Dr. Murray derived a weighted average of methylmercury concentration in canned tuna, both light and albacore, that is between 0.239 and 0.257 ppm. Murray, 10 Tr. 1257:25-28; TX 659, p. 17.

2. Averaging Frequency of Consumption Over Two Months Is Appropriate

134. Section 12821(b) requires that "the reasonably anticipated rate of exposure shall be based on the pattern and duration of exposure that is relevant to reproductive effects which provided the basis for the determination that the chemical is known to the state to cause reproductive toxicity." Golub, 4 Tr. 394:1-12; TX 2, p. 200.6. A "short duration" of exposure is the appropriate frame of reference through which to evaluate the potential harm caused by a reproductive toxicant. Murray, 11 Tr. 1279:16-1280:3; TX 2, p. 200.6.

135. The parties disputed whether exposure to methylmercury could be averaged over a period of time, rather than on a single day. Proposition 65 does not prohibit averaging exposure to a reproductive toxicant. Zeise, 16 Tr. 2036:16-24; TX 2, p. 200.6. According to Dr. Zeise, OEHHA has never taken a formal position on whether methylmercury exposure ought to be analyzed over a long term or during a single day only. Zeise, 16 Tr. 2036:16-24; 2043:7-9. OEHHA does not have a general rule for averaging any reproductive toxicant. Zeise, 16 Tr. 2036:16-24; 16 Tr. 2043:3-9.

a. Evidence Supporting Averaging Exposure to Methylmercury Over a Time Period Greater Than One Day

136. OEHHA's Statement of Reasons for section 12821(c)(2) dictates that exposure to reproductive toxins should be assessed on a "short-term" basis. Golub, 4 Tr. 397:3-23; TX 3A, p. 85. The Statement of Reasons does not define short-term, and according to Dr. Golub, there is no scientific consensus on the definition of short-term exposure in risk assessment. Golub, 4 Tr. 455:3-456:12.

137. Dr. Murray testified that in his opinion, two months is the proper "short duration" over which to average exposure to methylmercury under section 12821(b). Murray, 11 Tr. 1280:9-15. He justified this opinion based on two factors: (1) the period over which the developmental effects of a chemical occur, and (2) that the half-life of methylmercury in humans is approximately two months. Murray, 10 Tr. 1258:23-1259:5.

138. Dr. Murray recognized that it is not always appropriate to average developmental toxins. Murray, 10 Tr. 1258:21-22; 10 Tr. 1259:15-17. For example, some chemicals like thalidomide have a short half-life of a few hours and cause harm only during a few isolated, specific days of development. Murray, 10 Tr. 1259:15-23. As a result, averaging exposure to thalidomide over a period of two months would be inappropriate. Murray, 10 Tr. 1259:15-23; 11 Tr. 1283:8-25. Dr. Murray testified that where, as here, methylmercury has a two-month half-life, and where developmental harm has never been isolated to a specific day or period during development, averaging exposure to methylmercury over a two-month period is appropriate. Murray, 10 Tr. 1259:24-27; 10 Tr. 1260:15-18; 11 Tr. 1274:27-1275:10; 11 Tr. 1283:26-28.

139. Consistent with Dr. Murray, state and federal agencies that advise consumers of the risks associated with exposure to methylmercury through fish consumption average exposure to methylmercury over time. Murray, 11 Tr. 1284:12-17; 11 Tr. 1287:13-19. For example, the 2004 FDA/EPA Consumer Advisory (the "FDA Advisory") states that a pregnant woman can safely eat up to twelve ounces of low mercury fish, including canned light tuna, per week. TX 706. By not prohibiting women from eating all twelve ounces in one meal, or advising them to eat seven small fish meals per week, the FDA Advisory is implicitly averaging exposure over a one-week period at a minimum. Murray, 11 Tr. 1285:5-1287:12; TX 706. Likewise, the FDA Advisory's advice that women who consume more than the recommended amount of fish in one week should reduce their intake for the following week suggests that the FDA is averaging exposure over a period of at least three weeks. Murray, 11 Tr. 1288:4-20; 11 Tr. 1397:19-28; TX 706, p. 2. Further evidence of the FDA's averaging period is the FDA Advisory's recommendation that women can safely eat

six ounces of albacore per week. Murray, 11 Tr. 1306:10-21; TX 706. If the averaging period was limited to one week, the FDA would not advise women to consume six ounces of albacore in one week because the amount of methylmercury consumed during that period would exceed the EPA Reference Dose. Murray, 11 Tr. 1306:10-21.

140. Dr. Robert Brodberg testified that OEHHA averages exposure to methylmercury over a one-month period because it is not biologically appropriate to consider a daily intake of methylmercury. Brodberg, 16 Tr. 1938:26-1939:16; TX 514, p. 5. In reaching this decision, OEHHA reasoned "methylmercury is metabolized quite slowly in the body and has a half-life of more than two months. This means that short-term fluctuations (on a daily or weekly basis) in dietary intake affect blood mercury slowly." Brodberg, 16 Tr. 1938:26-1939:4; TX 514, p. 5.

b. Calculating Exposure to Methylmercury Over a Single Day Is Inappropriate

141. The State presented testimony that for chemicals causing developmental toxicity only the daily exposure should be taken into account. Rice, 2 Tr. 105:20-26. Dr. Rice presented "dose effect curve" graphs reflecting the mercury concentration levels in maternal and fetal blood that she predicted would result from eating canned tuna once every sixty days if the exposure were not averaged. Rice, 2 Tr. 115:14-117:10; TX 360E; TX 360F; TX 360G. According to Dr. Rice, when exposure to methylmercury is not averaged over a period of sixty days, the mercury concentration could range between approximately 0.1 ug to approximately 0.5 ug of methylmercury per day. TX 360E, TX 360G. She contended that the difference between averaging exposures versus considering exposure at a single meal "may be very significant in terms of what that means for the fetal brain." Rice, 2 Tr. 116:27-117:1. According to Dr. Rice, even at these extremely low levels exposure to methylmercury can "[go] from no effect to a profound effect very, very quickly as the dose increases." Rice, 2 Tr. 115:14-116:26; TX 360 E; TX 360 F; TX 360 G. (emphasis added)

142. Contrary to her testimony, during her time at the EPA Dr. Rice wrote that there are no studies addressing whether the effects on the fetal brain differ when methylmercury is taken in episodically or on a more continuous basis. Rice, 4 Tr. 342:24-343:13; TX 362, p. 15. Faced with this evidence, Dr. Rice conceded that if sufficient information is available regarding the mechanisms of a chemical and its effects, and a single exposure would not be sufficient to produce adverse effects, averaging is appropriate. Rice, 3 Tr. 181:24-182:6.

143. Relying on the same figures Dr. Rice used in her "dose effect curve," Dr. Murray demonstrated that the levels of methylmercury at issue in this case are far below any levels ever associated with harm to the fetal brain, and are well below the EPA Reference Dose for methylmercury. Murray, 11 Tr. 1275:28-1278:28; TX 825. To demonstrate this, Dr. Murray presented a graph containing a line corresponding to the EPA Reference Dose of 0.1 ug/kg/day for methylmercury. Dr. Murray used the Proposition 65 required weight of 58 kg to produce the EPA Reference Dose line of 5.8 ug of methylmercury per day. TX 825. His graph illustrates that the levels at issue in this case are far below the EPA Reference Dose, which is a daily intake that "is designed to not produce deleterious effects over the course of a lifetime of [daily] exposure." Murray, 11 Tr. 1278:8-27; Rice, 2 Tr. 69:19-21; TX 825.

144. Dr. Rice presented the only evidence supporting the conclusion that a single exposure to methylmercury could cause harm during rebuttal. Rice, 24 Tr. 3093:3-14; TX 423. Dr. Rice produced a series of abstracts where animals were exposed in a single dose to mercury levels that likely exceeded the levels of the Minamata poisoning.[29] Rice, 25 Tr. 3141:4-8; TX 423. The methylmercury levels given to the animals in the abstracts also exceeded the Tuna Canners' proposed MADL by more than a million-fold. Rice, 25 Tr.

[29] In the 1950's, a severe poisoning episode occurred in Japan, when a factory discharged large amounts of methylmercury into Minamata Bay. The high-dose exposure caused severe abnormalities. Rice, 2 Tr. 121:11-122:3.

3141:8-3142:23; 25 Tr. 3146:2-28; TX 423. These abstracts are unpersuasive because they do not support the idea that a single serving of tuna fish could contain enough methylmercury to harm the fetal brain.

145. For purposes of this case, the Court finds that averaging exposure to methylmercury over two months is the appropriate "short duration" under section 12821 of the California Code of Regulations.

B. Defining the Term "Average" Under the Statute

1. Evidence Construing Average to Be the Arithmetic Mean

146. Pursuant to section 12821(c)(2) , the "level of exposure [to methylmercury] shall be calculated using the reasonably anticipated rate of intake or exposure for *average users of the consumer product*" (emphasis added). The term "average" is not defined in the statute, the regulations, or in the Statement of Reasons. TX 1; TX 2, p. 200.6; TX 3A, pp. 84-85. The Tuna Canners presented evidence that the term "average" in section 12821(c)(2) means the arithmetic mean, and not, as the State argued, the median.[30]

147. As discussed above, the Frequency Survey data reflects that the average non-pregnant woman of childbearing age in California eats tuna once every 61.5 days and the average pregnant woman eats canned tuna once every 60 days. Wind, 18 Tr. 2223:1-3; TX 732A. These figures represent the average, or arithmetic mean, frequency with which women of childbearing age consume canned tuna in California. Murray, 12 Tr. 1436:1-12.

148. Dr. Murray testified the word "average" is not ambiguous in statistics, and that upon reading or hearing the word "average," he has never had to determine whether it meant median, mode, or central tendency instead of mean. Murray, 10 Tr. 1140:10-16; 12 Tr. 1461:12-1162:24. Dr. Murray testified that based on his extensive experience as a toxicologist and Proposition 65 consultant, it is appropriate to use the arithmetic mean to

[30] The State urged the Court to conclude that women of childbearing age in California consume canned tuna once every 22.5 days, which represents the median frequency of canned tuna consumption from Dr. Wind's report. Murray, 12 Tr. 1435:12-15.

determine "average exposure" of women to methylmercury in tuna fish. Murray, 12 Tr. 1436:3-5; 12 Tr. 1436:8-12.

149. Dr. Wind also testified that in his experience, the professional and common meaning of the term "average" is the arithmetic mean, and not the median. Wind, 18 Tr. 2229:19-18. According to Dr. Wind, widely used statistics textbooks at leading universities define the term "average" as "the sum of entries divided by number of entries," which is the definition of the arithmetic mean. Wind, 18 Tr. 2231:7-11; TX 843, p. 76. Furthermore, an "average" cannot be the median because the median represents the fiftieth percentile, whereas the mean is another measure of distribution. Wind, 18 Tr. 2232:3-5. Dr. Wind testified that the *San Francisco Chronicle* uses the word "average" to signify "mean" when it discussed the average monthly rainfall, or the average points, rebounds, and assists of different basketball players. Wind, 18 Tr. 2235:22-27; TX 845, pp. 1-2. In contrast, when discussing the median, the term "median" is specifically stated, such as when the *Chronicle* reported on the median home prices for October. Wind, 18 Tr. 2235:2-7.

150. OEHHA scientists Dr. Robert Brodberg and Dr. Zeise testified that when they apply "daily average" and "average daily intake" of tuna fish, they equate the "average" to the arithmetic mean. Brodberg, 16 Tr. 1942:14-18; Zeise, 16 Tr. 2018:23-26. Even Dr. Griffin admitted that he uses "average" to mean "the arithmetic mean" in his work. Griffin, 6 Tr. 703:13-17.

2. The State's Evidence Proffered to Support Reliance on the Median Rather Than the Mean

151. The State claims the term "average" in section 12821(c)(2) means the "median," "typical," or some other measure of central tendency. Based on Dr. Wind's report, the median for tuna consumption among pregnant women in California is 22.5 days. Griffin, 19 Tr. 2405:2-6; TX 397; Murray 12 Tr. 1435:12-25; TX 561, p. 13.[31]

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[31] Although the State contended that "average" could mean "typical," it conceded that "typical" is not used in the regulations. Griffin, 19 Tr. 2392:2-7; TX 2, p. 200.6. Dr. Wind (footnotes continued . . .)

152. The Court heard testimony from Dr. Dale Griffin that his "understanding" of the meaning of the term "average" is "typical." Griffin, 19 Tr. 2394:13-19. Yet, Dr. Griffin read the definition of "average" from several dictionaries and each dictionary included the "arithmetic mean" as a definition. Griffin, 19 Tr. 2391:11-2392:3; 19 Tr. 2388:12-22; 19 Tr. 2390:13-18; 19 Tr. 2391:23-2392:3. In his own work, Dr. Griffin uses "average" to mean "the arithmetic mean" in his work. Griffin, 6 Tr. 703:13-17. In Dr. Griffin's on-line warning sign experiment, he testified that the average reading time for the can label was 15 seconds, which he equated to the mean time. Griffin, 6 Tr. 703:13. Dr. Griffin also conceded that the *Harper Collins Dictionary of Statistics* states, "[b]y far, the most useful of measures of central tendency is the arithmetic mean. As a general rule, when the behavioral scientist uses the term 'average,' he means the mean." Griffin, 19 Tr. 2393:24-27; TX 403.

153. The State's statistics expert, Dr. Greenland, testified that the term "average" could mean typical, median, geometric mean, harmonic mean, trimmed mean, or Windsorized mean. *See,* Greenland, 20 Tr. 2619:20-2620:7. He admitted, however, that the most commonly understood meaning of the word "average" in statistics is the arithmetic mean. Greenland, 20 Tr. 2636:5-13.

3. Average Is the Arithmetic Mean

154. The Court finds that the common meaning of "average," and the way in which the witnesses, including the State's witnesses, use the term "average" is the arithmetic mean and not the median.

(...continued)
referred to a standard statistics book, *Introduction to the Practice of Statistics* by Moore and McCabe, which instructed "[d]on't confuse the average value of a variable, the mean, with its typical value, which we might describe as the median." Wind, 18 Tr. 2233:5-7; TX 844, p. 12.

C. Calculating Exposure to Methylmercury Based on Average Consumption Patterns

155. As discussed above, Dr. Murray calculated exposure to methylmercury from canned tuna from the following formula: C x S x F. Based on the foregoing discussion, C = 0.239-0.257 micrograms/gram of methylmercury, S= 64.4 grams of canned tuna/serving, and F = 1/60 or 0.017 servings/day. Multiplying these numbers together yields an exposure of 0.26-0.28 micrograms methylmercury per day, which is below the methylmercury MADL of 0.3 ug/day.

NATURALLY OCCURRING

I. THE WITNESSES

The issue of whether methylmercury is naturally occurring in canned tuna, and to what extent methylmercury naturally occurs in the product, are scientific questions addressed at the trial by experts presented by both parties.

A. The Tuna Canners' Witnesses

156. To prove that virtually all of the methylmercury in canned tuna is naturally occurring, the Tuna Canners presented the testimony of Dr. Francois Morel and Dr. James Joseph.

Dr. Francois Morel is an expert on geosciences, environmental science and engineering, aquatic chemistry and water oceanography. Morel, Volume 8 Transcript ("8 Tr.") 846:3; 8 Tr. 847:25-848:1; Trial Exhibit ("TX 645"). He is the Albert G. Blanke Professor of Geosciences at Princeton University, a chaired position. Morel, 8 Tr. 846:4-6. Dr. Morel earned an undergraduate degree in applied mathematics, and a Ph.D. from the California Institute of Technology in engineering sciences. Morel, 8 Tr. 846:26-28; 8 Tr. 847:8-17. Prior to joining Princeton's faculty, he was a professor in the Department of Civil & Environmental Engineering at the Massachusetts Institute of Technology, where he held an endowed professorship. Morel, 8 Tr. 846:10-22; TX 645, p. 1. Dr. Morel is the recipient

of many awards, including two prestigious awards given in the field of geosciences and oceanography. Morel, 8 Tr. 849:13-20; TX 645, p. 2. He is a fellow of the American Geophysical Union and has served on the editorial boards of four peer-reviewed journals. Morel, 8 Tr. 849:21-850:3; 8 Tr. 850:4-11. Dr. Morel has particular expertise in the manner in which trace metals, including mercury compounds, are found and are transported in the oceans. Morel, 8 Tr. 852:9-853:15.

Dr. James Joseph is a world-recognized expert on tuna biology, tuna population dynamics, tuna fisheries, resource conservation and management. Joseph, 13 Tr. 1545:25-28; 13 Tr. 1546:1-10. Dr. Joseph holds a Ph.D. in Fish Population Dynamics (Joseph, 13 Tr. 1486:11-22; TX 601, p. 1), and was the director of the Inter-American Tropical Tuna Commission ("IATTC") for 30 years. Joseph, 13 Tr. 1487:22-28. The IATTC is an international organization established by convention between thirteen nations, including the United States. Joseph, 13 Tr. 1487:20-28; 13 Tr. 1488:1-9, 28-1489:4; TX 601, p. 1. Dr. Joseph taught fishery science at universities and has authored over one hundred articles and books on fisheries and tuna. Joseph, 13 Tr. 1498:12-1499:4; TX 601, passim. Dr. Joseph was responsible for the IATTC's tuna food habit studies (Joseph, 13 Tr. 1546:13-20), and his expertise includes the feeding behavior of tuna, including tuna around Hawaii. Joseph, 13 Tr. 1501:5-7; 13 Tr. 1548:14-1549:14; 13 Tr. 1592:10-14. Dr. Joseph also worked as an expert for South American governments on anchovies and sardines. Joseph, 13 Tr. 1579:15-16. Dr. Joseph has testified before Congress, the United Nations and the legislatures of Latin American countries, and has served as an advisor to many international organizations, government ministries and heads of state, including the Emperor of Japan. Joseph, 13 Tr. 1497:15-1498:6; 13 Tr. 1502:24-1503:6; TX 601, p. 1. Dr. Joseph has received numerous awards for contributions to tuna science, marine science, the development of tuna fisheries and tuna conservation. Joseph, 13 Tr. 1503:7-1504:17; TX 601, pp. 1-2.

B. The State's Witnesses

157. To rebut the Tuna Canners' evidence that virtually all methylmercury in canned tuna is naturally occurring, the State presented four witnesses.

158. **Dr. William Fitzgerald** teaches marine sciences at the University of Connecticut. TX 141, p. 1. He has published widely on the topic of mercury cycling in the atmosphere and the oceans (TX 141, passim), and has co-authored peer-reviewed articles on these topics with Dr. Morel (Fitzgerald, 22 Tr. 2732:2-7). Dr. Fitzgerald's testimony was troubling to the Court in several respects.

159. First, in his published articles in textbooks and peer-reviewed articles, Dr. Fitzgerald has consistently written that atmospheric mercury levels have been increasing at a rate of approximately 1.4 percent per year (TX 159, p. 1116 (Fig.7)), and that comparing mercury levels in fish over time would be an effective test to determine the contribution, if any, of pollution to methylmercury in fish. Fitzgerald, 23 Tr. 2900:7-15; 23 Tr. 2910:20-2911:12; TX 859; TX 861, p. 296. In this case, however, Dr. Fitzgerald claims that mercury in the atmosphere is no longer increasing, although he was unclear about when the increase ceased. However, Dr. Fitzgerald has never expressed this opinion in any published work. Fitzgerald, 23 Tr. 2928:4-9.

160. Second, Dr. Fitzgerald has consistently published that the atmospheric deposition of mercury quickly spreads throughout the globe, including to its most remote regions. Fitzgerald, 23 Tr. 2935:3-7. He has never written a peer-reviewed article backing away from this theory. Fitzgerald, 23 Tr. 2935:8-14. Yet, in this case, Dr. Fitzgerald claims that recent increases in atmospheric mercury at several locations should be ignored because they are local and apply only to those areas. TX 143, pp. 6-7.

161. Third, Dr. Fitzgerald has recently published an article suggesting that coastal areas are a source for methylmercury in the ocean. TX 421. That theory is discussed below. However, Dr. Fitzgerald's hypothesis is based upon mathematical calculations that, during

trial, he recognized were incorrectly computed, but he does not intend to withdraw the numbers. Fitzgerald, 24 Tr. 2972:10-22; 24 Tr. 3012:5-3013:2.

162. **Dr. Dean Grubbs** is a recent Ph.D., who since 2001 has studied the stomach contents of tuna caught at state-run fish aggregating devices ("FADs") near the coast of Hawaii. Grubbs, 19 Tr. 2509:4-5. Dr. Grubbs is not a professor. Dr. Grubbs has no understanding of how mercury bioaccumulates in fish. Grubbs, 19 Tr. 2445:25-27.

163. **Dr. James Hurley** also was called to testify for the State. Dr. James Hurley is a professor at the University of Wisconsin, and is an expert in lakes and ponds. Hurley, 20 Tr. 2651:23-28; TX 169. Because Dr. Hurley has no expertise in the oceans, the Court excluded his testimony. Hurley, 21 Tr. 2705:1-21.

164. **Dr. Sander Greenland** is a professor of statistics at UCLA, with no experience in tuna or oceanography. Greenland, 20 Tr. 2610:10-12; TX 221. Dr. Greenland relied principally on the opinions of Dr. Grubbs for his assumptions and consequent calculations concerning tuna populations. Greenland, 20 Tr. 2615:2-2619:11.

II. MERCURY IN THE ENVIRONMENT

A. Mercury is a Naturally Occurring Element

165. Mercury is an element on the periodic table and is found everywhere in the environment. Morel, 8 Tr. 867:6-7; 8 Tr. 868:12-869:1; TX 802. In its inorganic form, mercury exists in three oxidation states: elemental mercury, mercury I and mercury II. Morel, 8 Tr. 869:7-26, 8 Tr. 870:14-25.

B. The Contribution of Pollution

166. Elemental mercury is the main form of mercury that is emitted from power plants into the atmosphere. Morel, 8 Tr. 872:13-16. Elemental mercury is not the type of mercury that exists in trace amounts in fish. Morel, 8 Tr. 871:17-22.

167. Elemental mercury can be in either liquid or vapor form and is soluble, meaning it can be dissolved in solutions, such as water. Morel, 8 Tr. 856:22-27; 8 Tr. 869:13-17.

168. There is a well-recognized global cycle for mercury, whereby emitted elemental mercury vapor is transported into the atmosphere, gets oxidized into ionic mercury (mercury II) and becomes more soluble in water as it falls to earth as rain. Morel, 8 Tr. 872:15-873:17.

169. The cycling of mercury comes through several sources, including from the oceans up into the atmosphere, from smokestacks, and from its presence in groundwater, rivers, lakes and streams. Morel, 8 Tr. 872:13-873:2; Fitzgerald, 22 Tr. 2737:8-16. The amount of mercury that is deposited on the surface waters of the ocean increases as atmospheric mercury levels rise, and equals the amount of mercury that is evaded into the atmosphere. Morel, 8 Tr. 902:13-23; TX 157, p. 3192 (Fig. 1). This equilibrium existed in pre-industrial times. Morel, 8 Tr. 903:10-12; TX 157, p. 3196 (Fig. 4).

170. Mercury cycling has existed since prehistoric times and is independent of human activity. Fitzgerald, 23 Tr. 2907:17-28; *see, e.g.*, TX 860. However, human industrial activity has increased the amount of elemental mercury deposited into the atmosphere, and atmospheric mercury levels have at least tripled in the last 100 years and increased at a rate of approximately 1.4 percent per year. TX 159, p. 1116 (Fig. 7); Morel, 8 Tr. 903:13-14. Dr. Fitzgerald testified that atmospheric mercury increased two to four times since the start of the Industrial Revolution. Fitzgerald, 21 Tr. 2900:16-22.

C. Methylmercury

171. Mercury takes on organic forms, such as methylmercury (monomethylmercury) and dimethylmercury, when mercury is bound directly to a carbon atom in an organic compound. Morel, 8 Tr. 870:28-871:12. There is no known emission of methylmercury from power plants or other pollution. Morel, 8 Tr. 872:13-25.

1. Methylmercury in Freshwater Systems

172. In freshwater systems, methylmercury is formed by biological processes that depend on anoxic[32] sediments in lake bottoms. Morel, 8 Tr. 874:4-16; 8 Tr. 875:19-25. In these anoxic sediments or layers, sulfate-reducing bacteria ("SRBs"), which are aquatic organisms that cannot live in the presence of oxygen, convert mercury II into methylmercury. Morel, 8 Tr. 856:10-13; 8 Tr. 874:4-9; 8 Tr. 875:19-24. If there is any oxygen present, the SRBs cannot survive. Morel, 8 Tr. 874:22-875:1.

2. The Oceans

173. The world's oceans are immense. For example, the Pacific Ocean is between 10,000 and 20,000 kilometers wide. Morel, 9 Tr. 1010:16-19.

174. The ocean consists of three layers. TX 805. The top layer is known as the mixed layer or surface layer, and is about 100 meters in depth. Morel, 8 Tr. 897:13-22. The mixed layer is so-named because it is mixed by the wind. Morel, 8 Tr. 897:14-17. Sunlight filters through the surface layer. Morel, 8 Tr. 898:18-24. Below the mixed layer is the thermocline, which is about 100 to 1,000 meters in depth. Morel, 8 Tr. 899:5-7. The bottom layer is the deep ocean, which is about 1,000 to 4,000 meters in depth. Morel, 8 Tr. 897:8-10.

175. There are many differences between oceans and freshwater systems. The PH in lakes is quite variable, but is constant in the oceans. Morel, 8 Tr. 876:22-877:10; Fitzgerald, 22 Tr. 2749:26-2750:10. Unlike lakes, the oceans are too oxic to support production of methylmercury by SRBs.[33] Morel, 8 Tr. 883:5-884:6; 8 Tr. 884:11-14. The water in lakes cycles differently than in the oceans because lakes are much smaller than oceans. Morel, 8 Tr. 881:8-26. In lakes, processes on the coastline affect what occurs in the middle, but due to their size, this is not the case in oceans. *Id.*

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[32] Anoxic means there is no oxygen present. Morel, 8 Tr. 874:19-21.

[33] There are few exceptions, including the Black Sea, coastal areas and very deep ocean trenches. Morel, 8 Tr. 883:5-884:6.

176. Dimethylmercury is only found in the oceans, principally at depth. Fitzgerald, 23 Tr. 2917:10-16. Dimethylmercury findings are relevant to methylmercury findings because, as Dr. Morel and Dr. Fitzgerald testified, degraded or decaying dimethylmercury is a possible source of methylmercury. Morel, 8 Tr. 977:20-978:5; Morel, 9 Tr. 1014:26-1015:1; Fitzgerald, 23 Tr. 2892:4-5; 2918:2-4. Dimethylmercury is not emitted as pollution, exists only in the oceans and is not created by SRBs. Morel, 9 Tr. 1015:5-17; 1016:2-7; Fitzgerald, 23 Tr. 2917:10-11.

3. Methylmercury in Tuna and Other Fish

177. Methylmercury is the form of mercury in canned tuna. Morel, 8 Tr. 871:17-22. All canned tuna contains trace amounts of methylmercury. First Joint Stipulation of Facts, p. 3-4. The Tuna Canners process yellowfin, albacore, skipjack and bigeye tuna. Joseph, 13 Tr. 1505:21-25; First Joint Stipulation of Facts, p. 2-4.

178. It is undisputed that methylmercury bioaccumulates over time in fish, including tuna. Grubbs, 19 Tr. 2445:22-24; Brodberg, 16 Tr. 1933:18-28; Morel, 8 Tr. 871:17-25; Joseph, 13 Tr. 1512:23-28. Bioaccumulation means that an element accumulates in organisms. Morel, 8 Tr. 858:13-14. All metal species, including methylmercury, can bioaccumulate if they get inside an organism. Morel, 8 Tr. 858:15-22. Methylmercury bioaccumulates in tuna over time because, as the tuna gets larger, the level of methylmercury in the tuna increases. Joseph, 13 Tr. 1512:23-1513:4, 13 Tr. 1539:13-23; Grubbs, 19 Tr. 2513:27-2514:2. Different species of tuna do not bioaccumulate methylmercury at hugely dissimilar rates. Morel, 9 Tr. 1073:1-4.

179. There was no evidence presented at trial that levels of methylmercury in tuna vary depending on location, season or diet.

180. The Tuna Canners cannot catch smaller tuna with lower levels of methylmercury because the practice would deplete world tuna stocks and would violate United States and international law and treaties. Joseph, 13 Tr. 1509:22-1510:6; 13 Tr. 1539:21-1540:11; TX 831, pp. 3-5; TX 833 (16 U.S.C. § 1851).

181. The Tuna Canners do not add methylmercury to canned tuna. Joint Stipulation of Facts, p. 5. It is undisputed that there is no currently known way to remove methylmercury from tuna or canned tuna products. *Id.*

III. VIRTUALLY ALL METHYLMERCURY IN TUNA IS NATURALLY OCCURRING

182. It is undisputed that methylmercury is not deposited in the ocean as a result of industrial pollution. Fitzgerald, 23 Tr. 2932:23-27; Morel, 8 Tr. 872:13-25. As noted above, methylmercury is created biologically by the methylation of elemental mercury by SRBs or through a chemical process in deep ocean vents.

183. In order for there to be a relationship between the methylmercury in the ocean and human generated pollution, inorganic mercury would have to be methylated in the mixed layer, the thermocline or the coastal regions. *See, e.g.*, TX 647. Dr. Morel testified persuasively that neither the methylation of mercury nor methylmercury itself has been observed in the mixed layer of the open ocean. Morel, 9 Tr. 1016:18-20; 25 Tr. 3174:8-12; TX 146, p. 1900.

184. There is no dispute that most of the methylmercury in the ocean exists completely independently of human activity. The State's expert, Dr. Fitzgerald, concedes that between fifty and seventy-five percent of the ocean's methylmercury is naturally occurring. Fitzgerald, 23 Tr. 2861:9-27. Dr. Morel testified that at least ninety-five percent of the methylmercury in the ocean is naturally occurring. Morel, 8 Tr. 956:13-15; 25 Tr. 3217:16-19. Indeed, Dr. Morel stated that the amount of methylmercury in the deep ocean that is anthropogenic is more likely 1.5% ("the best number"). Morel, 8 Tr. 954: 25-26. As for the percentage of methylmercury in tuna that is anthropogenic, according to Dr. Morel, "It is either zero or 1.5 per cent." Morel, 8 Tr. 954: 27-28. As detailed below, this Court finds Dr. Morel's opinion is more credible and better supported by the evidence presented.

185. Dr. Morel's opinion is based on: (1) comparisons of mercury concentration levels in century-old museum fish to modern fish; (2) a scientific study he conducted with a team of other scientists published in 1998 in which they found no difference in

methylmercury concentrations between fish populations caught in the same area twenty-seven years apart; and (3) the evidence indicating that the most likely source for methylmercury is in the deep ocean.

186. Dr. Fitzgerald agrees that even modest increases in atmospheric mercury would lead to increased levels of mercury in fish, if there is an anthropogenic source for the methylmercury. Fitzgerald, 23 Tr. 2899:19-25; 23 Tr. 2900:7-15; TX 859, p. 139; TX 861, p. 296. Dr. Fitzgerald knows of no peer-reviewed study that has found an increase in methylmercury in ocean fish during the time period when atmospheric mercury levels have increased (Fitzgerald, 23 Tr. 2902:15-22; 23 Tr. 2910:20-2911:12), and the State did not present any such studies.

187. The Tuna Canners presented scientific studies that show there has been no increase in the amount of methylmercury in ocean fish during the past 100 years. *See* TX 151; TX 152; TX 166; TX 647. These scientific studies support the conclusion that methylmercury in canned tuna exists almost exclusively from natural sources with a de minimus amount coming from anthropogenic sources.

A. Museum Studies Support the Conclusion That Methylmercury Exists in Fish Independent of Human Activity

188. The Court considered three studies comparing methylmercury concentrations in museum fish samples from the late 19th and early 20th centuries with modern fish samples. These studies demonstrate that the amount of methylmercury in ocean fish has not increased over time, despite increased contributions of anthropogenic mercury. TX 151; TX 152; TX 166.

189. The fundamental premise underlying each of these studies is that if methylmercury was formed from the deposition of industrial mercury pollution, then there should be more methylmercury in modern fish than in museum fish captured prior to the

industrial age.[34] Morel, 8 Tr. 892:9-21; TX 151, p. 552; TX 152, p. 636; TX 166, p. 1121. **Dr.** Fitzgerald agrees with this premise. Fitzgerald, 23 Tr. 2899:19-28; 23 Tr. 2900:7-15; 23 Tr. 2910:20-2911:12; TX 859; TX 861, p. 296.

190. The first paper, published by Miller et al. in *Science*, (the "Miller paper" (TX 166)), examines whether mercury in tuna and swordfish is naturally occurring. Morel, 8 Tr. 892:1-5. The study compared the mercury content of fish that were caught between 1878 and 1909 and preserved in museums with the mercury content of fish that were caught in the early 1970s. TX 166, p. 1121; Morel, 8 Tr. 892:9-21. In this study, both sets of samples were weighed the same way, there is no evidence the museum samples were contaminated and there was no methylmercury in the fish preservatives. TX 166, p. 1122; Morel, 8 Tr. 905:16-906:21. The study concluded that fish methylmercury levels did not increase, which led the authors to conclude that the methylmercury in fish is naturally occurring.[35] TX 166, p. 1122; Morel, 8 Tr. 892:17-21; 8 Tr. 894:19-22; 8 Tr. 904:17-27.

191. Dr. Morel candidly pointed out limitations in the Miller paper, including the fact that the fish that were compared were not of the same species and were not caught in the same areas. Morel, 8 Tr. 895:13-23. Given these deficiencies, the Miller paper is not conclusive evidence that methylmercury levels have not increased in fish. However, this evidence, when considered with later studies discussed below, lends support to the conclusion that methylmercury levels have not increased in fish as the result of pollution.

192. The second paper testing the anthropogenic contribution to ocean fish was published in 1972 by Barber, et al. (the "First Barber paper" TX 152;) in a peer-reviewed journal. Morel, 8 Tr. 890:15-16. The authors tested whether the mercury in tuna was from

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[34] See Section III.C.1, *infra.*, for a discussion regarding the increase of mercury emissions into the atmosphere, based on trial evidence.

[35] The average mercury level in the museum fish was .95 ppm; the average mercury level in the 1970s fish was .91 ppm. Morel, 8 Tr. 904:20-905:3; TX 166, p. 1122 (Table 1).

anthropogenic or natural sources by comparing antimora rostrata and other fish species caught in the 1880s against similar species caught in 1971-1972. TX 152, pp. 636-37; Morel, 8 Tr. 891:8-10. As with the Miller paper, the authors did not find an increase in the amount of methylmercury from the museum fish to the modern fish. Morel, 8 Tr. 903:15-19; TX 152, p. 636.

193. A third paper was published in a leading peer-reviewed publication (Morel, 8 Tr. 890:6-19), by Barber and his colleagues in 1984 (TX 151) ("Second Barber paper"), analyzing the anthropogenic contribution to methylmercury in the antimora rostrata which is a fish that lives between 2,000 and 3,000 meters deep in the ocean. Morel, 8 Tr. 895:9-896:6; TX 151, p. 552. This study improved on the First Barber paper by using the same species of fish and studying the size of the fish. Morel, 8 Tr. 907:10-28. The authors compared museum antimora samples collected in the 1880s with antimora samples collected in the 1970s and found no increase in methylmercury levels in the fish. Morel, 8 Tr. 908:1-17; TX 151, p. 552. The study did find high levels of methylmercury in the antimora. Morel, 8 Tr. 910:11-14; TX 151, p. 554.

194. According to Dr. Morel, the fact that the antimora live 2,000 to 3,000 meters deep in the ocean and have high levels of methylmercury makes it very unlikely that any of the methylmercury was created by man-made pollution. Morel, 8 Tr. 910:11-18. As Dr. Morel explains, the mercury that is deposited from the atmosphere into the oceans becomes diluted and very little of the mercury settles down to the deep ocean. Morel, 8 Tr. 910:20-28. Therefore, no anthropogenic pollution would be expected at such depths in the ocean. Morel, 8 Tr. 896:5-12.

195. Dr. Fitzgerald agrees with Dr. Morel on this point, and testified that he did not expect to see a change in methylmercury levels in the deep ocean antimora rostrata because there is very little anthropogenic mercury in the deep ocean. Fitzgerald, 23 Tr. 2853:5-7.

B. The Kraepiel Study Confirms That Methylmercury in Tuna Has Not Been Affected by Anthropogenic Mercury Emissions

196. In order to test whether methylmercury is rising with atmospheric mercury increases, Dr. Morel and his colleagues conducted a study in 1998 ("Kraepiel" or "Kraepiel study"). TX 647.

197. The Kraepiel study compared mercury levels in two groups of fish and tested three hypotheses using a three-box model – (1) that mercury is methylated in the mixed layer; (2) that mercury is methylated in the thermocline; and (3) that mercury is methylated in the deep ocean. Morel, 8 Tr. 912:14-19; 8 Tr. 929:15-25; TX 647, pp. 5552-53. The three-boxes of the model represent the three layers of the ocean and use the best scientifically available oceanic data. TX 647, pp. 5552-53. Dr. Fitzgerald criticized the use of Kraepiel's three-box model, claiming that it was too simple given the complexities of the ocean. TX 143, p. 4. However, it is common for scientists, including Dr. Fitzgerald, to use simple models in their work with the ocean. Fitzgerald, 22 Tr. 2794:3-4; Morel, 8 Tr. 970:11-16; TX 159, p. 1105. Kraepiel used this model because the goal was to determine the range of possibilities, not specific values. Morel, 8 Tr. 967:11-968:7. Dr. Morel testified that Kraepiel's three-box model is scientifically appropriate and sufficient to provide valid results. Morel, 8 Tr. 968:25-27. The Kraepiel study's model also took into account assumptions based on whether mercury levels increased linearly or exponentially. Morel, 25 Tr. 3177:27-3178:17; TX 647, p. 5553.

198. The Kraepiel study is published in a peer-reviewed journal and compares the methylmercury concentrations of two groups of yellowfin tuna that were caught in the Hawaii area in 1971 and 1998. TX 647, p. 5551. The study's premise, like that in the Miller and Barber papers, is that because there has been a net increase in atmospheric mercury between 1971 and 1998, it is expected that the amount of methylmercury in tuna caught in the same area would increase between 1971 and 1998. Morel, 8 Tr. 913:2-8; TX 647, p 5551.

199. The Kraepiel study model respecting increases of mercury emissions is based on data from Dr. Slemr, which shows that atmospheric mercury emissions increased from 1971 to 1990, followed by a decrease in the 1990s. Morel, 25 Tr. 3178:18-3179:25; TX 647, p. 5556; TX 654A. The Slemr data supports Kraepiel's premise that total atmospheric mercury emissions increased between 1971 and 1998. Morel, 8 Tr. 918:28-919:5; 8 Tr. 919:26-920:4; 8 Tr. 920:22-921:1. Kraepiel then calculated, based on this data, that methylmercury levels in the mixed layer would have increased fifteen percent between 1971 and 1998 if methylmercury is formed in the mixed layer, and eighteen percent if methylmercury is formed in the thermocline. TX 647, p. 5556.

200. For purposes of the 1971 group of fish, Kraepiel relied on the results of two studies by scientists (Thieleke and Rivers) analyzing methylmercury content in yellowfin tuna (the "Thieleke tuna" and the "Rivers tuna"). TX 647, p. 5554. The Thieleke tuna consisted of 100 samples and were caught within twenty miles of Hawaii. TX 647, p. 5554; TX 650, p. 14. The results of the Thieleke tuna study were presented in a manuscript thesis. TX 650. The Rivers tuna consisted of twenty-two samples. TX 647, p. 5554. The results of the Rivers tuna study were published in 1972. TX 649. It is unknown where the Rivers tuna were caught because Rivers used purchased skinless fillets of fish. TX 649, p. 257.

201. The 1998 group of fish were caught at the direction of the Kraepiel group. TX 647, pp. 5551-52. To ensure that the tuna being compared were similar to the tuna caught in 1971, Krapeil directed that the fish be the same species (yellowfin) and caught from the same geographic location (off the coast of Hawaii). TX 647, p. 5551. Due to commercial fishing restrictions in place in 1998, the 1998 fish were caught outside the fifty-mile limit off the Hawaiian coast. TX 647, p. 5551-52.

202. The fish were weight restricted to ensure that there was not a large difference in the frequency of mercury concentration levels between the two fish populations. Morel, 8 Tr. 936:22-28.

203. Kraepiel concludes that the average mercury concentrations of the 1998 tuna were nearly identical to (and in fact slightly less than) the 1971 tuna. Morel, 8 Tr. 930:14-

16; 8 Tr. 937:12-16; TX 647, p. 5554; TX 808. Therefore, the Kraepiel study supports the conclusion that there is almost no anthropogenic methylmercury in the ocean. Morel, 8 Tr. 939:25-940:15.

C. The State Did Not Rebut the Evidence that Methylmercury in the Ocean is Naturally Occurring

204. The State attacked the Kraepiel study in three regards: (1) that there was no net increase of mercury emissions between 1971 and 1998 and thus no increase in methylmercury in tuna could be expected; (2) the variability of the ocean is such that the model Kraepiel employed would not allow it to predict accurate results; and (3) the 1971 tuna and the 1998 tuna were not suitable for comparative purposes. The Court does not find any of these criticisms persuasive.

1. The State Did Not Prove That There Was No Net Increase in Atmospheric Mercury Emissions Between 1971 and 1998

205. The State did not refute effectively the evidence that mercury emissions have increased during the industrial age, and specifically between 1971 and 1998.

a. Mercury Emissions Increased Since Pre-Industrial Times

206. Dr. Fitzgerald published an article in 2001 in which he calculated that the amount of atmospheric mercury has increased 1.4 percent per year since pre-industrial times. TX 159, p. 1116 (Fig. 7). This reflects an increase from pre-industrial times to current times of nine megamoles of mercury in the atmosphere to twenty-six megamoles. Morel, 8 Tr. 917:10-12; TX 159, p. 1116 (Fig. 7). Dr. Fitzgerald also calculated that mercury levels in the mixed layer and the thermocline increased over the same time period.[36] Morel, 8 Tr. 917:8-9; TX 159, p. 1116 (Fig. 7). The article does not include a caveat indicating there may not have been an increase in atmospheric emissions in the last thirty years (Fitzgerald, 23 Tr.

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[36] Dr. Fitzgerald showed an increase in mercury levels from twenty-nine megamoles to fifty-four megamoles in the mixed layer and from 902 megamoles to 1,002 megamoles in the thermocline. TX 159, p. 1116 (Fig. 7).

2926:28-2927:25) or that emissions have tapered off (Fitzgerald, 23 Tr. 2928:4-9). Dr. Fitzgerald has not revised his estimate of a 1.4 percent per year increase in any published article. Fitzgerald, 23 Tr. 2927:22-2928:9; Morel, 25 Tr. 3236:4-10.

207. Further evidence supporting an increase in atmospheric mercury is reflected in data collected by Dr. Joseph Pacyna, who, according to Dr. Fitzgerald, is a well-regarded scientist. Fitzgerald, 23 Tr. 2928:18-23; TX 153. Dr. Pacyna's data shows that mercury emissions have increased from 1881 tonnes/year in 1990 to 2269 tonnes/year in 2000. Fitzgerald, 23 Tr. 2928:28-2929:2; TX 153. The data shows a large increase in Asia from 705 tonnes/year in 1990 to 1204 tonnes/year in 2000. TX 153. Until at least 2001, Dr. Fitzgerald agreed with Dr. Pacyna that total anthropogenic mercury emissions increased between 1990 and 2000. Fitzgerald, 23 Tr. 2929:18-22.

b. Mercury Emissions Increased Between 1971 and 1998

208. Despite Dr. Fitzgerald's agreement that mercury levels have increased since pre-industrial times, he quibbles with whether mercury levels increased between 1971 and 1998. Primarily, Dr. Fitzgerald opines that the Slemr data (TX 148), on which Kraepiel relies, shows that mercury levels declined beginning in 1990, and then plateaued in 1998. TX 143, p. 5. The evidence does not support Dr. Fitzgerald's opinion that there was no increase in mercury emissions and the Court accords it little weight for several reasons.

209. First, the Slemr data does not change the conclusion that mercury levels increased between 1971 and 1998. Even if the level of atmospheric mercury declined in the 1980s, there was still more mercury in the atmosphere than there had been in the early 1970s. Morel, 8 Tr. 919:26-920:1.

210. Second, Dr. Fitzgerald's opinion on whether there is good evidence for an increase in mercury between 1971 and 1998 has changed during this case. In his original expert report in this case, Dr. Fitzgerald stated there was no increase between 1971 and 1998. TX 143, p. 6. In his revised expert report, Dr. Fitzgerald changed the date range to between

1979 and 2000 or 2001. TX 143, p. 6. Dr. Fitzgerald admits that he has supporting data only from 1979, not 1971. Fitzgerald, 23 Tr. 2952:14-22.

211. Third, Dr. Fitzgerald claims that several data points measured by Dr. Slemr prior to 1990 that Kraepiel included should not be considered because the data points reflect local pollution and skew the results. Fitzgerald, 23 Tr. 2822:9-2823:23. Dr. Fitzgerald's own work and testimony refutes these arguments. First, Dr. Fitzgerald admits that it is close to a scientific consensus that elemental mercury – no matter where it comes from – gets emitted into the atmosphere, resides there for a year and travels around the earth and gets dispersed "rather broadly". Fitzgerald, 23 Tr. 2877:24-2878:2; 23 Tr. 2878:17-20; 23 Tr. 2880:10-15; 23 Tr. 2924:6-18; 23 Tr. 2925:6-14; TX 851, p. 77; TX 863, p. 1. Second, Dr. Fitzgerald published that mercury levels have been measured in pristine Arctic lakes, which refutes his argument that regional variability is relevant. Fitzgerald, 23 Tr. 2877:21-23.

c. The Variability of Mercury Levels Does Not Affect Kraepiel's Results

212. The State argues that the Kraepiel study rejected improperly the hypotheses that methylmercury is formed in the mixed layer or thermocline. Specifically, the State claims that Kraepiel failed to account for data showing seasonal and regional variables that affect methylmercury levels. Fitzgerald, 22 Tr. 2804:22-27; 23 Tr. 2839:19-21; 23 Tr. 2840:28-2841:22; 23 Tr. 2844:16-2845:19; TX 143, p. 9.

213. Dr. Morel testified that Kraepiel did not ignore this data (*see* TX 147), because it was not available when the Kraepiel study was written. Morel, 25 Tr. 3174:23-28. Dr. Morel also testified that Kraepiel did not address the variability issues in the Kraepiel study because the authors were concerned with average values over time, not with what happens within short time frames. Morel, 8 Tr. 969:25-970:10; 9 Tr. 1005:1-3; 25 Tr. 3203:14-28.

214. Dr. Morel testified that the Kraepiel authors redid the calculations using the average values from TX 147 and found that these variability factors had no impact on Kraepiel's conclusions. Morel, 8 Tr. 972:23-27; 25 Tr. 3175:1-3176:8, 14-19, 26-27; 25 Tr.

3201:2-26; TX 266. Moreover, TX 147 concludes that there was stability and homogeneity of the methylmercury in the mixed layer in the Hawaii region. TX 147,. 17; Morel, 25 Tr. 3176:20-25.

2. The State Did Not Establish That the 1971 and 1998 Fish Were Not Comparable

215. The State presented testimony through Dr. Grubbs and Dr. Greenland in support of its argument that the 1971 and 1998 tuna were not comparable.

216. Dr. Grubbs argues that the 1971 and 1998 fish are not the same because the distance at which the fish were caught (twenty miles from the coast of Hawaii versus outside fifty miles from Hawaii) is a possible confounding factor. Grubbs, 19 Tr. 2449:20-2450:2. In support of this argument, Dr. Grubbs cites his own data that suggests that the tuna which aggregate around nearshore fish aggregating devices ("FADs") eat different diets from offshore tuna. Grubbs, 19 Tr. 2439:11-2440:12. The evidence that the tuna were not comparable for purposes of the Kraepiel study is not credible and is not accorded any weight for several reasons.

a. The Distance at Which the Kraepiel Fish Were Caught Is Not a Confounding Factor

217. According to Dr. Grubbs, the 1971 and 1998 tuna ate different diets because they were caught in different areas of the ocean around Hawaii. Grubbs, 19 Tr. 2487:16-20; 20 Tr. 2594:3-5. In support of this theory, Dr. Grubb opines that most tuna who are caught inshore have experienced an inshore environmental, but most tuna who are swimming offshore never experience an inshore environment. Grubbs, 20 Tr. 2594:22-25. Dr. Grubbs bases his opinion on (1) stomach content analysis of tuna caught at various FADs around the coast of Hawaii and (2) two articles discussing migration rates of tuna between FADs. These criticisms are not supportable for ten reasons.

218. First, Dr. Grubbs has no evidence that different diets have any impact on methylmercury levels in prey fish, whether those levels are different for nearshore or offshore prey or tuna. Grubbs, 19 Tr. 2514:6-19.

219. Second, the FAD-related research in terms of migration rates and residence time has little relevance because less than five percent of the tuna population around Hawaii is associated with FADs. Grubbs, 20 Tr. 2551:18-27. The fish not associated with FADs swim unassociated throughout the Hawaiian region. Grubbs, 19 Tr. 2443:2-8.

220. Third, the tuna that do aggregate at FADs spend only a short time there. Yellowfin tuna have a mean residence time at nearshore FADs of seven to eight days. Joseph, 13 Tr. 1511:4-7; Grubbs, 20 Tr. 2564:14-17. This data is consistent with research findings of the residence time of yellowfin tuna at FADs in Japan. Grubbs, 20 Tr. 2564:2-2565:3; TX 219, p. 1.

221. Fourth, research shows that the fish that aggregate at FADs are small – much smaller than the fish that were compared by Kraepiel. TX 199, p. 42. Larger fish tend to stay at FADs for less time than smaller fish. TX 219. The tuna that do aggregate around FADs tend to be smaller than the fish caught in 1971 when there were no FADs. FADs were first introduced around Hawaii in 1977. Joseph, 13 Tr. 1536:1-5; Grubbs, 20 Tr. 2553:5-8. In 1971, the yellowfin were 2.5 to 3.5 years old and weighed about 85 pounds. TX 647, p. 1. In contrast, the yellowfin that aggregate around FADs generally are less than one year old and weigh about 1 to 5 kilograms (less than twenty pounds). Grubbs, 20 Tr. 2559:4-18; Joseph, 13 Tr. 1536:6-15; TX 199, p. 40.

222. Fifth, Dr. Grubbs' research cannot provide any data concerning where a tuna was swimming prior to capture. Grubbs, 20 Tr. 2565:27-2566:2. At most, Dr. Grubbs can opine that on any given day, a tuna swimming nearshore is eating different things than an offshore tuna. Grubbs, 19 Tr. 2520:11-17. The highly migratory nature of tuna makes their prey intake on any given day irrelevant to its bioaccumulation of methylmercury over time. Joseph, 13 Tr. 1493:19-1496:14; 13 Tr. 1513:9-1515:9; 13 Tr. 1516:1-22; TX 600. Tuna swim constantly and are literally never at rest. A tuna must flush water over its gills to breath; if it stops moving, it will suffocate and sink. Joseph, 13 Tr. 1511:24-1512:8. Tuna are built for speed, and can swim at speeds of up to fifty to sixty miles per hour. Joseph, 13 Tr. 1510:12-22. There are international treaties premised on the fact that tuna are highly

migratory. Joseph, 13 Tr. 1489:21-1490:7; TX 830; TX 831, pp. 5-6. The United Nations Convention on the Law of the Sea recognizes several species of tuna that are migratory. Joseph, 13 Tr. 1491:16-24; TX 832.

223. Both Dr. Joseph and Dr. Grubbs agree that most tuna will travel several hundred miles,[37] and some tuna will travel several thousand miles. Joseph, 13 Tr. 1516:15-18; Grubbs, 19 Tr. 2427:6-11; *see also* TX 600. Yellowfin tuna are known to travel 450-600 miles, on average, and can travel several thousand miles. Joseph, 13 Tr. 1516:14-18.[38]

224. Sixth, while the tuna are swimming constantly, they are eating constantly, up to three to five percent of their body weight daily. Joseph, 13 Tr. 1511:10-15; Grubbs, 19 Tr. 2512:25-28. If they do not eat constantly, they will starve to death. Joseph, 13 Tr. 1511:10-11. They are known as opportunistic feeders and eat what is available to them. Joseph, 13 Tr. 1511:12-14; Grubbs, 19 Tr. 2513:1-2. The tuna around Hawaii consume the same diet because they all move around, eating whatever is available. Joseph, 13 Tr. 1534:28-1535:14.

225. Seventh, each species of tuna, including yellowfin, is part of a single genetic stock. Joseph, 13 Tr. 1533:11-1534:27. Of particular relevance to Kraepiel is the fact that the yellowfin tuna within 100 miles of Hawaii are considered part of the same genetic population. Joseph, 13 Tr. 1534:14-27; TX 203, p. 215.

226. Eighth, the low transfer rates between inshore and offshore fish is limited to a small amount of FAD-related research. Dr. Grubbs claims that migration and in/off-shore transfer rates in the Hawaii region refute the highly migratory nature of tuna. Grubbs, 19 Tr. 2475:1-4. As sole support for this contention, Dr. Grubbs discussed two articles that reviewed migration rates in Hawaii between FADs, in particular the Cross Seamount.

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[37] Dr. Grubbs testified at his deposition that he is aware of studies by Dr. Sibert that tuna travel up to 600 miles. Grubbs, 20 Tr. 2573:18-24. At trial, Dr. Grubbs testified that yellowfin tuna travel "more on the order of 400 miles." Grubbs, 19 Tr. 2427:7-9. In any event, Dr. Grubbs agrees that tuna travel several hundreds of miles.

[38] The southern bluefin tuna is circumpolar, which means that they swim around the earth. Joseph, 13 Tr. 1494:2-18. Similarly, Pacific albacore tuna are known to migrate from the Pacific tropical regions to Japan and the western United States. Joseph, 13 Tr. 1494:22-1495:7.

Grubbs, 19 Tr. 2474:6-28; TX 201; TX 203. The Cross Seamount is an area about 160 miles off the southwest coast of Hawaii where fish congregate and thus this data from one area has minimal applicability to the 1998 tuna and none to the 1971 tuna. Joseph, 13 Tr. 1568:1-4. Only about 1000 tons out of 4 million tons of tuna are caught at Cross Seamount annually. Joseph, 13 Tr. 1568:5-10. These studies state that high tuna immigration and natural mortality rates make it difficult to support the assumption that the Cross Seamount populations are "resident," and further report that most tuna make short stopovers at the FADs and then leave, never to return. TX 201, p. 232; TX 203, p. 226.These papers do not reflect any evidence about tuna who are not associated with FADs and may swim in and out of the near shore area. TX 201; TX 203.

227. Ninth, the locations of the FADs at which Dr. Grubbs conducts his fish collections are not relevant to the distance at which the Krapeiel fish were caught. The thirteen nearshore FADs at which Dr. Grubbs sampled fish are all located between three and seventeen miles from shore. Grubbs, 19 Tr. 2465:18-20; 20 Tr. 2536:15-18.[39] The 1971-yellowfin tuna were caught within twenty miles from shore. Moreover, there were no FADs around Hawaii in 1971 when the Thieleke and Rivers tuna were caught, and thus Dr. Grubbs' FAD data is not applicable to those fish. Grubbs, 20 Tr. 2552:28-2553:4.

228. Dr. Grubbs discussed natural fish aggregating areas (ahi koas and two fathom curve) that existed in the 1970s. Grubbs, 20 Tr. 2553:26-2556:28. However, the ahi koas are within one or two miles from shore, and the fathom curves are within one mile and fifteen miles of Hawaii respectively. *Id.*

[39] Dr. Grubbs testified during his first day of testimony that the nearshore FADs are located "generally less than five, seven – about, well, less than 10 miles from shore." Grubbs, 19 Tr. 2440:4-6; *see* TX 407; TX 408A. Later that evening, prior to his second day of testimony, Dr. Grubbs conducted a computer search of thirteen of the fifty-two nearshore Hawaiian FADs. Grubbs, 20 Tr. 2535:3-10. During his second day of testimony, Dr. Grubbs testified that those thirteen nearshore Hawaiian FADs are within 3.1 to 16.6 miles from shore. Grubbs, 20 Tr. 2536:13-18.

229. Tenth, the prey diversity in Hawaii is such that most prey is widely available. Dr. Grubbs testified about a unique prey, the oplophoroid shrimp, which nearshore tuna eat. However, according to Dr. Grubbs' initial trial testimony, the oplophoroid are only found within two to seven miles from the Hawaiian shore, which would give this prey limited relevance to the nearshore fish, which were caught out to twenty miles from shore. Grubbs, 20 Tr. 2532:19-21. On the second day of his testimony, Dr. Grubbs changed his opinion to claim that the oplophoroid's habitat may extend out to twenty miles in one location near Hawaii. Grubbs, 20 Tr. 2533:27-2534:11. Dr. Grubbs' opinion is irrelevant because he does not know if the shrimp are actually there. Grubbs, 20 Tr. 2533:18-25; 20 Tr. 2534:12-14. Aside from the oplophoroid shrimp, all other types of yellowfin prey (including Sergestidae, Stomatopoda, Decapoda larvae, epipelagics, mesopelagics, Reef Teleosts, salps and squid) are widely distributed throughout the region, with some variation according to distance from shore. Grubbs, 20 Tr. 2538:15-26; 20 Tr. 2539:4-24; 20 Tr. 2540:2-7, 19-27; 20 Tr. 2541:16-2542:8; 20 Tr. 2542:15-2543:28; 20 Tr. 2544:1-2545:9; 20 Tr. 2545:26-2546:9; TX 409; TX 410; TX 411A. Dr. Grubbs testified that the tuna prey available by location was the same in the 1970s as it was in the 1990s. Grubbs, 19 Tr. 2516:4-11.

230. In sum, the Court finds that there is no persuasive evidence that tuna swimming within several hundred miles around the coast of the Hawaiian islands are not the same for purposes of comparing mercury levels. Given the speed and highly migratory nature of tuna, and the minimal weight accorded to the FAD data presented the effect of the distance differential between 20 miles and 50 miles is inconsequential.

b. Seasonal and Other Factors Do Not Affect Kraepiel's Results

231. Dr. Grubbs theorized that El Niño or La Niña activity might affect the results of the Kraepiel study. Grubbs, 20 Tr. 2592:18-25. However, Dr. Grubbs has no evidence that this activity affected the Kraepiel results. Grubbs, 20 Tr. 2592:18-23.

232. Dr. Grubbs also theorized that a change in tuna physiology when they spawn during the summer months might affect the results. Grubbs, 20 Tr. 2592:26-28. However,

all of the fish in the Kraepiel study were caught in the spring and fall months, and Dr. Grubbs has no evidence that changes in physiology affected methylmercury levels in the tuna, or that methylmercury levels in fish vary by season. Grubbs, 19 Tr. 2514:6-19; 20 Tr. 2593:1-3, 10-17.

c. Dr. Greenland's Critique Does Not Rebut the Kraepiel Study

233. In another attempt to discredit Kraepiel's conclusions, the State presented testimony from Dr. Greenland. Dr. Greenland does not have the expertise necessary to critique the results of the Kraepiel study. Dr. Greenland is a statistician – he is not an expert in fish biology and ecology. Greenland, 20 Tr. 2610:10-12; 20 Tr. 2611:18-20. Accordingly, the Court gives no weight to Dr. Greenland's opinions about whether certain issues should have been considered in the Kraepiel study. Greenland, 20 Tr. 2612:14-17.

234. Dr. Greenland himself clearly limited the scope of his own opinion, stating that he was not disputing the credibility of the Kraepiel study. Greenland, 20 Tr. 2614:14-16. Dr. Greenland opines that the Rivers and Thieleke fish should not have been combined. Greenland, 20 Tr. 2617:25-2618:4. However, Dr. Morel testified that he ran the calculation excluding the Rivers data, and there was no change in the results of the Kraepiel study. Morel, 9 Tr. 1017:18-1018:11. Dr. Greenland admitted that the Kraepiel results are the same even after the Rivers fish are excluded. Greenland, 20 Tr. 2641:14-2642:2.

D. Mercury is Most Likely Methylated in the Deep Ocean

235. As noted above, although there is persuasive evidence that there has been no increase in the methylmercury in fish over time and thus the methylmercury in fish is naturally occurring, the source of methylation of mercury has not been proven. Possible sources of methylation include the deep ocean, the mixed layer and thermocline, and perhaps industrial pollution. Dr. Fitzgerald has also published a paper in 2004 that for the first time suggests that the coast of the world's oceans can be a possible source of the methylmercury in ocean fish.

236. The best scientific evidence supports the conclusion that virtually all of methlymercury in tuna originates from deep ocean sources. This conclusion is based on (1) published data that shows an increase of monomethylmercury and dimethylmercury at depth; (2) samples of seawater from deep sea vents collected and analyzed by Dr. Fitzgerald that show an amount of methylmercury sufficient to account for all methylmercury in tuna; and (3) evidence that a chemical process can create methylmercury in hydrothermic vents.

1. There Is No Evidence that Mercury is Methylated in the Mixed Layer or Thermocline

237. It is generally accepted that mercury is not methylated in the mixed layer because mercury degrades rapidly in the presence of sunlight. Morel, 9 Tr. 1120:16-24; Fitzgerald, 23 Tr. 2862:21-23. Kraepiel tested the hypothesis that mercury is methylated in the mixed layer. TX 647, p. 5553. Kraepiel estimated a total 15 percent increase of mercury in the mixed layer between 1971 and 1998. TX 647, p. 5555. The Kraepiel study rejected the hypothesis that methylmercury is methylated in the mixed layer. *Id.*

238. The Kraepiel study's conclusions are validated by the fact that methylmercury has not been measured or observed in the mixed layer of the open ocean. Morel, 9 Tr. 1016:18-20; 25 Tr. 3174:8-12; Fitzgerald, 23 Tr. 2904:14-17; TX 146, p. 1900.

239. Kraepiel also tested the hypothesis that mercury is methylated in the thermocline. TX 647, p. 5555. Kraepiel estimated that mercury concentrations increased by 12 percent between 1971 and 1998. *Id.* Using the model and best available data, Kraepiel rejected the hypothesis that mercury is methylated in the thermocline. *Id.*

240. Dr. Fitzgerald has calculated a rate of increase for mercury in the thermocline of .4 percent per year. TX 159, p. 1116 (Fig. 7). Kraepiel did not use this calculation because it was not available when the Kraepiel study was prepared. Morel, 8 Tr. 925:12-24. Dr. Morel testified that, even if the data were available, Kraepiel likely would not have used the data because Kraepiel was concerned with just the equatorial Pacific Ocean where the fish were caught, not the whole ocean. Morel, 8 Tr. 926:6-12; 926:28-927:2.

241. Other evidence supports the conclusion that mercury is not methylated in the thermocline. There is no known mechanism by which methylation occurs in the thermocline, which is oxic and thus cannot support production of methylmercury by SRBs. Morel, 25 Tr. 3186:20-3187:14. Dr. Morel conducted an experiment to determine if mercury could be methylated in the thermocline but did not observe any methylation. Morel, 25 Tr. 3185:21-25; 25 Tr. 3187:10-14; TX 160. Dr. Morel was able to methylate mercury only when he made the water completely anoxic. Morel, 25 Tr. 3187:23-3188:2.

242. Although Dr. Fitzgerald believes that mercury can be methylated in the low oxygen zone of the thermocline, SRBs cannot survive in this area and methylation has never been observed in the thermocline. Fitzgerald, 24 Tr. 3013:3-8; Morel, 8 Tr. 874:26-975:1.

2. There Is More Than Enough Methylmercury Generated by Deep Ocean Vents to Account for Methylmercury in Ocean Fish

243. The Kraepiel study concludes that mercury may be methylated in the deep ocean. TX 647, p. 5557. According to the deep ocean theory, the source of methylmercury is either hydrothermal vents or the deep sediment. *Id.* Methylation of mercury has not been observed in deep ocean sediments. Fitzgerald, 22 Tr. 2742:27-2743:2; 23 Tr. 2923:9-27.

244. The deep ocean vent theory has been researched for twenty-five years. Morel, 9 Tr. 1110:21-26. Deep ocean hydrothermic vents are found in every ocean. Morel, 8 Tr. 982:25-26. Hydrothermic vents are at different layers of the oceans and allow for the distribution of methylmercury in the ocean. Morel, 8 Tr. 957:10-958:1; 8 Tr. 982:28-983:9; TX 810. There is evidence to show that mercury is methylated in deep ocean hydrothermic vents and spewed into the ocean waters. If hydrothermic vents are the source of methylmercury, then 100 percent of methylmercury in the ocean is naturally occurring. Morel, 25 Tr. 3217:4-11.

245. Dr. Fitzgerald agrees that the input of methylmercury from hydrothermal vents is natural. Fitzgerald, 22 Tr. 2753:8-11; 22 Tr. 2791:24-26. Both Dr. Morel and Dr. Fitzgerald agree that deep ocean vents are a major source of the methylmercury in the oceans. Morel, 25 Tr. 3217:13-19; Fitzgerald, 24 Tr. 3001:13-16. Indeed, according to Dr.

Fitzgerald's calculations, deep ocean vents produce enough methylmercury to account for about four times the amount of methylmercury that bioaccumulates in ocean fish each year. Fitzgerald, 23 Tr. 2946:11-2947:5; TX 544, p. 8.

246. Dr. Fitzgerald continues to research the deep ocean source and has no doubt that deep ocean vents are a source of methylmercury to the ocean. Fitzgerald, 24 Tr. 3014:2-5. According to Dr. Fitzgerald, if hydrothermal systems are the major source of methylmercury in the ocean, then changes in mercury pollution will have little effect on the mercury content of ocean fish. Fitzgerald, 23 Tr. 2947:22-2948:1; TX 544, p. 1.

247. There is substantial evidence to support the hydrothermic vent theory, including research conducted by Dr. Fitzgerald. Prior to this case, Dr. Fitzgerald submitted a grant proposal for federal government funding that provides evidence that methylmercury exists in deep-sea vents. Fitzgerald, 23 Tr. 2946:11-17; TX 544, p. 8. According to Dr. Fitzgerald's analysis in this grant proposal, the amount of methylmercury in the deep-sea vent sample he considered could account for four times the amount of methylmercury in fish. Fitzgerald, 23 Tr. 2946:4-2947:5; Morel, 8 Tr. 958:18-959:2; 8 Tr. 960:6-9; 8 Tr. 964:6-9; TX 544, pp. 1, 8.

248. Additionally, reputable scientists, including Dr. Fitzgerald, have observed that methylmercury and organic mercury compounds exist at deep ocean depths. One study co-authored by Dr. Fitzgerald found that methylmercury and dimethylmercury concentrations increase with depth in samples below the thermocline in the North Atlantic. Fitzgerald, 23 Tr. 2904:10-2905:3; Morel, 8 Tr. 975:6-14; 8 Tr. 976:14-977:15; TX 149, pp. 49-50. This study found very high levels of methylmercury at depths below the thermocline at eleven stations. Morel, 8 Tr. 976:6-13; TX 149, pp. 45, 50. Dr. Fitzgerald now states that one high value he published in TX 149 is mistaken. Morel, 25 Tr. 3232:3-8; Fitzgerald, 22 Tr. 2783:28-2784:14. Outside his opinion in this case, Dr. Fitzgerald has not published anything stating that his measurements are wrong. Morel, 25 Tr. 3234:10-12. Even if this value is excluded, Dr. Fitzgerald still found methylmercury concentrations below 1,000 meters. TX 149, p. 50.

249. Another study by Dr. Fitzgerald in the equatorial Pacific Ocean found methylmercury below the thermocline and that levels increased as the ocean depth increased. TX 146, pp. 1923-24; Morel, 8 Tr. 979:11-13; Morel, 25 Tr. 3224:9-16; Fitzgerald, 22 Tr. 2784:23-25; 23 Tr. 2905:9-12.

250. A third study conducted in the south and equatorial Atlantic Ocean found dimethylmercury below 1,000 meters. Morel, 8 Tr. 980:16-19; 8 Tr. 980:28-981:2; Fitzgerald, 23 Tr. 2922:12-20; TX 165, p. 950. Dr. Fitzgerald has published that higher concentrations of dimethylmercury could result from hydrothermal vents. Fitzgerald, 23 Tr. 2918:5-2919:18; TX 144, p. 83. In this study, the authors also found no methylmercury or dimethylmercury in the mixed layer. Fitzgerald, 23 Tr. 2922:2-5; TX 165, p. 944.

251. Dr. Morel testified that experiments have shown that mercury can be methylated chemically at high temperatures, in conditions similar to those found in hydrothermic vents. Morel, 8 Tr. 960:13-961:10. Dr. Morel also testified about organisms that live in hydrothermic vents. Morel, 8 Tr. 965:20-966:14. According to Dr. Morel, the DNA from these organisms show that they have a methylmercury-resistant gene. *Id.* This evidence is significant because, if these organisms are able to survive in high concentrations of methylmercury, something must detoxify the methylmercury. Morel, 8 Tr. 965:26-966:6.

252. Dr. Fitzgerald also testified that a change is not expected in methylmercury levels in the deep ocean antimora rostrata because there is very little anthropogenic mercury in the deep ocean. Fitzgerald, 23 Tr. 2853:2-7; Morel, 25 Tr. 3181:22.

3. Coastal Sediments Are Not the Source of Deep Ocean Methylmercury

253. To rebut the deep ocean vent theory, Dr. Fitzgerald offered his new coastal theory. According to this theory, mercury is methylated along the coast on the continental shelf and, by some unknown mechanism, is taken out to the open ocean, where the tuna swim and feed. TX 143, p. 2.

254. Dr. Fitzgerald did not publish any papers on the coastal theory until 2004, which was after he was retained by the State to work on this case. *See* TX 421.

a. Dr. Fitzgerald's Coastal Theory is Based on Scientifically Inappropriate Data

255. Dr. Fitzgerald's coastal theory is based solely on mercury measurements from three highly polluted areas: the Long Island Sound, Lavaca Bay, Texas and the Gulf of Trieste. TX 421, pp. 3, 10, 25. The Long Island Sound is located near New York City off the New Jersey coast and is known to be polluted. Morel, 8 Tr. 984:22-24; Fitzgerald, 23 Tr. 2938:21-24.

256. Lavaca Bay is highly polluted with mercury from industrial facilities and is designated a Superfund site. Morel, 8 Tr. 984:25-28; Fitzgerald, 23 Tr. 2942:19-23. The Gulf of Trieste is likewise polluted, and is described as the most mercury-contaminated area in the Mediterranean Sea. Morel, 8 Tr. 985:1-18; Fitzgerald, 23 Tr. 2942:24-28; TX 811, p. 1692.

257. Dr. Fitzgerald acknowledges that the land surrounding the Long Island Sound is heavily populated and has a long history of urbanization and industrial activity. Fitzgerald, 23 Tr. 2870:8-13; *see* TX 850, p. 157. In one Long Island Sound study, Dr. Fitzgerald found that higher measurements of trace metal fluxes corresponded with closer proximity to the pollution source. Fitzgerald, 23 Tr. 2870:14-17; TX 850, p. 157.

258. Despite the highly polluted nature of the Long Island Sound, Dr. Fitzgerald used measurements from the Long Island Sound to project to the coastal areas of the entire world. Fitzgerald, 23 Tr. 2873:12-14; 23 Tr. 2874:10-16; 23 Tr. 2875:4-10; TX 421, p. 10. Dr. Fitzgerald assumed that the areas he sampled off the Long Island Sound are typical of the world's coastal areas. Fitzgerald, 23 Tr. 2938:12-24; 23 Tr. 2941:6-13. However, Dr. Fitzgerald admits that many of the world's coasts do not have heavy population centers like the Long Island Sound. Fitzgerald, 23 Tr. 2943:2-5. Dr. Fitzgerald further admits that he does not have measurements from these less populated areas, but wishes he did. Fitzgerald, 23 Tr. 2943:6-7.

259. In his study, Dr. Fitzgerald measured dissolved methylmercury up to a depth of only thirty meters. Fitzgerald, 23 Tr. 2866:8-15; TX 421, p. 5. Dr. Fitzgerald has never measured methylmercury beyond the continental shelf on the surface waters or at the thirty-meter depth. Fitzgerald, 23 Tr. 2867:2-17.

260. The Court also is concerned with how Dr. Fitzgerald performed his calculations. Dr. Fitzgerald states in TX 421 that ten percent of the ocean is coastal zone, which is based on data in TX 862. TX 421, p. 26. TX 862 states, however, that the coastal area is 7.5 percent of the ocean. TX 862, p. 72. Dr. Fitzgerald admits that his ten percent total includes upwelling in the coastal zone. Fitzgerald, 23 Tr. 2913:9-12. In Dr. Fitzgerald's previous work, he did not include upwelling in the coastal zone. Fitzgerald, 23 Tr. 2911:13-17; TX 861, p. 292.

b. There Is No Method By Which Methylmercury Can Be Transported from the Coastal Zones to the Deep Ocean

261. Dr. Fitzgerald's paper on the coastal theory is silent on the issue of the possible mechanism that could transport methylmercury from the coast to the open ocean. Morel, 9 Tr. 1009:28-1010:6; TX 421. Dr. Fitzgerald now posits several possibilities about the mechanism. One theory is "bioadvection", which refers to water movement. Fitzgerald, 22 Tr. 2769:21-26; 22 Tr. 2772:14-17. Dr. Fitzgerald also postulates that fish could be transporting the methylmercury to the open ocean. Fitzgerald, 22 Tr. 2772:18-22.

i. Bioadvection is Scientifically Improbable

262. It is scientifically improbable that methylmercury moves in the water from the coastal areas to the open ocean. Dr. Fitzgerald's research shows that the amount of methylmercury decreases in the water going away from the coast. Fitzgerald, 23 Tr. 2870:14-17; 23 Tr. 2871:27-2872:4; Morel, 8 Tr. 988:9-21; TX 154, p. 47; TX 421, pp. 13, 25, 26; *see also* TX 850 (discussing other trace metals). Accordingly, the transfer of methylmercury from the coast to the ocean, if any, would not be 100 percent efficient. Morel, 8 Tr. 988:22-989:1. Dr. Fitzgerald does not disagree with Dr. Morel's opinion

(Fitzgerald, 22 Tr. 2773:7-11), and he does not discuss efficiency in his recently published paper on the coastal theory. Morel, 9 Tr. 1011:26-1012:3; TX 421.

263. Moreover, Dr. Morel testified that, based on his studies of trace metals in the ocean, transport of methylmercury from the coast to the open ocean is completely inefficient. Morel, 9 Tr. 1012:4-24. When coastal waters, which are freshwater, mix with the ocean water, the water becomes more buoyant. Fitzgerald, 23 Tr. 2862:13-17. Any methylmercury that is formed in this area would then float in the mixed layer and degrade in the sunlight. Fitzgerald, 23 Tr. 2862:18-23; Morel, 9 Tr. 1120:16-1121:3. Dr. Fitzgerald testified that he has never measured methylmercury or dimethylmercury in the mixed layer beyond the continental shelf. Fitzgerald, 23 Tr. 2890:18-20; 23 Tr. 2891:25-27.

264. It is possible that the methylmercury in the coastal area could sink to depths below the mixed layer. Methylmercury is particle reactive, which means that it reacts to particles and drops to the sediment. Morel, 8 Tr. 882:4-10; Fitzgerald, 23 Tr. 2863:12-16. When a coastal element is attached to a particle and starts to drift and settles, it is unlikely that the element will be transported to the middle of an ocean that is 10,000 to 20,000 kilometers wide. Morel, 8 Tr. 882:9-16.

265. Dr. Morel's testimony about iron undermines the probability that coastal methylmercury is transported to the open ocean. Iron is one of the best-studied trace elements, and studies indicate that the iron in the ocean, away from the coast, comes from the air or from the slow upwelling of deep waters. Morel, 25 Tr. 3171:23-24; 25 Tr. 3172:5-9. Iron is a good indicator to determine whether methylmercury in coastal sediments would appear in the mid-ocean because both iron and methylmercury are soluble and particle-reactive. Morel, 25 Tr. 3170:20-3171:3, 16-17; 25 Tr. 3173:24-27. Iron is a trace metal (like mercury) that is not transported from coastal areas to the deep ocean. Morel, 8 Tr. 853:12-15. There is usually a zero impact from coastal processes on the open ocean. Morel, 8 Tr. 983:15-20; 25 Tr. 3171:18-20. Elements that are particle reactive, including iron and mercury, essentially are eliminated a short distance from the coast. Morel, 25 Tr. 3173:28-3174:7.

266. A large amount of iron exists in the coastal waters of the oceans, and has been shown to flow from rivers. Morel, 8 Tr. 853:8-9; 25 Tr. 3171:5-6. River and coastal materials, such as iron and methylmercury, do not get transported to the middle of the ocean. Morel, 8 Tr. 882:15-16. Indeed, iron does not exist in large amounts in the open ocean. Morel, 8 Tr. 853:10-11; Fitzgerald, 22 Tr. 2773:20-23.

267. Further, over the past twenty years, mercury emissions from China, where there is a large continental shelf, have increased. Morel, 9 Tr. 1028:7-18; Morel, 25 Tr. 3180:13-15; 3181:12-21; TX 153. If methylmercury was being transported from the coast and entering tuna, then the methylmercury levels should have been higher in the 1998 tuna than the 1971 tuna, a contention not established here. Morel, 9 Tr. 1028:21-24.

ii. Tuna Do Not Feed Over the Continental Shelf

268. The continental shelf is an extension of the landmass under the surface of the ocean and has an average breadth is 40 to 50 miles. Joseph, 13 Tr. 1518:2-12. There is no continental shelf around the Hawaiian Islands. Joseph, 13 Tr. 1536:24-26. Based on Dr. Joseph's demonstrated knowledge, the Court finds that Dr. Joseph's testimony on the features of the continental shelf around the world is credible. *See* Joseph, 13 Tr. 1549:17-1551:9.

269. Less than 0.3 percent of the tuna that is canned are caught over the continental shelf of the Eastern Pacific Ocean. Joseph, 13 Tr. 1517:5-22; TX 602. Although there is no comparable information for the Atlantic or Indian Oceans, Dr. Joseph testified that there is no reason to believe that the data from the Eastern Pacific is significantly different for the Atlantic and Indian Oceans. Joseph, 13 Tr. 1573:12-22. According to Dr. Joseph, tuna behave similarly in all the oceans and the commercial fishing industry catches tuna where they swim – if the tuna were swimming over the continental shelf, the fishing industry would catch them there. Joseph, 13 Tr. 1516:24-27; 13 Tr. 1517:23-28; 13 Tr. 1578:23-27. Data regarding average annual yellowfin catches shows a distribution of catches that is similar across the oceans. Joseph, 13 Tr. 1527:11-18; TX 628; TX 629.

270. Most tuna species are caught in the upper mixed layer of the ocean. Joseph, 13 Tr. 1520:15-17. Tuna, including yellowfin, will make dives down several hundred feet to get fish. Joseph, 13 Tr. 1520:18-22; 13 Tr. 1521:10-18. In the Eastern Pacific, the depth of the water where tuna are caught ranges from several hundred meters to several thousand meters, but they are not caught where it is shallow along the coastline. Joseph, 13 Tr. 1522:18-1523:2; 13 Tr. 1524:4-1525:5; TX 602. Again, Dr. Joseph has no reason to believe that tuna would behave differently in other oceans. Joseph, 13 Tr. 1524:10-15.

271. The average depth of the water over the continental shelf around the world is about 130 meters, and not typically more than 200 meters. Joseph, 13 Tr. 1525:16-18. Dr. Joseph presented data that shows that only 0.231 percent of the world's tuna is caught in waters from zero to 200 meters in depth. Joseph, 13 Tr. 1525:19-1526:2; TX 602, p. 5.

272. According to the data, most tuna are caught in the middle of the ocean along the equator. Joseph, 13 Tr. 1527:11-14; TX 628; TX 629. This data demonstrates that the distribution of catches is similar in the Atlantic, Indian and Pacific Oceans. Joseph, 13 Tr. 1527:15-18; 13 Tr. 1529:10-1530:28.

273. Dr. Grubbs does not disagree with Dr. Joseph's figure that less than 0.3 percent of tuna are caught over the continental shelf of the Eastern Pacific. Grubbs, 20 Tr. 2588:17-23.

274. To refute Dr. Joseph's opinion that the 0.3 percent figure applies to the other oceans, the State presented a document to show that the continental shelf is wider in some areas along the Atlantic coast. TX 414. Dr. Grubbs testified that he knows that bluefin tuna are caught over the Western Atlantic continental shelf. Grubbs, 20 Tr. 2589:22-2590:22. However, Dr. Grubbs has no data on actual catches and bluefin tuna are not canned by the Tuna Canners. *Id.*

iii. Prey Fish Do Not Swim From the Continental Shelf to the Open Ocean

275. The Court also heard testimony about whether the prey that tuna eat swim from the coast to the open ocean. According to Dr. Joseph, the major stocks of small prey

fish, such as anchovies and sardines, are mostly found over the continental shelf. Joseph, 13 Tr. 1519:1-5; 13 Tr. 1519:26-1520:3-11. Tuna do not eat much of these smaller fish, which is evidenced by the fact that there is no significant overlap between catches of tuna and the small fish caught over the continental shelf. Joseph, 13 Tr. 1519:17-22; 13 Tr. 1520:3-11. The continental shelf anchovies do not migrate out to the deep ocean. Joseph, 13 Tr. 1537:7-9. The prey fish that tuna eat are found in the upper and middle depths of the ocean. Joseph, 13 Tr. 1523:12-16.

276. There are no mass migrations of prey fish from the continental shelf. Joseph, 13 Tr. 1522:4-13; TX 617. Commercial fishers fish for and catch prey fish over the continental shelf. Joseph, 13 Tr. 1522:7-13. Some prey fish larvae drift out past the continental shelf. Joseph, 13 Tr. 1580:6-21. Even if some larvae drift to the ocean, it is unlikely that tuna eat the larvae because the larvae do not spawn in the areas where tunas swim. Joseph, 13 Tr. 1582:4-7.

277. The State attempted to rebut Dr. Joseph's opinion by showing that one type of anchovy, Encrasicholina punctifer ("E. punctifer"), is a high seas anchovy that is found both on the coasts and the mid-ocean. TX 377; TX 378. TX 377 does not refute Dr. Joseph's opinions because only one type of prey food was involved and was consumed only by skipjack during certain seasons. TX 377, p. 4.

278. TX 378 is an abstract that studied the E. punctifer off the Philippines. TX 378, p. 1. The continental shelf around the Philippines is very narrow and the deep ocean is close to the coast, but the paper does not describe the distance of the coastal region from land. Joseph, 13 Tr. 1613:3-7, 11-14; TX 378.

279. Dr. Grubbs also testified that Dr. Joseph's assertion that there was no connection between the coastal areas and the open ocean was not accurate because the Japanese anchovy is found both at the coast and offshore. Grubbs, 19 Tr. 2504:8-23; TX 416; TX 417. Again, these studies do not refute Dr. Joseph's opinions. Dr. Grubbs agrees that anchovies and sardines are predominately coastal animals. Grubbs, 20 Tr. 2580:16-18. As for the Japanese anchovy, Dr. Grubbs admitted that the eggs and larvae of the anchovies

are pushed out into the offshore area by a current and grow and reproduce into a separate offshore population. Grubbs, 20 Tr. 2583:28-2584:8; *see* TX 417, p. 167. Dr. Grubbs also admitted that the methylmercury in the Japanese anchovy larvae is not detectable and he knows nothing about whether anchovy eggs contain methylmercury. Grubbs, 20 Tr. 2581:27-2582:2; *see also* TX 846, p. 1031. Further, Dr. Grubbs does not know of any papers that discuss mass migrations of sardines or anchovies from the coastal areas to the open ocean. Grubbs, 20 Tr. 2584:23-2585:1.

c. There Is Insufficient Methylmercury Methylated in the Coastal Zones to Support Methylmercury in Ocean Fish

280. Dr. Fitzgerald estimates that, if the world's coastal zone is calculated as ten percent of the world's oceans, then 3.3 nanograms per day of sediment flux (the equivalent of forty-three tons per year) of methylmercury is needed to account for the amount of methylmercury in ocean fish. Fitzgerald, 24 Tr. 2973:9-21; Morel, 9 Tr. 1005:27-1006:4; 9 Tr. 1007:12-17; TX 143, p. 10; TX 813. Dr. Fitzgerald has revised his 3.3 nanograms per day estimate to three nanograms per day. Morel, 9 Tr. 1011:19-25; *see* TX 421, p. 26.

281. If the coastal zone is calculated as 7.5 percent of the world's oceans (which is the proper calculation when upwelling is excluded), then the flux number increases to four nanograms per day. Fitzgerald, 24 Tr. 2973:20-22.

282. The sediment flux from the world's coastal areas to the ocean that Dr. Fitzgerald assumes based on the Long Island Sound data equals 1.8 nanograms per day. Morel, 9 Tr. 1007:8-11; TX 813; TX 421, p. 26. A flux of 1.8 nanograms per day does not account for 3.3 nanograms (or even three nanograms) per day.

III.

CONCLUSIONS OF LAW

PREEMPTION

I. PROPOSITION 65 AND PREEMPTION

1. Californians adopted the Safe Drinking Water & Toxic Enforcement Act of 1986 through its voter initiative process in November 1986 ("Proposition 65"). Proposition 65 prohibits the knowing and intentional exposure to "a chemical known to the state to cause cancer or reproductive toxicity without first giving clear and reasonable warning to such individual, except as provided in section 25249.10." TX 1, p. 1 (Cal. Health & Safety Code § 25249.6).

2. The doctrine of federal preemption is grounded in the Supremacy Clause of the United States Constitution. U.S. Const., art. VI, cl. 2; *Dowhal v. Smithkline Beecham Consumer Healthcare* (2004) 32 Cal.4th 910, 923; *Cipallone v. Liggett Group, Inc.* (1992) 505 U.S. 504, 516.

3. Under the Supremacy Clause, federal law may preempt the enforcement of a state regulation. *Dowhal*, 32 Cal.4th at 923. Similarly, Proposition 65's warning requirement does not apply "to exposure for which federal law governs warning in a manner that preempts state authority." TX 1, p. 4 (Cal. Health & Safety Code § 25249.10(a)).

4. Federal law will preempt the enforcement of a state regulation in several circumstances: (1) where Congress expressly intends to preempt state law; (2) where Congress has, by implication, intended to occupy the entire field of regulation; and (3) where there is conflict preemption. *Capital Cities Cable, Inc. v. Crisp* (1984) 467 U.S. 691, 698-99. Only conflict preemption is relevant in this case.

5. Conflict preemption exists when state law actually conflicts with federal law. *Dowhal*, 32 Cal.4th at 923. Conflict preemption exists in two situations: (1) when "'under

the circumstances of [a] particular case, [the challenged state law] stands as an obstacle to the accomplishment and execution of the full purposes of Congress'"; or (2) when it is impossible for a private party to comply with both federal and state law. *Crosby v. National Foreign Trade Council* (2000) 530 U.S. 363, 372. Here, both circumstances exist, therefore justifying federal conflict preemption.

6. The authority of the federal government to regulate the packaging and labeling of goods shipped in interstate or foreign commerce has been established. Any state statute that interferes with or frustrates a federal interstate commerce interest "must yield" to the "superior" federal power. *McDermott v. Wisconsin* (1913) 228 U.S. 115, 131-132. (Federal labeling requirement trumps Wisconsin regulations regarding terms on a package label.) This preemption authority over the content of food product labels arises not only when dealing with a federal statute. Reasonable exercise of the FDA discretion is equally preemptive. *Grocery Manufacturers of America Inc. v. Gerace* (2d.Cir 1985) 755 F.2d 993, 999. Federal regulations and appropriate agency determinations have no less preemptive effect than federal statutes. *Blum v. Bacon* (1982) 457 U.S. 132, 145-146.

7. Recently, the California Supreme Court held that when the State's warning requirement directly conflicts with the one that the FDA requires, the federal warning requirement prevails. *Dowhal*, 32 Cal.4th. at 929. In *Dowhal*, the Supreme Court opined that the FDA is the expert agency in nonprescription consumer protection. *Id.* at 934. Furthermore, the court reiterated the longstanding view that FDA has the authority to bar any warning that is misleading or any warning that conflicts with *its* consumer protection policies. *Id.*

8. In this case, the FDA issued a letter to the Attorney General of the State of California expressly stating that the "agency believes California cannot legally require the Proposition 65 warnings on tuna products because they are preempted under federal law, for two principal reasons." TX 727, p. 6. First, Proposition 65 warnings frustrate FDA's "carefully considered" approach with regard to methylmercury in tuna. *Id.* Second, a Proposition 65 warning omits facts that are necessary to place the information in context and

are therefore misleading and misbranding. *Id.* In other words, FDA's Letter informed the State of California that its Proposition 65 warning requirement for canned tuna conflicted with FDA's federal policy. TX 727, p. 6.

9. Like the FDA action in *Dowhal*, the FDA letter to the State Attorney General serves as an informal agency action, communicating FDA's position that Proposition 65 frustrates the purpose of FDA's carefully considered approach. *Id.*; *Dowhal*, 32 Cal.4th. at 929. Consistent with case precedent on this issue, this Court concludes that the FDA Preemption Letter should be accorded deference. *See Dowhal*, 32 Cal.4th at 928 (holding that FDA's letter to nicotine replacement therapy ("NRT") manufacturers was sufficiently definite and authoritative to be given deference). *See also Geier*, 529 U.S. at 883-84 (holding that comments by Department of Transportation accompanying its revision of the airbag rules and in statements in the Solicitor General's brief submitted on the agency's behalf should be accorded deference). The Supreme Court acknowledged the consequence of federal regulatory action like that in Dowhal and *Geier* when it quoted the latter decision: "Congress has delegated to the DOT (Department of Transportation, the regulatory agency in issue) authority to implement the statute; the subject matter is technical; and the relevant history and background are complex and extensive. The agency is likely to have a thorough understanding of its own regulation and its objectives and is '*uniquely qualified*' to comprehend the likely impact of state requirements." *Dowhal* 32 Cal.4th at 925, *citing Geier* 529 U.S. at 883 (emphasis added).

10. The *Dowhal* Court found that the FDA warning for NRT products served a "nuanced goal" of "inform[ing] pregnant women of the risks of NRT products, but in a way that will not lead some women, overly concerned about those risks, to continue smoking." *Dowhal*, 32 Cal.4th at 935. In so doing, the Court held that "[t]his [policy] creates a conflict with the state's more single-minded goal of informing the consumer of the risks." *Id.*

11. Similarly, the FDA/EPA 2004 Advisory in the present case serves a nuanced goal of informing pregnant women of the risks of methylmercury in tuna, but in a way that will not lead some women, overly concerned about those risks, to stop eating tuna altogether.

According to Dr. Sullivan and especially Dr. Beard, medical professionals do implement these advisories in their practice treating pregnant women. Likewise, this policy creates a conflict with the state's more single-minded goal of informing the consumer of the risks of eating tuna according to Proposition 65. Application of *Dowhal* in this case is fairly straightforward: California's Proposition 65, which is concerned exclusively with informing consumers of the risks of eating canned tuna, conflicts with FDA's carefully considered approach of informing consumers of the benefits *and* risks of eating canned tuna. Therefore, federal preemption is applicable here.

12. In sum, conflict preemption exists in this case because (1) Proposition 65 stands as an obstacle to the accomplishment and execution of the full purposes of Congress as bestowed upon the FDA according to the FDCA; and (2) it is impossible for the Tuna Canners to comply with the FDA/EPA 2004 Advisory as well as Proposition 65's warning requirement. Therefore, FDA's general policy of informing consumers about the benefits and risks of eating tuna, pursuant to the FDCA, preempts California's Proposition 65 with regard to methylmercury in tuna. "Conflict preemption does not require a direct contradiction between state and federal law. State law is preempted if state law stands as an obstacle to the accomplishment and execution of the *full purpose* and *objectives* of Congress." *Dowhal, supra* at 929.

II. BURDEN OF PROOF

13. The Tuna Canners have the burden of proof to establish their preemption defense. TX 1, p. 4 (Cal. Health & Safety Code § 25249.10(a)); Evid. Code §§ 115, 500; *see also Bronco Wine Co. v. Jolly* (2004) 33 Cal.4th 943, 956.

14. The standard of proof is the preponderance of the evidence. Evid. Code § 115; *Baxter Healthcare Corp. v. Denton* (2004) 120 Cal.App.4th 333, 365-66. The preponderance of the evidence standard requires the trier of fact to believe that the existence of a fact is more probable than its nonexistence. *Lillian F. v. Superior Court* (1984) 160 Cal.App.3d 314, 320.

15. The Tuna Canners have the initial burden of producing evidence to prove their preemption defense. Evid. Code § 550; *Mathis v. Morrissey* (1992) 11 Cal.App.4th 332, 346. The burden of production shifts to the State if the Tuna Canners provide evidence of such weight that a determination in the Tuna Canners' favor would necessarily be required in the absence of contradictory evidence. Evid. Code § 550.

16. Prior to trial, the Tuna Canners met their burden to establish preemption as a defense through their motion for judgment on the pleadings filed on August 25, 2005. However, the Court deferred ruling on the Tuna Canners' motion and allowed the State to produce evidence that a Proposition 65 warning can coexist with federal law and policy. The State had the opportunity to present warnings that are consistent with federal law and Proposition 65, but failed to do so, for the reasons developed earlier in this opinion.

17. This Court concludes that the Tuna Canners have met their burden of proof on the preemption defense. The Tuna Canners proved by a preponderance of the evidence that (1) any Proposition 65-compliant sign conflicts with federal law and policy both as to the message that should be conveyed to consumers about fish consumption, and as to the manner in which that message is to be conveyed; (2) the Griffin Shelf Sign and Griffin Can Label conflict with federal law and policy both as to the message that should be conveyed to consumers about fish consumption, and as to the manner in which that message is to be conveyed; (3) the PMC Campaign is too indefinite to be enforced, as it is nothing but a vague and unformed concept that requires constant court supervision and intervention in a manner unsupported by any authority; and (4) the FDA/EPA Advisory cannot be ordered as a Proposition 65 warning without conflicting with federal law and policy as to the manner in which the message concerning fish consumption is to be conveyed to consumers.

18. This Court concludes that the State did not produce evidence sufficient to rebut the Tuna Canners' evidence supporting preemption. Specifically, the State did not and indeed cannot present to the Court a Proposition 65-compliant sign that coexists with federal law and policy. The State also failed to sufficiently address the Court's concerns regarding the FDA Preemption Letter. *See* TX 727, p. 6. Even in the face of *Geier* and *Dowhal*, the

State argued that the FDA letter is not entitled to deference under the law. *See Geier*, 529 U.S. at 883; *Dowhal*, 32 Cal.4th at 928-29. Moreover, the State failed to sufficiently distinguish its case from our Supreme Court's decision in *Dowhal*, which found that Proposition 65 is preempted by FDA authority for warnings on NRT products. *See Dowhal*, 32 Cal.4th 910.

III. THE FDA PREEMPTION LETTER IS ENTITLED TO DEFERENCE

19. A federal agency's own views respecting whether a state law conflicts with federal law it administers are to be accorded *substantial* deference. *Sprietsma v. Mercury Marine* (2002) 537 U.S. 51, 67-68. FDA's views on labeling merit particular respect. *Henley v. FDA* (2d Cir. 1996) 77 F.3d 616, 620 ("FDA's determination of what labeling best reflects current scientific information regarding the risks and benefits" of an FDA-regulated product "involves a high degree of expert scientific analysis.") FDA expertise applies to warnings that should be given, as well as to those that should not. *Brooks v. Howmedica, Inc.* (8th Cir. 2001) 273 F.3d 785, 796. Our appellate courts have adopted the principle that federal agency action is no less preemptive than federal statutes when the agency is carrying out authority substantiated by Congressional statute. *Lopez v. World Savings & Loan* (2003) 105 Cal.App.4th 729, 736-737. See also *Fidelity Federal v. DeLaCuesta* (199) 458 U.S. 141, 153.

20. On several instances, the Supreme Court has focused on the specific position of the *federal* agency *vis a vis* the state or local statute. If the agency position clearly reflects a stand that challenges the state's conflicting yet specific requirement, then finding preemption is more likely appropriate. On the other hand, a more generalized *federal* pronouncement may not support preemption. This important legal distinction in the nature of the federal agency position was acknowledged cogently by Justice Marshall:

> [B]ecause agencies normally address problems in a detailed manner and can speak through a variety of means, including regulation, preambles, interpretive statements, and responses to comments, we can expect that they will make their intentions clear if they intend for their regulations to be exclusive. Thus, if an agency does not speak to the question of preemption,

> we will pause before saying that the mere volume and complexity of its regulations indicate that the agency did in fact intend to pre-empt. *Hillsborough County v. Automated Medical Laboratories Inc.* (1985) 471 U.S. 707, 718.

In *Hillsborough County*, the FDA had not challenged the position of the county directly on the particular issues raised in a local regulatory scheme on plasma centers in the county. On the other hand, here the FDA's letter to the Attorney General explicitly advises that Proposition 65 warnings are preempted because they are contrary to the FDA advisories and FDA policies regarding fish consumption. Here the "intentions" of the FDA are crystal clear, not dependent on "mere volumes of regulations." As another court noted, "Unlike general federal requirements, . . the warning requirements here reflect the sort of concerns regarding a specific device *or field of device regulation* which the regulations were designed to protect from potentially contradictory state requirements. This then is a case in which the Federal Government has weighed the competing interests relevant to the particular requirements in question, reached an unambiguous conclusion about how those competing interests should be resolved in a particular case or set of cases, and implemented that conclusion via a specific mandate on manufacturers or producers." *Papike v. Tambrands Inc.* 107 F.3d 737, 741 (9th.Cir. 1997)(emphasis added.)

21. The Court finds that FDA makes clear in the Preemption Letter that Proposition 65 warnings on tuna products are preempted for three reasons: (1) Proposition 65 warnings frustrate FDA's carefully considered approach to advising the public concerning the benefits and risks of consuming canned tuna; (2) point of purchase warnings conflict with FDA's longstanding opposition to warning signs in connection with the sale of food, and (3) Proposition 65 warnings conflict with federal law because such warnings on canned tuna would be misleading under section 403 of the FDCA (21 U.S.C. § 343). TX 727, p. 6.

22. In crafting its opinion letter, FDA drew from its extensive experience regulating food labels, administering the FDCA, evaluating the benefits of fish consumption, studying the issue of methylmercury in fish, and creating fish advisories. TX 727, p. 2. FDA's opinion was guided by similar considerations in the *Dowhal* and *Geier* cases, where the Court found conflict preemption.

23. As discussed above, in *Dowhal*, FDA drew upon its expertise to develop a message that balances the benefits and risks of NRT products, and determined that any Proposition 65-compliant warning for NRT would render the product misbranded. 32 Cal.4th 910, 928-931. The court allotted significant deference to the FDA's informal letter to the defendant NRT companies, which established a federal policy prohibiting defendants from giving consumers any warning other than the one approved by the FDA. *Id.* at 929.

24. In *Geier*, the court concluded that the Department of Transportation's interpretation of its safety standard should be accorded deference. *Geier*, 529 U.S. at 881. FDA's policy is similar to the Department of Transportation's in *Geier* and should be accorded similar deference here where (1) Congress delegated authority to FDA to implement the FDCA; (2) the subject matter is technical and complex; (3) FDA likely is uniquely qualified to understand and explain its own regulations and the impact of state requirements; and (4) FDA has explained the failings of warnings on food and has adhered consistently to the advisory approach in addressing the methylmercury in fish issue. *Id.*

25. The Preemption Letter states that any canned tuna warning that complies with Proposition 65 conflicts with federal law and is therefore preempted. TX 727, p. 1. In *Dowhal*, the Court held that:

> "[A]ny warning that conformed in substance to the FDA's warning would not comply with Health and Safety Code section 25249.6 because it would not provide clear and reasonable warning to the consumer that the product contained a chemical 'known . . . to cause . . . reproductive toxicity.' Thus, the FDA determination has effectively barred all warnings on labels that comply with Proposition 65."

32 Cal.4th at 928-29. Here, FDA's determination that any canned tuna warning that contains the core and mandatory language is preempted is likewise entitled to deference. *Id.*; *see also Geier*, 529 U.S. at 881.

26. It is immaterial that the Preemption Letter does not constitute formal agency action. The formality of a regulation or advisory opinion is not required for a governmental agency action to be afforded deference. *Geier*, 529 U.S. at 881. Informal agency action taken pursuant to congressionally granted authority can preempt state law. *Geier*, 529 U.S. at 884-85 (stating that "the Court has never before required a specific, formal agency statement identifying conflict in order to conclude that such a conflict exists."); *Bank of America v. City of San Francisco* (9th Cir. 2002) 309 F.3d 551, 563-64 (finding conflict preemption based on interpretation of national bank powers set forth in an amicus brief and two interpretative letters); *Dowhal*, 32 Cal.4th at 929 (finding preemptive intent in a FDA letter establishing its policy regarding FDA-approved warnings); *see also Auer v. Robbins* (1997) 519 U.S. 452, 462 (stating that a department's interpretation of its regulations in the form of a legal brief did not "make it unworthy of deference" and that "[t]here is simply no reason to suspect that the interpretation does not reflect the agency's fair and considered judgment on the matter in question.").

27. The Court also finds that it is irrelevant that a preemption letter was requested by the tuna industry. The Tuna Canners have a First Amendment right to petition the government. *United Mine Workers of America, Dist. 12 v. Ill. St. Bar. Assoc.* (1967) 389 U.S. 217, 222 (stating that the right to petition the government is "among the most precious of the liberties safe-guarded by the Bill of Rights.") Moreover, the Preemption Letter reflects FDA's own detailed reasoning process and is consistent with all actions FDA has taken with respect to mercury and fish consumption.

IV. PROPOSITION 65 AS APPLIED TO TUNA STANDS AS AN OBSTACLE TO THE ACCOMPLISHMENT AND EXECUTION OF THE PURPOSES AND OBJECTIVES OF CONGRESS

28. A state law:

> "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress – whether the 'obstacle' goes by the name of 'conflicting; contrary to; . . . repugnance; difference; irreconcilability; inconsistency; violation; curtailment; . . . interference,' or the like."

Geier, 529 U.S. at 873 (quoting *Hines v. Davidowitz* (1941) 312 U.S. 52, 67).

29. "What is a sufficient obstacle is a matter of judgment, to be informed by examining the federal statute as a whole and identifying its purpose and intended effects . . ." *Crosby*, 530 U.S. at 373. The Court examines the entire scheme of the federal law and whether state law would frustrate its purpose and operation. *Hines*, 312 U.S. at 67.

30. FDA made clear that Proposition 65-compliant warnings for canned tuna would "frustrate the carefully considered federal approach to advising consumers of both the benefits and the possible risks of eating fish and shellfish" and would communicate a risk to all consumers, not just the target audience of women of child-bearing age. TX 727, pp. 1-2. Further, the proposed means of communicating the message – through a point-of-purchase warning – contradicts federal policy. *Id.* A warning sign that refers to fish and shellfish, which would reduce consumption of all seafood (Cohen, 7 Tr. 808:6-809:24), directly contradicts federal policy. *See Dowhal*, 32 Cal.4th at 934-35.

31. Proposition 65-compliant warnings, which communicate only risks, conflicts with FDA's emphasis on communicating benefits first. This conflict is the same conflict found in *Dowhal*, where the Supreme Court held that FDA's nuanced goal to balance benefits and risks conflicts with Proposition 65's more single-minded goal of informing the consumer of the risks. 32 Cal.4th at 934-35.

32. Further, a Proposition 65 warning creates the danger of overexposing consumers to warnings, which could result in consumers ignoring all such statements. TX 727, p. 2. FDA's policy is to warn only in exceptional circumstances so as not to create a greater health problem. *Id.*; *see also* 71 Fed. Reg. 3921, 3922, 3925.

33. The Griffin Shelf Sign conflicts with FDA policy because it adheres to Dr. Griffin's avowed goal of simplifying the complex message of the FDA/EPA Advisory, necessarily conflicting with FDA's carefully constructed message. *See Dowhal*, 32 Cal.4th at 930 (stating that "[t]he complexity of the data regarding exposure to nicotine during pregnancy and the relative risks of smoking versus use of NRT products are not easily translated into consumer friendly language on an OTC package.")

34. Likewise, FDA has taken a nuanced approach concerning the message and method of communicating the issue of methylmercury in fish. TX 727, p. 6. FDA's deliberate and careful approach contrasts starkly with Dr. Griffin's hurried construction, based upon no experience with warning signs or health advisories. TX 727, p. 3; *see also Dowhal*, 32 Cal.4th at 934.

35. The FDA/EPA Advisory cannot be used as a point-of-purchase Proposition 65 warning, if indeed the State is suggesting that the Advisory be posted in stores. *See, e.g., Dowhal*, 32 Cal.4th at 929. The FDA made it clear that the method of communication is as important as the content of the message. Even if the advisory were to be provided verbatim in grocery stores, this method of distribution would conflict with federal policy on food warnings and warnings for canned tuna. Sullivan, 14 Tr. 1777:3-6; 14 Tr. 1778:25-28; 14 Tr. 1779:1-8; TX 727. Moreover, a blended warning, containing aspects of both the FDA/EPA Advisory and Proposition 65 language is likewise impermissible. *Dowhal*, 32 Cal.4th at 928-29.

V. IT IS IMPOSSIBLE FOR THE TUNA CANNERS TO COMPLY WITH BOTH FEDERAL LAW AND PROPOSITION 65

36. When it is impossible to comply with both a state and federal law, the state law is preempted. *Dowhal*, 32 Cal.4th at 934-35. The Court finds that the Tuna Canners cannot comply with Proposition 65 without rendering their products misbranded under federal law.

37. Section 403 of the FDCA prohibits misbranding of food products. 21 U.S.C. § 343. Section 343(a)(1) provides that food is misbranded if its labeling is false or

misleading. 21 U.S.C. § 343(a)(1). A label is "misleading" if the labeling fails to reveal facts material with respect to consequences that may result from the use of the article of food. 21 U.S.C. § 321(n).

38. Every Proposition 65 warning must contain the language "this product contains a chemical known to the state of California to cause birth defects or other reproductive harm", or words to that effect. *Dowhal*, 32 Cal.4th at 918. This is the core and mandatory language.

39. FDA's position is that any Proposition 65-compliant warning conflicts with federal law because the warning necessarily overstates the risks of eating canned tuna by taking them out of context and failing to state any health benefits. TX 727, p. 6. Any Proposition 65-compliant warning omits facts that are necessary to place the information in proper context. *Id.* The Preemption Letter makes clear that any Proposition 65-compliant warning conflicts with federal law because it does not state "any scientific basis as to the possible harm caused by the particular foods in question, or as to the amount of foods that would be required to cause such harm." TX 727, p. 6.

40. The FDA/EPA Advisory recommends consuming fish and shellfish as part of a healthy diet. TX 727, p. 1. The advisory also contains recommended amounts of canned tuna that should be consumed. *Id.* A Proposition 65-compliant warning does not contain this language. In contrast, such a warning effectively asserts that eating canned tuna – no matter the amount – causes birth defects or other reproductive harm. This statement is false, and therefore misleading, under the FDCA because it fails to reveal material facts – namely, the health benefits of tuna – with respect to consequences that may result from the use of the article of food. *See* 21 U.S.C. § 321(n). Further, the very fact that a warning sign would be posted in stores for a healthy product that the federal government encourages people to eat makes the sign misleading. The gravity of the mercury issue would be overstated and thus the sign, by virtue of its prominent placement, would be misleading.

41. Whether the Griffin Shelf Sign is misleading does not depend on it being easy to understand. This is irrelevant under federal law. *See Dowhal*, 32 Cal.4th at 931 (finding

that FDA has authority to prohibit truthful statements on a product label if they are "misleading.") The *Dowhal* Court rejected the argument that a literally truthful statement could not be preempted. 32 Cal.4th at 931 (finding that even a truthful warning can be misleading if the words are not stated in "such a manner and form, as are necessary for the protection of users."). *32 Cal.4th at 931 (citing 21 U.S.C. § 352(a))*. Thus, even a truthful shelf sign misleads consumers if it is not consistent with FDA's carefully considered approach. *Id.* In the instant case, the Griffin Shelf Sign is not consistent with FDA's targeted informational approach as evidenced in its 2004 FDA/EPA Advisory. Tx. 727.

42. For the foregoing reasons, this Court concludes that federal law and policy promulgated by the FDA preempts Proposition 65 warnings for canned tuna products.

VI. THE STATE'S PROPOSED WARNING FAILS TO COMPLY WITH PROPOSITION 65

43. No published cases have interpreted the language of Section 12601.

44. The State's proposed warning – the Griffin Shelf Sign – deliberately fails to comply with Proposition 65. Any Proposition 65-compliant sign "must clearly communicate that the chemical in question is known to the state to cause . . . birth defects or other reproductive harm. TX 2, p. 196 (22 CCR § 12601); *Ingredient Communications Council, Inc. v. Lungren* (1992) 2 Cal.App.4th 1480, 1486 ("ICC") (stating that "The message must clearly communicate that the chemical in question is known to the state to cause cancer, or birth defects or other reproductive harm. . . ." (italics in original)). This core language is mandatory in any warning. *Dowhal*, 32 Cal.4th at 918 (stating that "to conform to Proposition 65, defendants' products must carry a warning that 'this product contains nicotine, a chemical known to the state of California to cause reproductive harm,' or words to that effect.")

45. The Proposition 65 warning requirement does not exist in a vacuum, where "clear and reasonable" has a meaning independent of the statute. But the State's position is that "clear and reasonable" can be determined through an Internet survey and confirmed by a marketing professor. There is no support in Section 12601 for the State's argument that

Dr. Griffin's opinion that "clear" means "easy to process" and "easy to find." Indeed, Dr. Griffin did not test whether the core and mandatory language was clear and reasonable.

46. The Court concludes that the Griffin Shelf Sign is not Proposition 65 compliant. First, there is no support for the State's position that it can add to the core and mandatory language. Only businesses – such as the Tuna Canners – not the State and not the Court – can add to the core language. TX 2, p. 196 (22 CCR § 12601(a)). The FSOR for Section 12601 states that the prerogative to provide *additional* language belongs to the business:

> One commentator recommended allowing business to include additional information along with the basic statements set out in the 'safe harbor' provisions (citation omitted). This is allowed under subsection (a). A business may utilize the appropriate 'safe harbor' language and include other truthful and accurate information. While it would not comply with the 'safe harbor' and, therefore, be deemed clear and reasonable, it may still satisfy the requirements of the Act.

FSOR, p. 5 (RJN, Ex. A).

47. Second, the Griffin Shelf Sign is not Proposition 65-compliant because it adds language to the core message that dilutes the actual warning and makes it too cumbersome to read and understand. See 11 CCR 3202(b)) (stating that "certain phrases or statements in warnings are not clear and reasonable such as ... (2) additional words that contradict or obfuscate otherwise acceptable warning language.") The FSOR also acknowledges that Proposition 65 warnings are not intended to require any information other than the clear and reasonable language and that such language might pollute the mandatory Proposition 65 warning. The FSOR states:

> [i]f the exposed individual desires information about the chemical, it appears preferable that the information be obtained from the party responsible for the exposure after the warning, rather than through the warning. Otherwise the warning may become visually too congested and cumbersome to read and understand.

FSOR, p. 1 (RJN, Ex. A.)

48. The Griffin Shelf Sign actually buries the warning at the bottom of the page, positioned in a place that could cloud the warning message, and that Dr. Griffin himself

acknowledged would likely never be read. Griffin 6 Tr. 693:10-14; 6 Tr. 720:10-20; TX 365A.

49. Third, as Dr. Griffin testified, the Attorney General did not want Dr. Griffin to use the core and mandatory language in the sign. Griffin, 6 Tr. 678:25-679:10; 6 Tr. 682:15-685:13. Dr. Griffin's directive was to translate the FDA/EPA Advisory and make it more concise. Griffin, 6 Tr. 616:9-12; 6 Tr. 699:27. As directed, and in contravention of section 12601, Dr. Griffin did not include the core and mandatory language in his sign – "this product contains a chemical known to the state of California to cause birth defects or other reproductive harm." TX 365A. The sign does not include the word "Warning." Id. Instead, it is titled an advisory. Id. Finally, the sign does not mention the State of California. Id.; see FSOR, p. 25 (RJN, Ex. A) (stating that "the reference to the 'State of California' [in a warning] is intended to lend authority to the warning message and is an important part of it.") Even if the words "Warning" and "State" can be eliminated from a Proposition 65 warning, the Griffin Shelf Sign does not contain the core and mandatory language. Accordingly, it is not Proposition 65-compliant.

MADL

I. APPLICABLE STATUTORY PROVISIONS AND REGULATORY BACKGROUND

50. Proposition 65 is codified at Health & Safety Code sections 25249.5-25249.13. Pursuant to section 25249.6:

> *Required Warning Before Exposure to Chemicals Known to Cause Cancer or Reproductive Toxicity*. No person in the course of doing business shall knowingly and intentionally expose any individual to a chemical known to the state to cause cancer or reproductive toxicity without first giving clear and reasonable warning to such individual, except as provided in Section 25249.10.

TX 1, p.1 (Cal. Health & Safety Code § 25249.6).

51. The California Health and Safety Code section 25249.10(c) provides that:

> *Exemptions from Warning Requirement*. Section 25249.6 shall not apply to:

> (c) An exposure for which the person responsible can show that the exposure poses no significant risk assuming lifetime exposure at the level in question for substances known to the state to cause cancer, and that the exposure will have no observable effect assuming exposure at one thousand (1000) times the level in question for substances known to the state to cause reproductive toxicity, based on evidence and standards which form the scientific basis for the listing of such chemical pursuant to subdivision (a) of Section 25249.8. In any action brought to enforce Section 25249.6, the burden of showing that an exposure meets the criteria of this subdivision shall be on the defendant.

TX 1, p. 4-5 (Cal. Health & Safety Code § 25249.10(c)).

52. The regulations implementing Proposition 65 are found in Title 22 of the California Code of Regulations section 12000 *et seq.* The following sections are particularly applicable to the identification of the NOEL for methylmercury and the calculation of the MADL for methylmercury:

- Section 12801(a) outlines the general framework for establishing the NOEL under Proposition 65, and mandates that the NOEL shall be divided by one thousand (1,000) to arrive at an MADL. TX 2, p. 200.4.
- Section 12803 sets out the "safe harbor" method for preparing a quantitative risk assessment to calculate a NOEL for a listed chemical. Under section 12803(a)(1) "only studies producing the reproductive effect which provides the basis for the determination that a chemical is known to the state to cause reproductive toxicity, shall be utilized for the determination of the NOEL." Sections 12803(a)(2) & (3) lists the factors to consider when considering the suitability of using a toxicology study in a risk assessment. TX 2, p. 200.5.
- Section 12803(a)(2) states that "animal bioassay studies shall meet generally accepted scientific principles, including the thoroughness of experimental protocol, the degree to which dosing resembles the expected manner of human exposure, the temporal exposure pattern, the duration of the study, the purity of the test material, the number and size of exposed groups, and the route of exposure and the extent of occurrence of effects."

- Section 12803(a)(3) states that the "quality and suitability of available epidemiological data shall be appraised to determine whether the study is appropriate as the basis of an assessment considering such factors as the selection of exposed and reference groups, the reliable ascertainment of exposure, and completeness of follow-up. Biases and confounding factors shall be identified and quantified."
- Under Section 12803(a)(4), only the most sensitive study deemed to be of sufficient quality can be used for establishing a NOEL. TX 2, p. 200.5.
- Section 12803(a)(7) provides that where data in the most sensitive study deemed to be of sufficient quality do not allow for the determination of a NOEL, a NOEL may be derived by dividing the LOEL by a factor of 10. TX 2, p. 200.5.
- Section 12803(b) mandates that a NOEL shall be converted to a milligram per day dose level by multiplying the assumed human body weight by the NOEL. It also mandates that when the applicable reproductive effect is upon the fetus, a human body weight of 58 kg shall be assumed. TX 2, p. 200.5.

53. Section 12821 of the California Code of Regulations, entitled "Level of Exposure to Chemicals Causing Reproductive Toxicity," outlines the required procedures for calculating exposure to methylmercury in canned tuna. TX 2, p. 200.6.

II. BURDEN OF PROOF

54. The Tuna Canners have the burden of proof to establish that the Tuna Canners' products are below the MADL for methylmercury. TX 2, p. 200.5 (Cal. Health & Safety Code § 12803); Evid. Code §§ 115, 500. The standard of proof is the preponderance of the evidence. Evid. Code § 115; *Baxter Healthcare Corp. v. Denton* (2004) 120 Cal. App. 4th 333, 365-66. Preponderance of the evidence means evidence that, when weighed with that opposed to it, has more convincing force and the greater probability of truth. *Leslie G. v. Perry & Assocs.* (1996) 43 Cal. App. 4th 472, 483. The Court finds that the Tuna Canners have met their burden of proving the following:

A. The Tuna Canners' Risk Assessment Complies with Section 12803

55. A risk assessor calculating a NOEL under sections 12803 is required to select the study producing the lowest NOEL from the most sensitive study deemed to be of sufficient quality. TX 2, p. 200.5 (Cal. Health & Safety Code § 12803(a)(4)). Because Proposition 65 is concerned with chemicals that cause reproductive toxicity, suitable studies under section 12803 must evaluate prenatal exposure to a chemical. The Court finds that the Tuna Canners' risk assessment prepared by their expert, Dr. Murray, complies with section 12803 for the following reasons:

56. The Bornhausen study was properly selected as the study that produced the lowest NOEL from most sensitive study deemed to be of sufficient quality under section 12803(a)(1) and (4).

57. The Bornhausen study researchers maintained the purity of the test material and the route of exposure under § 12803(a)(3) by controlling the rats' methylmercury exposure to a carefully defined oral dose through a gavage administration. The use of four separate groups, including one control group, ensured that the researchers could accurately observe the postnatal effects of prenatal exposure to varying levels of methylmercury. OEHHA's reliance on the Bornhausen study to prepare the draft MADL in 1993 lends additional support to the suitability of the Bornhausen study under section 12803. Likewise, the fact that the Burbacher study calculated the same NOEL as the Bornhausen study confirms the reliability of the Bornhausen study under section 12803.

58. The State's primary objection to the suitability of the Bornhausen study under section 12803 was directed at its use of rats, rather than human, subjects. The Court rejects this argument because the statute specifically contemplates the use of animal bioassay studies to calculate a NOEL. TX 2, p. 200.5 (Cal. Health & Safety Code § 12803(a)(3)). Aside from its objection to the use of animal studies, the State did not present any persuasive evidence undermining the thoroughness of the experimental protocol used in the Bornhausen study, the degree to which dosing resembled the expected manner of human exposure, the

temporal exposure pattern, the duration of the Bornhausen study, the number and size of the four groups used in the Bornhausen study, or the extent of occurrence of effects.

59. The Court finds that the additional calculation performed by Dr. Rice to convert the Burbacher NOEL, which was identical to the Bornhausen NOEL, to a human NOEL was improper under section 12803. Section 12803 does not require adjustments to NOELs derived from animal studies, nor are there any guidelines in the regulations governing calculations to adjust an animal NOEL to a human NOEL. Indeed, OEHHA has used animal studies for *every* published MADL except for lead and ethylene oxide, and has *never* adjusted an animal LOEL or NOEL to a human NOEL. The OSHA PELs used for the lead and ethylene oxide MADLs have NOEL surrogates, and therefore comply with section 12803.

60. The Court finds that Dr. Rice improperly relied on the Faroe Islands study to calculate a NOEL for methylmercury under section 12803. The suitability of epidemiological studies under section 12803(a)(2) requires that a study have exposed and reference groups. TX 2, p. 200.5 (Cal. Health & Safety Code § 12803(a)(2)). The Faroe Islands study had neither. The Faroe Islands researchers were also unable to obtain reliable ascertainments of exposure to methylmercury because they did not document the amount of methylmercury consumed by the pregnant women. The Faroe Islands study also failed to measure pre- and postnatal exposure to PCBs and DDT, and to account for the confounding effects that exposure to these chemicals will have on the results of the Boston Naming Test. The Faroe Islands study did not identify and quantify confounding factors and did not have complete follow-up of all children in the study. The Court is particularly troubled by the fact that when the researchers controlled for PCB exposure, there was no statistically significant correlation between methylmercury and performance on the Boston Naming Test, which served as the basis for Dr. Rice's MADL.

61. The Court also finds that the State improperly relied on a BMD from the Faroe Islands study as a substitute for a NOEL or a LOEL under section 12803. The benchmark dose calculations of Dr. Rice that seek to model a dose response relationship do

not cure this defect with the Faroe Islands study, nor do they provide the necessary "reliable ascertainment of exposure" that is required under section 12803(a)(2). Proposition 65 requires a NOEL or LOEL to establish an MADL, and the BMDs are not the same as for a NOEL or a LOEL. The BMD is not a surrogate for a NOEL or LOEL. An MADL cannot be established on the basis of a BMD. Based on the foregoing, the Court finds that it is improper to rely on the Faroe Islands study and a BMD to calculate a NOEL for methylmercury under section 12803. The Court notes that the impropriety of using a BMD analysis as the basis for an MADL is highlighted by Dr. Rice's calculating virtually the same MADL from the Seychelles Islands study as she did from the Faroe Islands study, even though the Seychelles study found no adverse effects from methylmercury exposure.

62. Based on Dr. Murray's calculations and his testimony, and rejecting Dr. Rice's proposed MADL, the Court finds that the NOEL for methylmercury under section 12803 is 0.005 mg/kg/day, and that the MADL for methylmercury is 0.3 micrograms/day.

B. The Level of Exposure to Methylmercury Is Below the MADL for Methylmercury

63. California Code of Regulations section 12821 outlines the exposure guidelines for determining whether the level of exposure to methylmercury in canned tuna exceeds the MADL for methylmercury. TX 2, p. 200.6.

64. The Court finds that Dr. Murray's formula for calculating levels of methylmercury complies with section 12821.

1. Averaging Exposure to Methylmercury Over Two Months Is Appropriate

65. Based on Dr. Murray's testimony, the Court finds that for purposes of this case, averaging exposure to methylmercury is appropriate under section 12821(b). Section 12821(b) states that the reasonably anticipated rate of exposure "shall be based on the pattern and duration of exposure that is relevant to the reproductive effect which provided the basis for the determination that a chemical is known to the state to cause reproductive toxicity." TX 2, p. 200.6 (Cal. Code of Regulations § 12821(b)). Dr. Murray testified that

methylmercury has a two-month half-life. This was not contested. Because developmental harm caused by methylmercury exposure has never been isolated to a specific day, the Court finds that it is appropriate to average exposure to methylmercury over the time period during which methylmercury remains in the body. This finding is supported by the fact that both OEHHA and the FDA Advisory averages exposure to methylmercury over a period of time. In making this finding, the Court rejects the State's evidence proffered in support of its argument that exposure to methylmercury should not be averaged. Based on the foregoing, the Court finds that it is appropriate to average exposure to methylmercury over a period of two months.

2. The Term "Average" Means the Arithmetic Mean and Not the Median

66. Section 12821(c)(2) states that "[f]or exposures to consumer products, the level of exposure shall be calculated using the reasonably anticipated rate of intake or exposure for *average* users of the consumer product...." TX 2, p. 200.6 (Cal. Health & Safety Code § 12821(c)(2)) (emphasis added). The parties disputed the meaning of the word "average" as it is used in section 12821(c)(2). It is undisputed, however, that neither the statute, the regulations, nor the Statement of Reasons defines the term "average."

67. When a term used in a statute is undefined, the Court should first examine the actual language of the statute and apply the ordinary, everyday meaning of the words, unless the statute specifically designates a special meaning. *Halbert's Lumber, Inc. v. Lucky Stores, Inc.* (1992) 6 Cal.App.4th 1233, 1238-9. If the meaning of the word is without ambiguity, doubt, or uncertainty then the language controls. *Id.* If the meaning of the word is not clear, the Court must refer to the legislative history.[40] *Id.* at 1239. If the legislative history does not indicate a clear meaning, then the Court should apply "reason, practicality and common

[40] The parties agreed that there is no legislative history that provides guidance on the meaning of the term "average." The Statement of Reasons also does not provide guidance.

sense to the language. If possible, the words should be interpreted to make them workable and reasonable, in accord with common sense and justice, and to avoid an absurd result." *Id.*

68. The Court finds as a matter of law that the term "average" used in section 12821(c) is not unclear. Experts from both parties, including Dr. Wind, Dr. Griffin, and Dr. Brodberg, as well as the OEHHA scientists Dr. Zeise and Dr. Golub, all testified that both the professional and common definition of the term "average" is the arithmetic mean, and not the median. The Court declines the State's request to "interpret away clear language in favor of an ambiguity that does not exist." *People v. O'Neil* (1997) 56 Cal.App.4th 1126, 1132.

69. Even if the Court entertained the State's suggestion that the meaning of the word "average" is ambiguous, applying "reason, practicality and common sense" still leads the Court to find that "average" means the arithmetic mean. As discussed in the preceding paragraph, the evidence presented shows that "average" more often than not means the "arithmetic mean" among professional and common uses. Expert testimony, statistics handbooks and common reference materials support this conclusion. *See, e.g.*, Wind, 18 Tr. 2233:5-7; 18 Tr. 2231:7-11; TX 843, p. 76; TX 844, p. 12.

70. The Court also finds that to interpret the term "average" in section 12821 to mean typical, median, geometric mean, harmonic mean, trimmed mean, or Windsorized mean, it would be interpreting the statute in a manner that would render it unconstitutionally vague. *See,* Greenland, 20 Tr. 2619:20-2620:7. *In re Timothy R.* (1988) 202 Cal.App.3d 593, 597 (citing *Grayned v. City of Rockford* (1972) 408 U.S. 104). Had the Legislature intended to use these more obscure definitions of the term "average," it would have made its intention clear.

71. Based on the foregoing, the Court finds that the word "average" as it is used in section 12821(c) is not unclear but clear, and means the mean. Assuming arguendo that it is unclear, reason, practicality, and common sense dictate that the term means the "arithmetic mean."

3. Dr. Murray Properly Calculated Exposure to Methylmercury in the Tuna Canners' Products

72. Performing Dr. Murray's calculation (S x F x C), the Court finds that the level of exposure to methylmercury in the Tuna Canners' products is between 0.26-0.28 micrograms of methylmercury per day, averaged over a period of two months.

C. The Tuna Canners Satisfied Their Burden of Proof – Canned Tuna Is Exempt from the Warning Requirements of Proposition 65

73. Because the MADL for methylmercury is 0.3 ug/day, and the exposure of the average woman of childbearing age and/or pregnant woman to methylmercury in the Tuna Canners' products is between 0.26-0.28 ug/day, the Tuna Canners have met their burden of proof that canned tuna is exempt from the warning requirements of Proposition 65 as specified in Cal. Health & Safety Code section 25249.10(c).

NATURALLY OCCURRING

I. STATUTORY PROVISIONS

74. Californians adopted the Safe Drinking Water & Toxic Enforcement Act of 1986 through its voter initiative powers in November 1986 ("Proposition 65"). Proposition 65 prohibits the knowing and intentional exposure to "a chemical known to the state to cause cancer or reproductive toxicity without first giving clear and reasonable warning to such individual, except as provided in section 25249.10." TX 1, p. 1 (Cal. Health & Safety Code § 25249.6).

75. Human consumption of a food is not an exposure for purposes of Section 25249.6 to a listed chemical in the food to the extent that the person responsible for the exposure can show that the chemical is naturally occurring in the food. TX 2, p. 196 (22 CCR 12501(b)). A chemical is "'naturally occurring' if it is a natural constituent of a food, or if it is present in a food solely as a result of absorption or accumulation of the chemical which is naturally present in the environment in which the food is raised, or grown, or

obtained." TX 2, pp. 195-96 (22 CCR 12501(a)(1)). A chemical is naturally occurring only to the extent that the chemical did not result from any known human activity. TX 2, p. 196 (22 CCR § 12501(a)(3)).

76. The problem with the naturally occurring exception is that its language is ambiguous. 22 CCR §12501. Although section 12501(a) attempts to clarify what is meant by "naturally occurring," the statute as a whole fails to offer precise guidance when dealing with a chemical in food that is both naturally occurring and the possible result of human activity. This is the dilemma that the Court faces in the present case.

77. No one is absolutely certain about the source of methylmercury in open ocean fish such as tuna. Rather, the source of methylmercury in open ocean fish is a matter of hypotheses and scientific dispute. Fitzgerald, 22 Tr. 2733:7-14. The Tuna Canners expert, Dr. Morel, testified that *at least* ninety-five percent of the methylmercury in the ocean is naturally occurring, leaving approximately five percent of methylmercury in tuna potentially attributable to anthropogenic sources. Morel, 8 Tr. 956:13-15; 9 Tr. 1044:27-1045:7; 9 Tr. 1047:12-1049:6; 25 Tr. 3217:16-19. Similarly, the State's expert, Dr. Fitzgerald, conceded that between fifty and seventy percent of the ocean's methylmercury is naturally occurring, leaving approximately fifty to thirty percent of methylmercury in the ocean attributable to human activity. Fitzgerald, 23 Tr. 2861:9-27; 22 Tr. 2733:15-19. Thus, both parties' expert witnesses agree that methylmercury in tuna is both naturally occurring and in some way the result of human activity.

78. Even after taking Dr. Morel's testimony as true, the fact remains that a very small portion of the methylmercury in tuna is still potentially attributable to human activity. As a matter of law, this Court must determine whether methylmercury in tuna is naturally occurring within the meaning of the "naturally occurring" exception under section 12501.

79. The exact breakdown of how much of a chemical must be naturally occurring and how much of a chemical may be anthropogenic for it to qualify for the exception is not specified in the statute. *See* §12501. Because this is a matter of first impression, it is

necessary for this Court to undergo traditional statutory construction in order to ascertain and effectuate the legislature's intent as to what is meant by "naturally occurring."

80. The fundamental rule of statutory construction is that the court should ascertain the intent of the legislature as to effectuate the purpose of the law. *Palmer v. GTE California Inc.* (2003) 30 Cal.4th 1265, 1271 (citations omitted). In the case of a statute passed by an initiative measure, it is to ascertain and effectuate the intent of the voters. *People v. Hazelton* (1996) 14 Cal.4th 101, 105. First, the Court looks to the words of the statute, giving them their usual and ordinary meaning. *Palmer*, 30 Cal.4th at 1271. The words of the statute are the most reliable indicator of the legislator's intent. *Id.* "Of course, language of a statute should not be given a literal meaning if doing so would result in absurd consequences which the Legislature did not intend." *People v. Broussard* (1993) 5 Cal.4th 1067, 1071 (citations omitted). "In such circumstances, the intent prevails over the letter, and the letter will, if possible, be so read as to conform to the spirit of the act." *Id.* (citations omitted). Thus, in order to determine whether the "naturally occurring" exception under section 12501 includes chemicals that are both the result of natural sources and anthropogenic sources, we begin with an analysis of the plain language of the statute.

A. Statutory Language

81. "In interpreting the meaning of a statute we begin, as we must, with the language used. Under familiar rules of construction, words in a statute must be given the meaning they bear in ordinary usage; the meaning of the enactment may not be determined from a single word or sentence; the words must be construed in context, and provisions relating to the same subject matter must be harmonized to the extent possible." *Title Ins. & Trust Co. v. County of Riverside* (1989) 48 Cal.3d 84, 91 (citations omitted).

82. Section 12501 provides that, "[h]uman consumption of a food shall not constitute an 'exposure' for purposes of Health and Safety Code section 25249.6 to a listed chemical in the food to the extent that the person responsible for the contact can show that the chemical is naturally occurring in food." §12501(a). A chemical is considered "naturally occurring" if "it is a natural constituent of a food, or if it is present in a food solely as a result

of absorption or accumulation of the chemical which is naturally present in the environment in which the food is raised, or grown, or obtained." §12501(a)(1). The chemical is not naturally occurring to the extent that it is the result of any known human activity or failure to observe "good agricultural or good manufacturing practices" such as the "addition of chemicals to irrigation water applied to soil or crops." §12501(a)(3)-(4). Even where the chemical is a naturally occurring one, the regulations require that the producer, manufacturer, distributor, or holder of the food at all times utilize measures to reduce the chemical to the lowest level feasible. §12501(b); *See also Nicolle-Wagner v. Deukmejian* (1991) 230 Cal.App.3d 652, 656.

83. Reading section 12501 in its context, it is apparent that the drafters were particularly concerned with not exempting chemicals in food that are a result of *known human activity*. For example, section 12501(a)(3) provides that "[a]chemical is naturally occurring only to the extent that the chemical did not result from any *known human activity*." §12501(a)(3) (emphasis added). Subsection (a)(4) states, "[w]here a chemical contaminant can occur naturally in a food, the chemical is naturally occurring only to the extent that it was not avoidable by good agricultural or good manufacturing practices." §12501(a)(4).

84. The addition of the word "known" in subsection (a)(3) taken together with the language in (a)(4) seem to convey that the drafters intended on only exempting chemicals in food that are naturally occurring or the result of *uncontrollable human activity*. Had the drafters opted not to include the word "known," the interpretation of the statute would likely be different. Therefore, after reviewing the plain language of the statute, it is logical to conclude that a chemical fits within the exception when that chemical is significantly, but, conclusively, naturally occurring and partly, but also likely, the result of *uncontrollable human activity*. If, however, the manufacturer or producer could avoid altogether or decrease the amount of that chemical in the food product, then that chemical is not exempt under section 12501.

85. This careful reading of the statute is supported by case precedent. *See Nicolle-Wagner*, 230 Cal.App.3d 652. In *Nicolle-Wagner*, the Court of Appeals was asked

to determine whether the "naturally occurring" exception, which was promulgated by the Health and Welfare Agency pursuant to Proposition 65, conflicts with the language of Proposition 65, and whether the regulation is reasonably necessary to effectuate the purpose of Proposition 65. *Id.* at 654.

86. The plaintiff in *Nicolle-Wagner* argued that Proposition 65 created no categorical exemption for naturally occurring carcinogens or naturally occurring reproductive toxins, which are as threatening to health as man-made toxins. *Id.* at 657. The plaintiff maintained that there is no scientific basis for distinguishing between man-made and naturally occurring substances, and that Proposition 65 did not sanction such distinctions. *Id.* Alternatively, defendants asserted that section 12501 is lawful and reasonably necessary to effectuate the statutory purpose of Proposition 65. *Id.* Further, defendants contended that while it is true that the statute purports to regulate all listed chemicals, warnings are required only when a business "exposes" an individual to a listed chemical. *Id.* at 658. Because the statute does not define the term "exposes," the agency has the authority to define the term in order to implement the statute and its purposes. *Id.* The Court ruled in favor of defendants and upheld the "naturally occurring" exception, holding that the statute was entirely consistent with the purpose of Proposition 65 and it was reasonably necessary to effectuate the purposes of the act. *Id.* at 654.

87. In upholding the statutory exception, the Court reasoned, "foods that have been eaten for thousands of years are healthful, despite the presence of small amounts of naturally occurring toxins. Were these substances not exempted from [Proposition 65's requirements], the manufacturer or seller of such products would bear the burden of proving ... that the exposure poses no 'significant risk' to individuals." *Id.* at 660. The Court noted that the ballot arguments in favor of Proposition 65 explained that "[Proposition 65] applies only to businesses that *know* they are putting one of the chemicals out into the environment." *Id.* at 659 (emphasis in original). "A chemical is not 'put' into the environment, if it is naturally occurring." *Id.* The Court concluded that the statutory language along with the subtle expressions of the electorate's intent "indicate that Proposition 65 sought to regulate

toxic substances which are deliberately added or put into the environment by human activity." *Id.* at 659.

88. Thus, the primary focus of the "naturally occurring" exception based on the language of the statute is the relative control that the manufacturer has on the chemical in their food product. Does the manufacturer "put" the chemical in their food product? Can the manufacturer "reduce" the amount of a chemical in their food product? Here, the Tuna Canners do not have control over the level of methylmercury in their canned tuna product. Based on this record, the Tuna Canners do not "put" methylmercury in canned tuna in any way. Joint Stipulation of Facts, p. 5. It is also undisputed that there is no currently known way to "reduce" methylmercury in tuna or canned tuna products. *Id.* Therefore, methylmercury in tuna fits within the "naturally occurring" exception because its existence is not the result of *known human activity.*

89. The Court's conclusion that methylmercury in tuna fits within the naturally occurring exception is further supported when the statutory purpose of Proposition 65 is considered.

B. Statutory Purpose

90. A Court will turn to the legislative history and wider historical circumstances of the statute's enactment in order to ascertain the intent of the legislature so as to effectuate the purpose of the law. *Coachella Valley Mosquito v. California Public Employment Relations Bd.* (2005) 35 Cal.4th 1072, 1087-1090. The legislative history for the "naturally occurring" exception is silent on the subject of chemicals in food that are part naturally occurring and part anthropogenic.

91. In *Nicolle-Wagner*, the Court of Appeal looked to subtle expressions of the electorate's intent and the ballot arguments both for and against Proposition 65 in an effort to effectuate the purpose of the law. *Nicolle-Wagner*, 230 Cal.App.3d at 659. Those sources indicated that "Proposition 65 sought to regulate toxic substances which are *deliberately added or put into the environment by human activity.*" *Id.* (emphasis added). "The controlling language of the Proposition, now Health and Safety Code section 25249.6,

provides that 'no person in the course of doing business shall *knowingly and intentionally expose* any individual,' thereby suggesting that some degree of human activity which results in toxins being added to the environment is required." *Id.* (emphasis in original).

92. The Court was persuaded "on balance that the better view is that the electorate did not intend naturally occurring substances to be controlled by Proposition 65." *Id.* at 660. "Use of terms such as 'knowingly and intentionally' and 'putting' implies that human conduct which results in toxins being *added* to the environment is the activity to be controlled." *Id.* (emphasis in original). Moreover, Proposition 65 created exemptions to the warning requirement for exposures that the person can show that the exposure poses no significant risk. *Id.*

93. Since the Proposition plainly provided for categorical exemptions to the regulation, "it would not be inconsistent for the Agency to enact regulations defining more specifically those exposures which pose an insignificant risk to individuals." *Id.* at 660, fn. 3. Henceforth, the naturally occurring exemption furthers the statutory purpose of the Proposition by safeguarding the effectiveness of warnings that are given, and in removing from the regulatory scrutiny those substances that pose only an "insignificant risk" of cancer or birth defects, within the meaning of the statute. *Id.* at 661.

94. This Court finds that, like methylmercury in tuna, chemicals in food that are the result of both natural and *uncontrollable* human activity are exempt under the "naturally occurring" exception and do not frustrate the purpose of Proposition 65, which is to regulate toxic substances that are deliberately added or put into the environment by human activity. *See* Health & Safety Code §25249 et seq. It would not make sense for the "naturally occurring" exception to be reserved only for those chemicals that are one hundred percent the result of natural sources. Science, by its very nature, allows for some degree of uncertainty. Because science does not demand absolute certainty, the law on science cannot demand anything different. As a result, the "naturally occurring" exception does allow for some flexibility when the business in question has no control over the amount of a chemical

in food that is the result of human activity (i.e. general pollution), especially when the anthropogenic amount, as in this case, and this Court so finds, is de minimus.

II. BURDEN OF PROOF

95. The Tuna Canners have the burden of proof to establish that methylmercury is naturally occurring in canned tuna. TX 2, p. 196 (22 CCR § 12501(b)); Evid. Code §§ 115, 500.

96. The standard of proof is the preponderance of the evidence. Evid. Code § 115; *Baxter Healthcare Corp. v. Denton* (2004) 120 Cal. App. 4th 333, 365-66. The preponderance of the evidence standard requires the trier of fact to believe that the existence of a fact is more probable than its nonexistence. *Lillian F. v. Superior Court* (1984) 160 Cal.App.3d 314, 323.

97. The Tuna Canners have the initial burden of producing evidence to prove that canned tuna is naturally occurring. Evid. Code § 550; *Mathis v. Morrissey* (1992) 11 Cal. App. 4th 332, 346. The burden of production then shifts to the State if the Tuna Canners provide evidence of such weight that a determination in the Tuna Canners' favor would necessarily be required in the absence of contradictory evidence. Evid. Code § 550.

III. METHYLMERCURY IN CANNED TUNA IS NATURALLY OCCURRING

98. The Tuna Canners met their burden of proof that virtually all methylmercury in canned tuna is naturally occurring by providing substantial evidence through credible expert witnesses. The State's witness conceded that up to seventy percent of methylmercury in tuna is naturally occurring. Fitzgerald, 23 Tr. 2861:9-27.

99. It appears from the evidence that methylmercury is a natural constituent of tuna, and is almost exclusively absorbed from the ocean environment independently of human pollution. The Tuna Canners do not put methylmercury into canned tuna, and there is no known way for them to remove methylmercury from their products.

100. Proposition 65 is designed to be directed to conduct that the defendant can control. *See* TX 2, p. 196 (22 CCR 12501(a)(4)). The logical interpretation of naturally occurring is that it means that a product is not fortified with a listed substance. The rationale

for the naturally occurring exemption is the presumption that foods that have been eaten for many years are healthful, despite the presence of a small amount of naturally occurring chemicals. *See Nicolle-Wagner*, 230 Cal.App.3d at 660-61.

101. Even if the naturally occurring exemption to Proposition 65 is narrower than whether a product is fortified with a listed chemical, methylmercury in tuna is naturally occurring under 22 CCR 12501(a)(1) . Methylmercury is naturally present in the ocean environment and the amount of methylmercury in this environment, and in the tuna, has not responded to human pollution. This is clear. The reasons for this are less clear. It appears likely that the source of methylmercury is the oceans is deep ocean vents, which according to the State's witness Dr. Fitzgerald, produce enough methylmercury to account for all methylmercury in ocean fish. But even if the source is something else, the fact remains that methylmercury in fish, including tuna, does not respond to human pollution, and is a natural part of the product's environment.

102. It is undisputed that the Tuna Canners do not add methylmercury to canned tuna and that there is no process to remove methylmercury from canned tuna.

103. Because of international laws and treaties, the Tuna Canners cannot catch and can tuna that contains less methylmercury.

104. Accordingly, the Court finds that the methylmercury in canned tuna falls within the naturally occurring exception under §12501 and is therefore exempt from Proposition 65's warning requirement.

IV.

ORDER

PREEMPTION

104. Any Proposition 65-compliant warning that the State proposes to apply to the sale of canned tuna conflicts with Federal law and policy and is preempted by the Supremacy Clause of the United States Constitution.

105. The complaints against the Tuna Canners allege violations of the Business and Professions Code section 17200. These violations are premised on the Tuna Canners' alleged violations of Proposition 65. *See* People's Complaint at ¶ 33; PMC's Complaint at ¶ 53. Because the Court finds that Proposition 65 is preempted in this case, there is no underlying cause of action upon which an unlawful business practices claim can be based. Accordingly, the section 17200 cause of action must be dismissed. *See People v. Duz-Mor Diagnostic Laboratory, Inc.* (1998) 68 Cal.App.4th 654, 673 (stating that the Unfair Competition Act requires a violation of law, and that a defense to the underlying offense is a defense under the Act).

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106. The complaints against the Tuna Canners allege violations of Business and Professions Code section 17200 predicated on the Tuna Canners' alleged violations of Proposition 65. *See* People's Complaint at ¶ 33; PMC's Complaint at ¶ 53. Because the Court finds that the Tuna Canners are exempt from the warning requirement under Proposition 65, there can be no underlying cause of action upon which to base an unlawful business practices claim. Accordingly, the section 17200 cause of action is dismissed. *See People v. Duz-Mor Diagnostic Laboratory, Inc.* (1998) 68 Cal.App.4th 654, 673 (stating that the Unfair Competition Act requires a violation of law, and that a defense to the underlying offense is a defense under the Act).

NATURALLY OCCURRING

107. Based on the convincing evidence presented by the Tuna Canners, the Court concludes that virtually all the methylmercury in canned tuna is naturally occurring.

108. The complaints against the Tuna Canners allege violations of the Business and Professions Code section 17200. These violations are premised on the Tuna Canners' alleged violations of Proposition 65. *See* People's Complaint at ¶ 33; PMC's Complaint at ¶ 53. Because the Court finds that the methylmercury in canned tuna is naturally occurring, there is no exposure under Proposition 65 and therefore no underlying cause of action upon

which an unlawful business practices claim can be based. Accordingly, the section 17200 cause of action must be dismissed. *See People v. Duz-Mor Diagnostic Laboratory, Inc.* (1998) 68 Cal.App.4th 654, 673 (stating that the Unfair Competition Act requires a violation of law, and that a defense to the underlying offense is a defense under the Act).

109. This Proposed Findings of Fact and Conclusions of Law is issued consistent with the dictates of CCP §632 and California Rule of Court 232. It will become final unless a party objects consistent with the time limits of objection after service of the Tentative Decision.

DATE: May 11, 2006

ROBERT L. DONDERO
Presiding Judge Superior Court

EXHIBIT "A"

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

August 12, 2005

Bill Lockyer
Attorney General of the State of California
Office of the Attorney General
1300 "I" Street
P.O. Box 944255
Sacramento, California 94244-2550

Dear Mr. Lockyer:

On June 21, 2004, your office filed suit in San Francisco Superior Court, in The People of the State of California v. Tri-Union Seafoods, LLC, et al., (Case No.: CGC -04-432394) seeking an injunction and civil penalties to remedy defendants' alleged failure to warn consumers that canned and packaged tuna products sold by defendants were "exposing consumers to chemicals known to the State of California to cause cancer and reproductive harm." The chemicals described in the complaint are mercury and mercury compounds.

Under the Safe Drinking Water and Toxic Enforcement Act of 1986, Health and Safety Code section 25249.6 ("Proposition 65"), businesses must provide persons with a "clear and reasonable warning" before exposing them to such chemicals. According to the above-cited complaint, on July 1, 1987, methylmercury was added to the list of chemicals known to the State of California to cause reproductive toxicity and, on May 1, 1996, methylmercury compounds were added to the list of chemicals known to the State of California to cause cancer.

The warnings that would be required on the defendants' products if the lawsuit is successful are some derivation of the following: "WARNING: This product contains a chemical known to the State of California to cause cancer," and "WARNING: This product contains a chemical known to the State of California to cause birth defects or other reproductive harm."[1]

FDA believes that such warnings are preempted under federal law. They frustrate the carefully considered federal approach to advising consumers of both the benefits and possible risks of eating fish and shellfish; accordingly federal law preempts these Proposition 65 warnings

[1] Proposition 65 does not specify the form or wording of the warning. Section 12601 of the California Regulations (22 CCR 12601) addresses Clear and Reasonable Warnings, and provides generally that "[t]he message must clearly communicate that the chemical in question is known to the state to cause cancer, or birth defects or other reproductive harm." Section 12601(a). The regulations provide a "safe harbor" warning for carcinogens and reproductive toxicants. The safe harbor warning for reproductive toxicants states, "WARNING: This product contains a chemical known to the State of California to cause birth defects or other reproductive harm." Section 12601(b)(4)(B). While this provision states that persons are not precluded from providing other warnings that satisfy the requirements of the regulation (Section 12601(a)), it does not provide further clarification as to acceptable warnings.

concerning mercury and mercury compounds in tuna. Furthermore, FDA believes that compliance with both the Federal Food, Drug, and Cosmetic Act ("Act") and Proposition 65 is impossible and, as a result, the latter is preempted under federal law.

The Act provides broad authority to the FDA to regulate the labels of food products. However, rather than requiring warnings for every single ingredient or product with possible deleterious effects, FDA has deliberately implemented a more nuanced approach, relying primarily on disclosure of ingredient information and nutrition information, taking action in instances of adulterated and misbranded foods[2] and, only under exceptional circumstances, requiring manufacturers to provide warnings on their labels.[3] As part of this deliberate regulatory approach, FDA has required warnings only in those instances where there is clear evidence of a hazard, in order to avoid overexposing consumers to warnings, which could result in them ignoring all such statements, and hence creating a far greater public health problem.[4]

FDA has been studying the issue of methylmercury in fish for several years. In so doing, it has compiled substantial data, and has developed significant expertise in analyzing the pertinent scientific issues, together with the consumer education aspects of this matter. As a result, the agency believes that it is uniquely qualified to determine how to handle the public health concerns related to methylmercury in fish. After many years of analysis on this issue, FDA has chosen to issue an advisory rather than to require a warning on fish and shellfish (collectively, "seafood") product labels for several reasons. First, consumer advisories are communicated to the target audience directly, rather than to all consumers. Second, FDA believes that the advisory approach is more effective than a product label statement in relaying the complex messages about mercury in seafood.[5] Third, a label statement that reaches the public at large can

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[2] FDA has adulteration and misbranding authority by virtue of sections 402 and 403 of the Act.

[3] For example, 21 C.F.R. 172.804(e)(2) requires that any food containing the sweetener aspartame must bear the following statement: "Phenylketonurics: contains phenylalanine"; 21 C.F.R. 101.17(g) requires juices that have not been specifically processed to prevent, reduce or eliminate the presence of pathogens to bear the following statement: "WARNING: This product has not been pasteurized and, therefore, may contain harmful bacteria that can cause serious illness in children, the elderly, and persons with weakened immune systems"; and 21 C.F.R. 101.17(d) requires food products that derive more than 50 percent of its total caloric value from either whole protein, protein hydrolysates, amino acid mixtures, or a combination of these, and that is represented for use in weight reduction to bear the following statement: "WARNING: Very low calorie protein diets (below 400 Calories per day) may cause serious illness or death. Do Not Use for Weight Reduction in Such Diets Without Medical Supervision. Not for use by infants, children, or pregnant or nursing women."

[4] "When confronted with a problem that threatens the general public, FDA has promulgated regulations requiring placement of warning statements on the food label. For example, in 21 C.F.R. 101.17(d), the agency requires a warning on protein products promoted for weight reduction. However, FDA is unwilling to require a warning statement in the absence of clear evidence of a hazard....[as the agency] is concerned that it would overexpose consumers to warnings. As a result, consumers may ignore, and become inattentive to, all such statements." 56 F.R. 28592, 28615; Preamble to the Proposed Rule on Food Labeling; Declaration of Ingredients (1991).

[5] For instance, the 2004 Advisory, as discussed below, provides information on the relative amounts of mercury in different types of seafood, including "canned light tuna", and "albacore (white) tuna", the number of ounces that the targeted population can eat per week of each of the different types of seafood, together with the types of seafood that

also have unintended adverse public health consequences. FDA focus group results have suggested that people who are not in the target audience (i.e., women who are not nursing and not likely to become pregnant, and men) might eat less fish or refrain from eating fish altogether when they receive information about the mercury content of fish and possible harmful health effects to the targeted audience (i.e., pregnant women, women who might become pregnant, nursing mothers, and young children).

The agency issued its first methylmercury in fish advisory in the mid 1990s. As more information has come to light regarding the relative benefits and possible risks of eating seafood, FDA has revised the advisory to change its emphasis. For instance, in July 2002, the FDA Food Advisory Committee ("FAC") recommended that FDA clarify the language of the existing advisory, develop a quantitative exposure assessment, and increase monitoring for methylmercury. Recognizing the importance of a coordinated and consistent message on this issue, it also recommended that FDA and EPA combine their two independent advisories. The FAC recommendations were addressed by the two agencies as follows:

- FDA and EPA jointly held four stakeholder meetings between July 29 and July 31, 2003, regarding methylmercury in seafood. The meetings consisted of a series of formal presentations from FDA and EPA, followed by a general discussion in which participants provided comments on the progress toward a joint advisory.
- FDA conducted focus group testing in November 2003 to assess consumers' understanding of the existing advisory.
- The exposure assessment, which had been conducted by FDA, underwent a peer review in August 2003.
- Additional seafood monitoring data were collected during 2002 and 2003.

Revisions to the advisory were made in consideration of these activities in addition to the prior recommendations made by the FAC. This draft advisory ("2003 Draft Advisory") was then presented to the FAC for its review and released to the public on December 10, 2003.

On March 10, 2004, the FAC provided additional recommendations for the FDA and EPA to consider, including providing a list of seafood that have low levels of mercury, a list of common names of seafood, clarifying the portion size to make it easier to understand, making portion size consistent between variety and frequencies of consumption, and including a Web site in the advisory for those who might want further information. The FAC also recommended that FDA and EPA avoid the need to issue multiple advisories by designing the advisory in such a way that it is understood by more than just the original target audience. FDA and EPA considered these recommendations as they refined the 2003 Draft Advisory.

On March 19, 2004, FDA and EPA released the 2004 Advisory, "What You Need to Know About Mercury in Fish and Shellfish." The objective of the 2004 Advisory, as described in the

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the targeted population should altogether avoid. This level of detail would be difficult to provide on a product label. Furthermore, this should be contrasted with the substance of the Proposition 65 warnings referenced at the beginning of this letter.

Backgrounder document released simultaneously therewith, is to inform women who may become pregnant, pregnant women, nursing mothers, and parents of young children as to how to get the positive health benefits from eating fish and shellfish, while minimizing their mercury exposure.

The 2004 Advisory provides three principal recommendations for women and young children. These recommendations incorporate the relative mercury levels of "canned light tuna" and "albacore (white) tuna" in relation to each other as well as in relation to other seafood, together with advice as to how frequently these tuna products can be consumed by the targeted audience.

> 1. Do not eat Shark, Swordfish, King Mackerel, or Tilefish because they contain high levels of mercury.
> 2. Eat up to 12 ounces (two average meals) a week of a variety of fish and shellfish that are lower in mercury.
>
> - Five of the most commonly eaten fish that are low in mercury are shrimp, canned light tuna, salmon, pollock, and catfish.
> - Another commonly eaten fish, albacore ("white") tuna has more mercury than canned light tuna. So, when choosing your two meals of fish and shellfish, you may eat up to six ounces (one average meal) of albacore tuna per week.
>
> 3. Check local advisories about the safety of fish caught by family and friends in your local lakes, rivers and coastal areas. If no advice is available, eat up to six ounces (one average meal) per week of fish you catch from local waters, but don't consume any other fish during that week.
>
> Follow these same recommendations when feeding fish and shellfish to your young child, but serve smaller portions.
> [Emphasis added]

As subsequent steps, FDA and EPA are engaged in a comprehensive educational campaign to reach the targeted audience. The agencies are working with state, local, and tribal health departments to get information out into their communities. Physicians, other health professionals, and health care associations are being sent information to distribute through their offices. Extensive outreach through the media is also planned. Radio and television stations, health editors at newspapers, magazines, and other popular media will be contacted to encourage them to carry public service messages. The 2004 Advisory will also be an important part of a comprehensive food safety education program to be used by educators of pregnant women.

In addition to issuing these advisories, FDA has used its expertise in this area to advance the public health other ways. For example, FDA employed its expertise on mercury in food and food labeling in resolving the Omega-3 fatty acid health claim petitions: On September 8, 2004, FDA issued its decision to allow qualified health claims involving Omega-3 fatty acids and a

reduced risk of coronary heart disease.[6] Omega-3 fatty acids are abundant in a variety of fish. FDA stated in these letters that it would consider exercising enforcement discretion for the following qualified health claim:

> "Supportive but not conclusive research shows that consumption of EPA and DHA omega-3 fatty acids may reduce the risk of coronary heart disease. One serving of [Name of the food] provides [ ] gram of EPA and DHA omega-3 fatty acids. [See nutrition information for total fat, saturated fat, and cholesterol content.]"

FDA also considered, and rejected, the suggestion by petitioner Martek that the presence of mercury in seafood needed to be addressed in the health claim.[7] With regard to the petitioner's argument that when the health claim appeared on a fish product, such as tuna, it should be accompanied by an advisory statement suggesting a limited weekly intake for a vulnerable population of pregnant women, women of childbearing age, nursing mothers, and young children, our response was as follows:

> "FDA disagrees with the petitioners' contention that the omega-3 fatty acid qualified health claim should be accompanied by a product label statement about mercury content of fish and possible harmful health effects to the vulnerable population of pregnant women, women who might become pregnant, nursing mothers, and young children. For some time, FDA has been addressing the issue of reducing the exposure to the harmful effects of mercury by communicating with this target population (pregnant women, women who might become pregnant, nursing mothers, and parents of young children) through the use of consumer advisories. The latest consumer advisory was issued in March 2004 jointly by FDA and the Environmental Protection Agency. This advisory includes information about mercury and makes recommendations about the kinds and amount of fish to eat and to avoid.

[6] Health Claim Petitions: Omega-3 Fatty Acids and Reduced Risk of Coronary Heart Disease (Docket No. 2003Q-0401) (Letter responding to Wellness petition can be found at http://www.cfsan.fda.gov/~dms/ds-ltr38.html) (Letter responding to Martek petition can be found at http://www.cfsan.fda.gov/~dms/ds-ltr37.html).

[7] Specifically, the Martek petition argued four principal points in this regard: (1) that when the health claim appears on fish (such as tuna), it should be accompanied by an advisory statement suggesting a limited weekly intake for a vulnerable population of pregnant women, women of childbearing age, nursing mothers, and young children; (2) that certain fish (including shark, swordfish, king mackerel, and tile fish), and other fish that are similarly high in methylmercury, should be ineligible to bear the proposed health claim; (3) that sources of omega-3 fatty acids derived from fish (such as fish oils) should be ineligible for the health claim unless the oil has been tested and found to contain less than 0.025 ppm of mercury; and, (4) that the presence of mercury may offset the cardio-protective effects of omega-3 fatty acids, and therefore, that the claim would be misleading if it appeared on fish that contained elevated levels of mercury. FDA rejected all of these points after extensive review of the applicable science and considerable deliberation.

> Agencies are granted broad discretion in determining the means by which to pursue policy goals . . . FDA has decided that it is preferable not to use a label statement about mercury and possible harmful effects to pregnant women, women who might become pregnant, nursing mothers and young children as a condition for the agency's enforcement discretion for the omega-3 fatty acid qualified health claims." [Footnotes omitted]

For all of the public health reasons stated above, FDA believes that California should not interfere with FDA's carefully considered approach of advising consumers of both the benefits and possible risks of eating seafood.

Furthermore, the agency believes California cannot legally require the Proposition 65 warnings on tuna products because they are preempted under federal law, for two principal reasons. First, FDA has been given broad authority to regulate the labels of food products, and has deliberately implemented its regulatory authority with a nuanced approach, relying primarily on disclosure of ingredient information and nutrition information and, only under exceptional circumstances, requiring manufacturers to provide warnings on their labels. After years of analysis of the methylmercury in tuna issue, the agency remains convinced that the issuance of an advisory remains the preferred route for advising the public. The Proposition 65 warnings frustrate this carefully considered agency approach, causing federal law to preempt California's warnings.

Second, the Proposition 65 warnings purport to convey factual information, namely that methylmercury is known to cause cancer and reproductive harm. However, it is done without any scientific basis as to the possible harm caused by the particular foods in question, or as to the amounts of such foods that would be required to cause this harm. Stated differently, these warnings omit facts which are necessary to place the information in its proper context. As a result, FDA believes that the Proposition 65 warnings are misleading under section 403 of the Act, causing tuna products with such warnings to be misbranded under federal law. Tuna manufacturers would not be able to comply both with Proposition 65 and the Act and, hence, the Proposition 65 warnings are conflict preempted under federal law.

For all of the above-stated reasons, the agency believes that Proposition 65 is preempted by federal law with respect to the proposed warnings concerning mercury and mercury compounds in tuna.

Sincerely,

Lester M. Crawford, D.V.M., Ph.D.
Commissioner of Food and Drugs

cc: Robert E. Brackett, Ph.D, Director CFSAN
Joan E. Denton, Director, Office of Environmental Health Hazard Assessment, Proposition 65 Implementation

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SUPERIOR COURT OF THE STATE OF CALIFORNIA

COUNTY OF SAN FRANCISCO

PEOPLE OF THE STATE OF CALIFORNIA, ex rel. BILL LOCKYER, Attorney General of the State of California, Plaintiff, vs. TRI-UNION SEAFOODS, LLC; DEL MONTE CORPORATION; BUMBLE BEE SEAFOODS, LLC; and DOES 1 through 100, Defendants.	Consolidated Case Nos. CGC-01-402975 and CGC-04-432394 CERTIFICATE OF SERVICE BY MAIL [Code of Civil Procedure 1013a(4)]

I, Alisa Hollander, Secretary to the Presiding Judge of the San Francisco Superior Court, certify that I am over the age of 18 years and not a party to the within action.

On May 11, 2006, I served the attached *Decision* on the parties in said action by placing a true copy in a sealed envelope with postage thereon fully prepaid in the United States mail at San Francisco, California, addressed as follows:

SEE SERVICE LIST ATTACHED.

DATED: May 11, 2006

Alisa Hollander

ALISA HOLLANDER
Secretary to the Presiding Judge of
the San Francisco Superior Court

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