

1 152. The Court heard testimony from Dr. Dale Griffin that his “understanding” of
2 the meaning of the term “average” is “typical.” Griffin, 19 Tr. 2394:13-19. Yet, Dr. Griffin
3 read the definition of “average” from several dictionaries and each dictionary included the
4 “arithmetic mean” as a definition. Griffin, 19 Tr. 2391:11-2392:3; 19 Tr. 2388:12-22; 19 Tr.
5 2390:13-18; 19 Tr. 2391:23-2392:3. In his own work, Dr. Griffin uses “average” to mean
6 “the arithmetic mean” in his work. Griffin, 6 Tr. 703:13-17. In Dr. Griffin’s on-line
7 warning sign experiment, he testified that the average reading time for the can label was 15
8 seconds, which he equated to the mean time. Griffin, 6 Tr. 703:13. Dr. Griffin also
9 conceded that the *Harper Collins Dictionary of Statistics* states, “[b]y far, the most useful of
10 measures of central tendency is the arithmetic mean. As a general rule, when the behavioral
11 scientist uses the term ‘average,’ he means the mean.” Griffin, 19 Tr. 2393:24-27; TX 403.

12 153. The State’s statistics expert, Dr. Greenland, testified that the term “average”
13 could mean typical, median, geometric mean, harmonic mean, trimmed mean, or
14 Winsorized mean. See, Greenland, 20 Tr. 2619:20-2620:7. He admitted, however, that the
15 most commonly understood meaning of the word “average” in statistics is the arithmetic
16 mean. Greenland, 20 Tr. 2636:5-13.

17 **3. Average Is the Arithmetic Mean**

18 154. The Court finds that the common meaning of “average,” and the way in which
19 the witnesses, including the State’s witnesses, use the term “average” is the arithmetic mean
20 and not the median.
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26 (...continued)
27 referred to a standard statistics book, *Introduction to the Practice of Statistics* by Moore
28 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.

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

7 **Dr. James Joseph** is a world-recognized expert on tuna biology, tuna population
8 dynamics, tuna fisheries, resource conservation and management. Joseph, 13 Tr. 1545:25-
9 28; 13 Tr. 1546:1-10. Dr. Joseph holds a Ph.D. in Fish Population Dynamics (Joseph, 13 Tr.
10 1486:11-22; TX 601, p. 1), and was the director of the Inter-American Tropical Tuna
11 Commission ("IATTC") for 30 years. Joseph, 13 Tr. 1487:22-28. The IATTC is an
12 international organization established by convention between thirteen nations, including the
13 United States. Joseph, 13 Tr. 1487:20-28; 13 Tr. 1488:1-9, 28-1489:4; TX 601, p. 1. Dr.
14 Joseph taught fishery science at universities and has authored over one hundred articles and
15 books on fisheries and tuna. Joseph, 13 Tr. 1498:12-1499:4; TX 601, passim. Dr. Joseph
16 was responsible for the IATTC's tuna food habit studies (Joseph, 13 Tr. 1546:13-20), and his
17 expertise includes the feeding behavior of tuna, including tuna around Hawaii. Joseph, 13
18 Tr. 1501:5-7; 13 Tr. 1548:14-1549:14; 13 Tr. 1592:10-14. Dr. Joseph also worked as an
19 expert for South American governments on anchovies and sardines. Joseph, 13 Tr. 1579:15-
20 16. Dr. Joseph has testified before Congress, the United Nations and the legislatures of Latin
21 American countries, and has served as an advisor to many international organizations,
22 government ministries and heads of state, including the Emperor of Japan. Joseph, 13 Tr.
23 1497:15-1498:6; 13 Tr. 1502:24-1503:6; TX 601, p. 1. Dr. Joseph has received numerous
24 awards for contributions to tuna science, marine science, the development of tuna fisheries
25 and tuna conservation. Joseph, 13 Tr. 1503:7-1504:17; TX 601, pp. 1-2.

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1 **B. The State's Witnesses**

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

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

9 159. First, in his published articles in textbooks and peer-reviewed articles, Dr.
10 Fitzgerald has consistently written that atmospheric mercury levels have been increasing at a
11 rate of approximately 1.4 percent per year (TX 159, p. 1116 (Fig.7)), and that comparing
12 mercury levels in fish over time would be an effective test to determine the contribution, if
13 any, of pollution to methylmercury in fish. Fitzgerald, 23 Tr. 2900:7-15; 23 Tr. 2910:20-
14 2911:12; TX 859; TX 861, p. 296. In this case, however, Dr. Fitzgerald claims that mercury
15 in the atmosphere is no longer increasing, although he was unclear about when the increase
16 ceased. However, Dr. Fitzgerald has never expressed this opinion in any published work.
17 Fitzgerald, 23 Tr. 2928:4-9.

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

24 161. Third, Dr. Fitzgerald has recently published an article suggesting that coastal
25 areas are a source for methylmercury in the ocean. TX 421. That theory is discussed below.
26 However, Dr. Fitzgerald's hypothesis is based upon mathematical calculations that, during
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1 trial, he recognized were incorrectly computed, but he does not intend to withdraw the
2 numbers. Fitzgerald, 24 Tr. 2972:10-22; 24 Tr. 3012:5-3013:2.

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

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

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

15 **II. MERCURY IN THE ENVIRONMENT**

16 **A. Mercury is a Naturally Occurring Element**

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

21 **B. The Contribution of Pollution**

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

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

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1 168. There is a well-recognized global cycle for mercury, whereby emitted
2 elemental mercury vapor is transported into the atmosphere, gets oxidized into ionic mercury
3 (mercury II) and becomes more soluble in water as it falls to earth as rain. Morel, 8 Tr.
4 872:15-873:17.

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

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

19 **C. Methylmercury**

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

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1 **1. Methylmercury in Freshwater Systems**

2 172. In freshwater systems, methylmercury is formed by biological processes that
3 depend on anoxic³² sediments in lake bottoms. Morel, 8 Tr. 874:4-16; 8 Tr. 875:19-25. In
4 these anoxic sediments or layers, sulfate-reducing bacteria (“SRBs”), which are aquatic
5 organisms that cannot live in the presence of oxygen, convert mercury II into
6 methylmercury. Morel, 8 Tr. 856:10-13; 8 Tr. 874:4-9; 8 Tr. 875:19-24. If there is any
7 oxygen present, the SRBs cannot survive. Morel, 8 Tr. 874:22-875:1.

8 **2. The Oceans**

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

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

18 175. There are many differences between oceans and freshwater systems. The PH
19 in lakes is quite variable, but is constant in the oceans. Morel, 8 Tr. 876:22-877:10;
20 Fitzgerald, 22 Tr. 2749:26-2750:10. Unlike lakes, the oceans are too oxic to support
21 production of methylmercury by SRBs.³³ Morel, 8 Tr. 883:5-884:6; 8 Tr. 884:11-14. The
22 water in lakes cycles differently than in the oceans because lakes are much smaller than
23 oceans. Morel, 8 Tr. 881:8-26. In lakes, processes on the coastline affect what occurs in the
24 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.

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

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

8 **3. Methylmercury in Tuna and Other Fish**

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

13 178. It is undisputed that methylmercury bioaccumulates over time in fish,
14 including tuna. Grubbs, 19 Tr. 2445:22-24; Brodberg, 16 Tr. 1933:18-28; Morel, 8 Tr.
15 871:17-25; Joseph, 13 Tr. 1512:23-28. Bioaccumulation means that an element accumulates
16 in organisms. Morel, 8 Tr. 858:13-14. All metal species, including methylmercury, can
17 bioaccumulate if they get inside an organism. Morel, 8 Tr. 858:15-22. Methylmercury
18 bioaccumulates in tuna over time because, as the tuna gets larger, the level of methylmercury
19 in the tuna increases. Joseph, 13 Tr. 1512:23-1513:4, 13 Tr. 1539:13-23; Grubbs, 19 Tr.
20 2513:27-2514:2. Different species of tuna do not bioaccumulate methylmercury at hugely
21 dissimilar rates. Morel, 9 Tr. 1073:1-4.

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

24 180. The Tuna Cannery cannot catch smaller tuna with lower levels of
25 methylmercury because the practice would deplete world tuna stocks and would violate
26 United States and international law and treaties. Joseph, 13 Tr. 1509:22-1510:6; 13 Tr.
27 1539:21-1540:11; TX 831, pp. 3-5; TX 833 (16 U.S.C. § 1851).

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

4 **III. VIRTUALLY ALL METHYLMERCURY IN TUNA IS NATURALLY**
5 **OCCURRING**

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

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

16 184. There is no dispute that most of the methylmercury in the ocean exists
17 completely independently of human activity. The State's expert, Dr. Fitzgerald, concedes
18 that between fifty and seventy-five percent of the ocean's methylmercury is naturally
19 occurring. Fitzgerald, 23 Tr. 2861:9-27. Dr. Morel testified that at least ninety-five percent
20 of the methylmercury in the ocean is naturally occurring. Morel, 8 Tr. 956:13-15; 25 Tr.
21 3217:16-19. Indeed, Dr. Morel stated that the amount of methylmercury in the deep ocean
22 that is anthropogenic is more likely 1.5% ("the best number"). Morel, 8 Tr. 954: 25-26. As
23 for the percentage of methylmercury in tuna that is anthropogenic, according to Dr. Morel,
24 "It is either zero or 1.5 per cent." Morel, 8 Tr. 954: 27-28. As detailed below, this Court
25 finds Dr. Morel's opinion is more credible and better supported by the evidence presented.

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

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

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

11 187. The Tuna Cannery presented scientific studies that show there has been no
12 increase in the amount of methylmercury in ocean fish during the past 100 years. *See* TX
13 151; TX 152; TX 166; TX 647. These scientific studies support the conclusion that
14 methylmercury in canned tuna exists almost exclusively from natural sources with a de
15 minimus amount coming from anthropogenic sources.

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

18 188. The Court considered three studies comparing methylmercury concentrations
19 in museum fish samples from the late 19th and early 20th centuries with modern fish
20 samples. These studies demonstrate that the amount of methylmercury in ocean fish has not
21 increased over time, despite increased contributions of anthropogenic mercury. TX 151; TX
22 152; TX 166.

23 189. The fundamental premise underlying each of these studies is that if
24 methylmercury was formed from the deposition of industrial mercury pollution, then there
25 should be more methylmercury in modern fish than in museum fish captured prior to the
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1 industrial age.³⁴ Morel, 8 Tr. 892:9-21; TX 151, p. 552; TX 152, p. 636; TX 166, p. 1121.
2 Dr. Fitzgerald agrees with this premise. Fitzgerald, 23 Tr. 2899:19-28; 23 Tr. 2900:7-15; 23
3 Tr. 2910:20-2911:12; TX 859; TX 861, p. 296.

4 190. The first paper, published by Miller et al. in *Science*, (the "Miller paper" (TX
5 166)), examines whether mercury in tuna and swordfish is naturally occurring. Morel, 8 Tr.
6 892:1-5. The study compared the mercury content of fish that were caught between 1878
7 and 1909 and preserved in museums with the mercury content of fish that were caught in the
8 early 1970s. TX 166, p. 1121; Morel, 8 Tr. 892:9-21. In this study, both sets of samples
9 were weighed the same way, there is no evidence the museum samples were contaminated
10 and there was no methylmercury in the fish preservatives. TX 166, p. 1122; Morel, 8 Tr.
11 905:16-906:21. The study concluded that fish methylmercury levels did not increase, which
12 led the authors to conclude that the methylmercury in fish is naturally occurring.³⁵ TX 166,
13 p. 1122; Morel, 8 Tr. 892:17-21; 8 Tr. 894:19-22; 8 Tr. 904:17-27.

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

20 192. The second paper testing the anthropogenic contribution to ocean fish was
21 published in 1972 by Barber, et al. (the "First Barber paper" TX 152;) in a peer-reviewed
22 journal. Morel, 8 Tr. 890:15-16. The authors tested whether the mercury in tuna was from
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25 ³⁴ See Section III.C.1, *infra*, for a discussion regarding the increase of mercury
26 emissions into the atmosphere, based on trial evidence.

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

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

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

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

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

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

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

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

21 198. The Kraepiel study is published in a peer-reviewed journal and compares the
22 methylmercury concentrations of two groups of yellowfin tuna that were caught in the
23 Hawaii area in 1971 and 1998. TX 647, p. 5551. The study’s premise, like that in the
24 Miller and Barber papers, is that because there has been a net increase in atmospheric
25 mercury between 1971 and 1998, it is expected that the amount of methylmercury in tuna
26 caught in the same area would increase between 1971 and 1998. Morel, 8 Tr. 913:2-8; TX
27 647, p 5551.

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1 199. The Kraepiel study model respecting increases of mercury emissions is based
2 on data from Dr. Slemr, which shows that atmospheric mercury emissions increased from
3 1971 to 1990, followed by a decrease in the 1990s. Morel, 25 Tr. 3178:18-3179:25; TX 647,
4 p. 5556; TX 654A. The Slemr data supports Kraepiel's premise that total atmospheric
5 mercury emissions increased between 1971 and 1998. Morel, 8 Tr. 918:28-919:5; 8 Tr.
6 919:26-920:4; 8 Tr. 920:22-921:1. Kraepiel then calculated, based on this data, that
7 methylmercury levels in the mixed layer would have increased fifteen percent between 1971
8 and 1998 if methylmercury is formed in the mixed layer, and eighteen percent if
9 methylmercury is formed in the thermocline. TX 647, p. 5556.

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

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

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

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

1 16; 8 Tr. 937:12-16; TX 647, p. 5554; TX 808. Therefore, the Kraepiel study supports the
2 conclusion that there is almost no anthropogenic methylmercury in the ocean. Morel, 8 Tr.
3 939:25-940:15.

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

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

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

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

16 **a. Mercury Emissions Increased Since Pre-Industrial Times**

17 206. Dr. Fitzgerald published an article in 2001 in which he calculated that the
18 amount of atmospheric mercury has increased 1.4 percent per year since pre-industrial times.
19 TX 159, p. 1116 (Fig. 7). This reflects an increase from pre-industrial times to current times
20 of nine megamoles of mercury in the atmosphere to twenty-six megamoles. Morel, 8 Tr.
21 917:10-12; TX 159, p. 1116 (Fig. 7). Dr. Fitzgerald also calculated that mercury levels in
22 the mixed layer and the thermocline increased over the same time period.³⁶ Morel, 8 Tr.
23 917:8-9; TX 159, p. 1116 (Fig. 7). The article does not include a caveat indicating there may
24 not have been an increase in atmospheric emissions in the last thirty years (Fitzgerald, 23 Tr.

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26

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

1 2926:28-2927:25) or that emissions have tapered off (Fitzgerald, 23 Tr. 2928:4-9). Dr.
2 Fitzgerald has not revised his estimate of a 1.4 percent per year increase in any published
3 article. Fitzgerald, 23 Tr. 2927:22-2928:9; Morel, 25 Tr. 3236:4-10.

4 207. Further evidence supporting an increase in atmospheric mercury is reflected
5 in data collected by Dr. Joseph Pacyna, who, according to Dr. Fitzgerald, is a well-regarded
6 scientist. Fitzgerald, 23 Tr. 2928:18-23; TX 153. Dr. Pacyna's data shows that mercury
7 emissions have increased from 1881 tonnes/year in 1990 to 2269 tonnes/year in 2000.
8 Fitzgerald, 23 Tr. 2928:28-2929:2; TX 153. The data shows a large increase in Asia from
9 705 tonnes/year in 1990 to 1204 tonnes/year in 2000. TX 153. Until at least 2001, Dr.
10 Fitzgerald agreed with Dr. Pacyna that total anthropogenic mercury emissions increased
11 between 1990 and 2000. Fitzgerald, 23 Tr. 2929:18-22.

12 **b. Mercury Emissions Increased Between 1971 and 1998**

13 208. Despite Dr. Fitzgerald's agreement that mercury levels have increased since
14 pre-industrial times, he quibbles with whether mercury levels increased between 1971 and
15 1998. Primarily, Dr. Fitzgerald opines that the Slemr data (TX 148), on which Kraepiel
16 relies, shows that mercury levels declined beginning in 1990, and then plateaued in 1998.
17 TX 143, p. 5. The evidence does not support Dr. Fitzgerald's opinion that there was no
18 increase in mercury emissions and the Court accords it little weight for several reasons.

19 209. First, the Slemr data does not change the conclusion that mercury levels
20 increased between 1971 and 1998. Even if the level of atmospheric mercury declined in the
21 1980s, there was still more mercury in the atmosphere than there had been in the early 1970s.
22 Morel, 8 Tr. 919:26-920:1.

23 210. Second, Dr. Fitzgerald's opinion on whether there is good evidence for an
24 increase in mercury between 1971 and 1998 has changed during this case. In his original
25 expert report in this case, Dr. Fitzgerald stated there was no increase between 1971 and 1998.
26 TX 143, p. 6. In his revised expert report, Dr. Fitzgerald changed the date range to between
27

28

1 1979 and 2000 or 2001. TX 143, p. 6. Dr. Fitzgerald admits that he has supporting data only
2 from 1979, not 1971. Fitzgerald, 23 Tr. 2952:14-22.

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

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

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

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

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

1 3201:2-26; TX 266. Moreover, TX 147 concludes that there was stability and homogeneity
2 of the methylmercury in the mixed layer in the Hawaii region. TX 147, 17; Morel, 25 Tr.
3 3176:20-25.

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

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

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

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

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

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

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

5 220. Third, the tuna that do aggregate at FADs spend only a short time there.
6 Yellowfin tuna have a mean residence time at nearshore FADs of seven to eight days.
7 Joseph, 13 Tr. 1511:4-7; Grubbs, 20 Tr. 2564:14-17. This data is consistent with research
8 findings of the residence time of yellowfin tuna at FADs in Japan. Grubbs, 20 Tr. 2564:2-
9 2565:3; TX 219, p. 1.

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

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

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

4 223. Both Dr. Joseph and Dr. Grubbs agree that most tuna will travel several
5 hundred miles,³⁷ and some tuna will travel several thousand miles. Joseph, 13 Tr. 1516:15-
6 18; Grubbs, 19 Tr. 2427:6-11; *see also* TX 600. Yellowfin tuna are known to travel 450-600
7 miles, on average, and can travel several thousand miles. Joseph, 13 Tr. 1516:14-18.³⁸

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

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

18 226. Eighth, the low transfer rates between inshore and offshore fish is limited to a
19 small amount of FAD-related research. Dr. Grubbs claims that migration and in/off-shore
20 transfer rates in the Hawaii region refute the highly migratory nature of tuna. Grubbs, 19 Tr.
21 2475:1-4. As sole support for this contention, Dr. Grubbs discussed two articles that
22 reviewed migration rates in Hawaii between FADs, in particular the Cross Seamount.

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

28 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.

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

11 227. Ninth, the locations of the FADs at which Dr. Grubbs conducts his fish
12 collections are not relevant to the distance at which the Krapeiel fish were caught. The
13 thirteen nearshore FADs at which Dr. Grubbs sampled fish are all located between three and
14 seventeen miles from shore. Grubbs, 19 Tr. 2465:18-20; 20 Tr. 2536:15-18.³⁹ The 1971-
15 yellowfin tuna were caught within twenty miles from shore. Moreover, there were no FADs
16 around Hawaii in 1971 when the Thieleke and Rivers tuna were caught, and thus Dr.
17 Grubbs' FAD data is not applicable to those fish. Grubbs, 20 Tr. 2552:28-2553:4.

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

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25 ³⁹ Dr. Grubbs testified during his first day of testimony that the nearshore FADs are located
26 "generally less than five, seven – about, well, less than 10 miles from shore." Grubbs, 19
27 Tr. 2440:4-6; see TX 407; TX 408A. Later that evening, prior to his second day of
28 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.

1 229. Tenth, the prey diversity in Hawaii is such that most prey is widely available.
2 Dr. Grubbs testified about a unique prey, the oplophoroid shrimp, which nearshore tuna eat.
3 However, according to Dr. Grubbs' initial trial testimony, the oplophoroid are only found
4 within two to seven miles from the Hawaiian shore, which would give this prey limited
5 relevance to the nearshore fish, which were caught out to twenty miles from shore. Grubbs,
6 20 Tr. 2532:19-21. On the second day of his testimony, Dr. Grubbs changed his opinion to
7 claim that the oplophoroid's habitat may extend out to twenty miles in one location near
8 Hawaii. Grubbs, 20 Tr. 2533:27-2534:11. Dr. Grubbs' opinion is irrelevant because he does
9 not know if the shrimp are actually there. Grubbs, 20 Tr. 2533:18-25; 20 Tr. 2534:12-14.
10 Aside from the oplophoroid shrimp, all other types of yellowfin prey (including Sergestidae,
11 Stomatopoda, Decapoda larvae, epipelagics, mesopelagics, Reef Teleosts, salps and squid)
12 are widely distributed throughout the region, with some variation according to distance from
13 shore. Grubbs, 20 Tr. 2538:15-26; 20 Tr. 2539:4-24; 20 Tr. 2540:2-7, 19-27; 20 Tr.
14 2541:16-2542:8; 20 Tr. 2542:15-2543:28; 20 Tr. 2544:1-2545:9; 20 Tr. 2545:26-2546:9; TX
15 409; TX 410; TX 411A. Dr. Grubbs testified that the tuna prey available by location was the
16 same in the 1970s as it was in the 1990s. Grubbs, 19 Tr. 2516:4-11.

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

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

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

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

1 all of the fish in the Kraepiel study were caught in the spring and fall months, and Dr.
2 Grubbs has no evidence that changes in physiology affected methylmercury levels in the
3 tuna, or that methylmercury levels in fish vary by season. Grubbs, 19 Tr. 2514:6-19; 20 Tr.
4 2593:1-3, 10-17.

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

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

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

20 **D. Mercury is Most Likely Methylated in the Deep Ocean**

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

28

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

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

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

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

18 239. Kraepiel also tested the hypothesis that mercury is methylated in the
19 thermocline. TX 647, p. 5555. Kraepiel estimated that mercury concentrations increased by
20 12 percent between 1971 and 1998. *Id.* Using the model and best available data, Kraepiel
21 rejected the hypothesis that mercury is methylated in the thermocline. *Id.*

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

28

1 241. Other evidence supports the conclusion that mercury is not methylated in the
2 thermocline. There is no known mechanism by which methylation occurs in the
3 thermocline, which is oxic and thus cannot support production of methylmercury by SRBs.
4 Morel, 25 Tr. 3186:20-3187:14. Dr. Morel conducted an experiment to determine if mercury
5 could be methylated in the thermocline but did not observe any methylation. Morel, 25 Tr.
6 3185:21-25; 25 Tr. 3187:10-14; TX 160. Dr. Morel was able to methylate mercury only
7 when he made the water completely anoxic. Morel, 25 Tr. 3187:23-3188:2.

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

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

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

17 244. The deep ocean vent theory has been researched for twenty-five years. Morel,
18 9 Tr. 1110:21-26. Deep ocean hydrothermic vents are found in every ocean. Morel, 8 Tr.
19 982:25-26. Hydrothermic vents are at different layers of the oceans and allow for the
20 distribution of methylmercury in the ocean. Morel, 8 Tr. 957:10-958:1; 8 Tr. 982:28-983:9;
21 TX 810. There is evidence to show that mercury is methylated in deep ocean hydrothermic
22 vents and spewed into the ocean waters. If hydrothermic vents are the source of
23 methylmercury, then 100 percent of methylmercury in the ocean is naturally occurring.
24 Morel, 25 Tr. 3217:4-11.

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

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

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

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

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

1 249. Another study by Dr. Fitzgerald in the equatorial Pacific Ocean found
2 methylmercury below the thermocline and that levels increased as the ocean depth increased.
3 TX 146, pp. 1923-24; Morel, 8 Tr. 979:11-13; Morel, 25 Tr. 3224:9-16; Fitzgerald, 22 Tr.
4 2784:23-25; 23 Tr. 2905:9-12.

5 250. A third study conducted in the south and equatorial Atlantic Ocean found
6 dimethylmercury below 1,000 meters. Morel, 8 Tr. 980:16-19; 8 Tr. 980:28-981:2;
7 Fitzgerald, 23 Tr. 2922:12-20; TX 165, p. 950. Dr. Fitzgerald has published that higher
8 concentrations of dimethylmercury could result from hydrothermal vents. Fitzgerald, 23 Tr.
9 2918:5-2919:18; TX 144, p. 83. In this study, the authors also found no methylmercury or
10 dimethylmercury in the mixed layer. Fitzgerald, 23 Tr. 2922:2-5; TX 165, p. 944.

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

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

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

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

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

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

5 255. Dr. Fitzgerald's coastal theory is based solely on mercury measurements from
6 three highly polluted areas: the Long Island Sound, Lavaca Bay, Texas and the Gulf of
7 Trieste. TX 421, pp. 3, 10, 25. The Long Island Sound is located near New York City off
8 the New Jersey coast and is known to be polluted. Morel, 8 Tr. 984:22-24; Fitzgerald, 23 Tr.
9 2938:21-24.

10 256. Lavaca Bay is highly polluted with mercury from industrial facilities and is
11 designated a Superfund site. Morel, 8 Tr. 984:25-28; Fitzgerald, 23 Tr. 2942:19-23. The
12 Gulf of Trieste is likewise polluted, and is described as the most mercury-contaminated area
13 in the Mediterranean Sea. Morel, 8 Tr. 985:1-18; Fitzgerald, 23 Tr. 2942:24-28; TX 811, p.
14 1692.

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

20 258. Despite the highly polluted nature of the Long Island Sound, Dr. Fitzgerald
21 used measurements from the Long Island Sound to project to the coastal areas of the entire
22 world. Fitzgerald, 23 Tr. 2873:12-14; 23 Tr. 2874:10-16; 23 Tr. 2875:4-10; TX 421, p. 10.
23 Dr. Fitzgerald assumed that the areas he sampled off the Long Island Sound are typical of the
24 world's coastal areas. Fitzgerald, 23 Tr. 2938:12-24; 23 Tr. 2941:6-13. However, Dr.
25 Fitzgerald admits that many of the world's coasts do not have heavy population centers like
26 the Long Island Sound. Fitzgerald, 23 Tr. 2943:2-5. Dr. Fitzgerald further admits that he
27 does not have measurements from these less populated areas, but wishes he did. Fitzgerald,
28 23 Tr. 2943:6-7.

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

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

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

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

20 **i. Bioadvection is Scientifically Improbable**

21 262. It is scientifically improbable that methylmercury moves in the water from the
22 coastal areas to the open ocean. Dr. Fitzgerald's research shows that the amount of
23 methylmercury decreases in the water going away from the coast. Fitzgerald, 23 Tr.
24 2870:14-17; 23 Tr. 2871:27-2872:4; Morel, 8 Tr. 988:9-21; TX 154, p. 47; TX 421, pp. 13,
25 25, 26; *see also* TX 850 (discussing other trace metals). Accordingly, the transfer of
26 methylmercury from the coast to the ocean, if any, would not be 100 percent efficient.
27 Morel, 8 Tr. 988:22-989:1. Dr. Fitzgerald does not disagree with Dr. Morel's opinion
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1 (Fitzgerald, 22 Tr. 2773:7-11), and he does not discuss efficiency in his recently published
2 paper on the coastal theory. Morel, 9 Tr. 1011:26-1012:3; TX 421.

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

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

17 265. Dr. Morel's testimony about iron undermines the probability that coastal
18 methylmercury is transported to the open ocean. Iron is one of the best-studied trace
19 elements, and studies indicate that the iron in the ocean, away from the coast, comes from
20 the air or from the slow upwelling of deep waters. Morel, 25 Tr. 3171:23-24; 25 Tr. 3172:5-
21 9. Iron is a good indicator to determine whether methylmercury in coastal sediments would
22 appear in the mid-ocean because both iron and methylmercury are soluble and particle-
23 reactive. Morel, 25 Tr. 3170:20-3171:3, 16-17; 25 Tr. 3173:24-27. Iron is a trace metal (like
24 mercury) that is not transported from coastal areas to the deep ocean. Morel, 8 Tr. 853:12-
25 15. There is usually a zero impact from coastal processes on the open ocean. Morel, 8 Tr.
26 983:15-20; 25 Tr. 3171:18-20. Elements that are particle reactive, including iron and
27 mercury, essentially are eliminated a short distance from the coast. Morel, 25 Tr. 3173:28-
28 3174:7.

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

8 276. There are no mass migrations of prey fish from the continental shelf. Joseph,
9 13 Tr. 1522:4-13; TX 617. Commercial fishers fish for and catch prey fish over the
10 continental shelf. Joseph, 13 Tr. 1522:7-13. Some prey fish larvae drift out past the
11 continental shelf. Joseph, 13 Tr. 1580:6-21. Even if some larvae drift to the ocean, it is
12 unlikely that tuna eat the larvae because the larvae do not spawn in the areas where tunas
13 swim. Joseph, 13 Tr. 1582:4-7.

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

19 278. TX 378 is an abstract that studied the *E. punctifer* off the Philippines. TX
20 378, p. 1. The continental shelf around the Philippines is very narrow and the deep ocean is
21 close to the coast, but the paper does not describe the distance of the coastal region from
22 land. Joseph, 13 Tr. 1613:3-7, 11-14; TX 378.

23 279. Dr. Grubbs also testified that Dr. Joseph's assertion that there was no
24 connection between the coastal areas and the open ocean was not accurate because the
25 Japanese anchovy is found both at the coast and offshore. Grubbs, 19 Tr. 2504:8-23; TX
26 416; TX 417. Again, these studies do not refute Dr. Joseph's opinions. Dr. Grubbs agrees
27 that anchovies and sardines are predominately coastal animals. Grubbs, 20 Tr. 2580:16-18.
28 As for the Japanese anchovy, Dr. Grubbs admitted that the eggs and larvae of the anchovies

1 are pushed out into the offshore area by a current and grow and reproduce into a separate
2 offshore population. Grubbs, 20 Tr. 2583:28-2584:8; *see* TX 417, p. 167. Dr. Grubbs also
3 admitted that the methylmercury in the Japanese anchovy larvae is not detectable and he
4 knows nothing about whether anchovy eggs contain methylmercury. Grubbs, 20 Tr.
5 2581:27-2582:2; *see also* TX 846, p. 1031. Further, Dr. Grubbs does not know of any papers
6 that discuss mass migrations of sardines or anchovies from the coastal areas to the open
7 ocean. Grubbs, 20 Tr. 2584:23-2585:1.

8
9 **c. There Is Insufficient Methylmercury Methylated in the Coastal Zones to Support Methylmercury in Ocean Fish**

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

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

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

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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

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

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

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

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

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

4 9. Like the FDA action in *Dowhal*, the FDA letter to the State Attorney General
5 serves as an informal agency action, communicating FDA's position that Proposition 65
6 frustrates the purpose of FDA's carefully considered approach. *Id.*; *Dowhal*, 32 Cal.4th. at
7 929. Consistent with case precedent on this issue, this Court concludes that the FDA
8 Preemption Letter should be accorded deference. *See Dowhal*, 32 Cal.4th at 928 (holding
9 that FDA's letter to nicotine replacement therapy ("NRT") manufacturers was sufficiently
10 definite and authoritative to be given deference). *See also Geier*, 529 U.S. at 883-84
11 (holding that comments by Department of Transportation accompanying its revision of the
12 airbag rules and in statements in the Solicitor General's brief submitted on the agency's
13 behalf should be accorded deference). The Supreme Court acknowledged the consequence of
14 federal regulatory action like that in *Dowhal* and *Geier* when it quoted the latter decision:
15 "Congress has delegated to the DOT (Department of Transportation, the regulatory agency in
16 issue) authority to implement the statute; the subject matter is technical; and the relevant
17 history and background are complex and extensive. The agency is likely to have a thorough
18 understanding of its own regulation and its objectives and is '*uniquely qualified*' to
19 comprehend the likely impact of state requirements." *Dowhal* 32 Cal.4th at 925, *citing Geier*
20 529 U.S. at 883 (emphasis added).

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

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

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

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

19 **II. BURDEN OF PROOF**

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

23 14. The standard of proof is the preponderance of the evidence. Evid. Code
24 § 115; *Baxter Healthcare Corp. v. Denton* (2004) 120 Cal.App.4th 333, 365-66. The
25 preponderance of the evidence standard requires the trier of fact to believe that the existence
26 of a fact is more probable than its nonexistence. *Lillian F. v. Superior Court* (1984) 160
27 Cal.App.3d 314, 320.

28

1 15. The Tuna Canners have the initial burden of producing evidence to prove
2 their preemption defense. Evid. Code § 550; *Mathis v. Morrissey* (1992) 11 Cal.App.4th
3 332, 346. The burden of production shifts to the State if the Tuna Canners provide evidence
4 of such weight that a determination in the Tuna Canners' favor would necessarily be required
5 in the absence of contradictory evidence. Evid. Code § 550.

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

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

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

1 State argued that the FDA letter is not entitled to deference under the law. *See Geier*, 529
2 U.S. at 883; *Dowhal*, 32 Cal.4th at 928-29. Moreover, the State failed to sufficiently
3 distinguish its case from our Supreme Court's decision in *Dowhal*, which found that
4 Proposition 65 is preempted by FDA authority for warnings on NRT products. *See Dowhal*,
5 32 Cal.4th 910.

6 **III. THE FDA PREEMPTION LETTER IS ENTITLED TO DEFERENCE**

7 19. A federal agency's own views respecting whether a state law conflicts with
8 federal law it administers are to be accorded *substantial* deference. *Sprietsma v. Mercury*
9 *Marine* (2002) 537 U.S. 51, 67-68. FDA's views on labeling merit particular respect.
10 *Henley v. FDA* (2d Cir. 1996) 77 F.3d 616, 620 ("FDA's determination of what labeling best
11 reflects current scientific information regarding the risks and benefits" of an FDA-regulated
12 product "involves a high degree of expert scientific analysis.") FDA expertise applies to
13 warnings that should be given, as well as to those that should not. *Brooks v. Howmedica,*
14 *Inc.* (8th Cir. 2001) 273 F.3d 785, 796. Our appellate courts have adopted the principle that
15 federal agency action is no less preemptive than federal statutes when the agency is carrying
16 out authority substantiated by Congressional statute. *Lopez v. World Savings & Loan* (2003)
17 105 Cal.App.4th 729, 736-737. See also *Fidelity Federal v. DeLaCuesta* (199) 458 U.S.
18 141, 153.

19 20. On several instances, the Supreme Court has focused on the specific position
20 of the *federal* agency *vis a vis* the state or local statute. If the agency position clearly reflects
21 a stand that challenges the state's conflicting yet specific requirement, then finding
22 preemption is more likely appropriate. On the other hand, a more generalized *federal*
23 pronouncement may not support preemption. This important legal distinction in the nature
24 of the federal agency position was acknowledged cogently by Justice Marshall:
25

26 [B]ecause agencies normally address problems in a detailed manner and can
27 speak through a variety of means, including regulation, preambles,
28 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,

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

5 In *Hillsborough County*, the FDA had not challenged the position of the county directly on
6 the particular issues raised in a local regulatory scheme on plasma centers in the county. On
7 the other hand, here the FDA's letter to the Attorney General explicitly advises that
8 Proposition 65 warnings are preempted because they are contrary to the FDA advisories and
9 FDA policies regarding fish consumption. Here the "intentions" of the FDA are crystal
10 clear, not dependent on "mere volumes of regulations." As another court noted, "Unlike
11 general federal requirements, . . . the warning requirements here reflect the sort of concerns
12 regarding a specific device *or field of device regulation* which the regulations were designed
13 to protect from potentially contradictory state requirements. This then is a case in which the
14 Federal Government has weighed the competing interests relevant to the particular
15 requirements in question, reached an unambiguous conclusion about how those competing
16 interests should be resolved in a particular case or set of cases, and implemented that
17 conclusion via a specific mandate on manufacturers or producers." *Papike v. Tambrands*
18 *Inc.* 107 F.3d 737, 741 (9th.Cir. 1997)(emphasis added.)
19

20 21. The Court finds that FDA makes clear in the Preemption Letter that
21 Proposition 65 warnings on tuna products are preempted for three reasons: (1)
22 Proposition 65 warnings frustrate FDA's carefully considered approach to advising the
23 public concerning the benefits and risks of consuming canned tuna; (2) point of purchase
24 warnings conflict with FDA's longstanding opposition to warning signs in connection with
25 the sale of food, and (3) Proposition 65 warnings conflict with federal law because such
26 warnings on canned tuna would be misleading under section 403 of the FDCA (21 U.S.C.
27 § 343). TX 727, p. 6.
28

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

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

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

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

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

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1 32 Cal.4th at 928-29. Here, FDA's determination that any canned tuna warning that contains
2 the core and mandatory language is preempted is likewise entitled to deference. *Id.*; *see also*
3 *Geier*, 529 U.S. at 881.

4 26. It is immaterial that the Preemption Letter does not constitute formal agency
5 action. The formality of a regulation or advisory opinion is not required for a governmental
6 agency action to be afforded deference. *Geier*, 529 U.S. at 881. Informal agency action
7 taken pursuant to congressionally granted authority can preempt state law. *Geier*, 529 U.S.
8 at 884-85 (stating that "the Court has never before required a specific, formal agency
9 statement identifying conflict in order to conclude that such a conflict exists."); *Bank of*
10 *America v. City of San Francisco* (9th Cir. 2002) 309 F.3d 551, 563-64 (finding conflict
11 preemption based on interpretation of national bank powers set forth in an amicus brief and
12 two interpretative letters); *Dowhal*, 32 Cal.4th at 929 (finding preemptive intent in a FDA
13 letter establishing its policy regarding FDA-approved warnings); *see also Auer v. Robbins*
14 (1997) 519 U.S. 452, 462 (stating that a department's interpretation of its regulations in the
15 form of a legal brief did not "make it unworthy of deference" and that "[t]here is simply no
16 reason to suspect that the interpretation does not reflect the agency's fair and considered
17 judgment on the matter in question.").

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

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

4 28. A state law:

5 “stands as an obstacle to the accomplishment and execution of the full
6 purposes and objectives of Congress – whether the ‘obstacle’ goes by the
7 name of ‘conflicting; contrary to; . . . repugnance; difference;
8 irreconcilability; inconsistency; violation; curtailment; . . . interference,’ or
9 the like.”

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

11 29. “What is a sufficient obstacle is a matter of judgment, to be informed by
12 examining the federal statute as a whole and identifying its purpose and intended effects . . .”

13 *Crosby*, 530 U.S. at 373. The Court examines the entire scheme of the federal law and
14 whether state law would frustrate its purpose and operation. *Hines*, 312 U.S. at 67.

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

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

28 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.

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

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

12 35. The FDA/EPA Advisory cannot be used as a point-of-purchase Proposition 65
13 warning, if indeed the State is suggesting that the Advisory be posted in stores. *See, e.g.,*
14 *Dowhal*, 32 Cal.4th at 929. The FDA made it clear that the method of communication is as
15 important as the content of the message. Even if the advisory were to be provided verbatim
16 in grocery stores, this method of distribution would conflict with federal policy on food
17 warnings and warnings for canned tuna. Sullivan, 14 Tr. 1777:3-6; 14 Tr. 1778:25-28; 14
18 Tr. 1779:1-8; TX 727. Moreover, a blended warning, containing aspects of both the
19 FDA/EPA Advisory and Proposition 65 language is likewise impermissible. *Dowhal*,
20 32 Cal.4th at 928-29.

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

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

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

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

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

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

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

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

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

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

11 **VI. THE STATE’S PROPOSED WARNING FAILS TO COMPLY WITH**
12 **PROPOSITION 65**

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

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

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

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

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

9 One commentator recommended allowing business to include additional
10 information along with the basic statements set out in the 'safe harbor'
11 provisions (citation omitted). This is allowed under subsection (a). A
12 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.

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

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

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

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

26 48. The Griffin Shelf Sign actually buries the warning at the bottom of the page,
27 positioned in a place that could cloud the warning message, and that Dr. Griffin himself
28

1 acknowledged would likely never be read. Griffin 6 Tr. 693:10-14; 6 Tr. 720:10-20;
2 TX 365A.
3 49. Third, as Dr. Griffin testified, the Attorney General did not want Dr. Griffin
4 to use the core and mandatory language in the sign. Griffin, 6 Tr. 678:25-679:10; 6
5 Tr. 682:15-685:13. Dr. Griffin's directive was to translate the FDA/EPA Advisory and make
6 it more concise. Griffin, 6 Tr. 616:9-12; 6 Tr. 699:27. As directed, and in contravention of
7 section 12601, Dr. Griffin did not include the core and mandatory language in his sign --
8 "this product contains a chemical known to the state of California to cause birth defects or
9 other reproductive harm." TX 365A. The sign does not include the word "Warning." Id.
10 Instead, it is titled an advisory. Id. Finally, the sign does not mention the State of California.
11 Id.; see FSOR, p. 25 (RJN, Ex. A) (stating that "the reference to the 'State of California' [in
12 a warning] is intended to lend authority to the warning message and is an important part of
13 it.") Even if the words "Warning" and "State" can be eliminated from a Proposition 65
14 warning, the Griffin Shelf Sign does not contain the core and mandatory language.
15 Accordingly, it is not Proposition 65-compliant.

16

17 MADL

18 **I. APPLICABLE STATUTORY PROVISIONS AND REGULATORY**
19 **BACKGROUND**

20 50. Proposition 65 is codified at Health & Safety Code sections 25249.5-
21 25249.13. Pursuant to section 25249.6:

22 Required Warning Before Exposure to Chemicals Known to Cause Cancer or
23 Reproductive Toxicity. No person in the course of doing business shall
24 knowingly and intentionally expose any individual to a chemical known to the
25 state to cause cancer or reproductive toxicity without first giving clear and
26 reasonable warning to such individual, except as provided in Section
27 25249.10.

25

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

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

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

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

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

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

- 15 • Section 12801(a) outlines the general framework for establishing the NOEL
16 under Proposition 65, and mandates that the NOEL shall be divided by one
17 thousand (1,000) to arrive at an MADL. TX 2, p. 200.4.
- 18 • Section 12803 sets out the “safe harbor” method for preparing a quantitative
19 risk assessment to calculate a NOEL for a listed chemical. Under section
20 12803(a)(1) “only studies producing the reproductive effect which provides
21 the basis for the determination that a chemical is known to the state to cause
22 reproductive toxicity, shall be utilized for the determination of the NOEL.”
23 Sections 12803(a)(2) & (3) lists the factors to consider when considering the
24 suitability of using a toxicology study in a risk assessment. TX 2, p. 200.5.
- 25 • Section 12803(a)(2) states that “animal bioassay studies shall meet generally
26 accepted scientific principles, including the thoroughness of experimental
27 protocol, the degree to which dosing resembles the expected manner of
28 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.”

- 1 • Section 12803(a)(3) states that the “quality and suitability of available
2 epidemiological data shall be appraised to determine whether the study is
3 appropriate as the basis of an assessment considering such factors as the
4 selection of exposed and reference groups, the reliable ascertainment of
5 exposure, and completeness of follow-up. Biases and confounding factors
6 shall be identified and quantified.”
- 7 • Under Section 12803(a)(4), only the most sensitive study deemed to be of
8 sufficient quality can be used for establishing a NOEL. TX 2, p. 200.5.
- 9 • Section 12803(a)(7) provides that where data in the most sensitive study
10 deemed to be of sufficient quality do not allow for the determination of a
11 NOEL, a NOEL may be derived by dividing the LOEL by a factor of 10.
12 TX 2, p. 200.5.
- 13 • Section 12803(b) mandates that a NOEL shall be converted to a milligram per
14 day dose level by multiplying the assumed human body weight by the NOEL.
15 It also mandates that when the applicable reproductive effect is upon the
16 fetus, a human body weight of 58 kg shall be assumed. TX 2, p. 200.5.
- 17 53. Section 12821 of the California Code of Regulations, entitled “Level of
18 Exposure to Chemicals Causing Reproductive Toxicity,” outlines the required procedures for
19 calculating exposure to methylmercury in canned tuna. TX 2, p. 200.6.

20 **II. BURDEN OF PROOF**

21 54. The Tuna Canners have the burden of proof to establish that the Tuna
22 Canners’ products are below the MADL for methylmercury. TX 2, p. 200.5 (Cal. Health &
23 Safety Code § 12803); Evid. Code §§ 115, 500. The standard of proof is the preponderance
24 of the evidence. Evid. Code § 115; *Baxter Healthcare Corp. v. Denton* (2004) 120 Cal. App.
25 4th 333, 365-66. Preponderance of the evidence means evidence that, when weighed with
26 that opposed to it, has more convincing force and the greater probability of truth. *Leslie G.*
27 *v. Perry & Assocs.* (1996) 43 Cal. App. 4th 472, 483. The Court finds that the Tuna Canners
28 have met their burden of proving the following:

1 **A. The Tuna Cannery's Risk Assessment Complies with Section 12803**

2 55. A risk assessor calculating a NOEL under sections 12803 is required to select
3 the study producing the lowest NOEL from the most sensitive study deemed to be of
4 sufficient quality. TX 2, p. 200.5 (Cal. Health & Safety Code § 12803(a)(4)). Because
5 Proposition 65 is concerned with chemicals that cause reproductive toxicity, suitable studies
6 under section 12803 must evaluate prenatal exposure to a chemical. The Court finds that the
7 Tuna Cannery's risk assessment prepared by their expert, Dr. Murray, complies with section
8 12803 for the following reasons:

9 56. The Bornhausen study was properly selected as the study that produced the
10 lowest NOEL from most sensitive study deemed to be of sufficient quality under section
11 12803(a)(1) and (4).

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

21 58. The State's primary objection to the suitability of the Bornhausen study under
22 section 12803 was directed at its use of rats, rather than human, subjects. The Court rejects
23 this argument because the statute specifically contemplates the use of animal bioassay
24 studies to calculate a NOEL. TX 2, p. 200.5 (Cal. Health & Safety Code § 12803(a)(3)).
25 Aside from its objection to the use of animal studies, the State did not present any persuasive
26 evidence undermining the thoroughness of the experimental protocol used in the Bornhausen
27 study, the degree to which dosing resembled the expected manner of human exposure, the
28

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

3 59. The Court finds that the additional calculation performed by Dr. Rice to
4 convert the Burbacher NOEL, which was identical to the Bornhausen NOEL, to a human
5 NOEL was improper under section 12803. Section 12803 does not require adjustments to
6 NOELs derived from animal studies, nor are there any guidelines in the regulations
7 governing calculations to adjust an animal NOEL to a human NOEL. Indeed, OEHHA has
8 used animal studies for *every* published MADL except for lead and ethylene oxide, and has
9 *never* adjusted an animal LOEL or NOEL to a human NOEL. The OSHA PELs used for the
10 lead and ethylene oxide MADLs have NOEL surrogates, and therefore comply with section
11 12803.

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

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

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

11 62. Based on Dr. Murray’s calculations and his testimony, and rejecting
12 Dr. Rice’s proposed MADL, the Court finds that the NOEL for methylmercury under section
13 12803 is 0.005 mg/kg/day, and that the MADL for methylmercury is 0.3 micrograms/day.

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

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

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

21 **1. Averaging Exposure to Methylmercury Over Two Months Is**
22 **Appropriate**

23 65. Based on Dr. Murray’s testimony, the Court finds that for purposes of this
24 case, averaging exposure to methylmercury is appropriate under section 12821(b). Section
25 12821(b) states that the reasonably anticipated rate of exposure “shall be based on the pattern
26 and duration of exposure that is relevant to the reproductive effect which provided the basis
27 for the determination that a chemical is known to the state to cause reproductive toxicity.”
28 TX 2, p. 200.6 (Cal. Code of Regulations § 12821(b)). Dr. Murray testified that

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

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

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

18 67. When a term used in a statute is undefined, the Court should first examine the
19 actual language of the statute and apply the ordinary, everyday meaning of the words, unless
20 the statute specifically designates a special meaning. *Halbert's Lumber, Inc. v. Lucky Stores,*
21 *Inc.* (1992) 6 Cal.App.4th 1233, 1238-9. If the meaning of the word is without ambiguity,
22 doubt, or uncertainty then the language controls. *Id.* If the meaning of the word is not clear,
23 the Court must refer to the legislative history.⁴⁰ *Id.* at 1239. If the legislative history does
24 not indicate a clear meaning, then the Court should apply "reason, practicality and common
25

26
27 ⁴⁰The parties agreed that there is no legislative history that provides guidance on the
28 meaning of the term "average." The Statement of Reasons also does not provide guidance.

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

3 68. The Court finds as a matter of law that the term "average" used in section
4 12821(c) is not unclear. Experts from both parties, including Dr. Wind, Dr. Griffin, and
5 Dr. Brodberg, as well as the OEHHA scientists Dr. Zeise and Dr. Golub, all testified that
6 both the professional and common definition of the term "average" is the arithmetic mean,
7 and not the median. The Court declines the State's request to "interpret away clear language
8 in favor of an ambiguity that does not exist." *People v. O'Neil* (1997) 56 Cal.App.4th 1126,
9 1132.

10 69. Even if the Court entertained the State's suggestion that the meaning of the
11 word "average" is ambiguous, applying "reason, practicality and common sense" still leads
12 the Court to find that "average" means the arithmetic mean. As discussed in the preceding
13 paragraph, the evidence presented shows that "average" more often than not means the
14 "arithmetic mean" among professional and common uses. Expert testimony, statistics
15 handbooks and common reference materials support this conclusion. *See, e.g.,* Wind, 18 Tr.
16 2233:5-7; 18 Tr. 2231:7-11; TX 843, p. 76; TX 844, p. 12.

17 70. The Court also finds that to interpret the term "average" in section 12821 to
18 mean typical, median, geometric mean, harmonic mean, trimmed mean, or Windsorized
19 mean, it would be interpreting the statute in a manner that would render it unconstitutionally
20 vague. *See, Greenland*, 20 Tr. 2619:20-2620:7. *In re Timothy R.* (1988) 202 Cal.App.3d
21 593, 597 (citing *Grayned v. City of Rockford* (1972) 408 U.S. 104). Had the Legislature
22 intended to use these more obscure definitions of the term "average," it would have made its
23 intention clear.

24 71. Based on the foregoing, the Court finds that the word "average" as it is used
25 in section 12821(c) is not unclear but clear, and means the mean. Assuming arguendo that it
26 is unclear, reason, practicality, and common sense dictate that the term means the "arithmetic
27 mean."
28

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

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

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

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

13 NATURALLY OCCURRING

14
15 **I. STATUTORY PROVISIONS**

16 74. Californians adopted the Safe Drinking Water & Toxic Enforcement Act of
17 1986 through its voter initiative powers in November 1986 ("Proposition 65"). Proposition
18 65 prohibits the knowing and intentional exposure to "a chemical known to the state to cause
19 cancer or reproductive toxicity without first giving clear and reasonable warning to such
20 individual, except as provided in section 25249.10." TX 1, p. 1 (Cal. Health & Safety Code
21 § 25249.6).

22 75. Human consumption of a food is not an exposure for purposes of Section
23 25249.6 to a listed chemical in the food to the extent that the person responsible for the
24 exposure can show that the chemical is naturally occurring in the food. TX 2, p. 196 (22
25 CCR 12501(b)). A chemical is "'naturally occurring' if it is a natural constituent of a food,
26 or if it is present in a food solely as a result of absorption or accumulation of the chemical
27 which is naturally present in the environment in which the food is raised, or grown, or
28

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

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

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

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

25 79. The exact breakdown of how much of a chemical must be naturally occurring
26 and how much of a chemical may be anthropogenic for it to qualify for the exception is not
27 specified in the statute. *See* §12501. Because this is a matter of first impression, it is
28

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

3 80. The fundamental rule of statutory construction is that the court should
4 ascertain the intent of the legislature as to effectuate the purpose of the law. *Palmer v. GTE*
5 *California Inc.* (2003) 30 Cal.4th 1265, 1271 (citations omitted). In the case of a statute
6 passed by an initiative measure, it is to ascertain and effectuate the intent of the voters.
7 *People v. Hazelton* (1996) 14 Cal.4th 101, 105. First, the Court looks to the words of the
8 statute, giving them their usual and ordinary meaning. *Palmer*, 30 Cal.4th at 1271. The
9 words of the statute are the most reliable indicator of the legislator's intent. *Id.* "Of course,
10 language of a statute should not be given a literal meaning if doing so would result in absurd
11 consequences which the Legislature did not intend." *People v. Broussard* (1993) 5 Cal.4th
12 1067, 1071 (citations omitted). "In such circumstances, the intent prevails over the letter,
13 and the letter will, if possible, be so read as to conform to the spirit of the act." *Id.* (citations
14 omitted). Thus, in order to determine whether the "naturally occurring" exception under
15 section 12501 includes chemicals that are both the result of natural sources and
16 anthropogenic sources, we begin with an analysis of the plain language of the statute.

17 **A. Statutory Language**

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

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

1 of absorption or accumulation of the chemical which is naturally present in the environment
2 in which the food is raised, or grown, or obtained.” §12501(a)(1). The chemical is not
3 naturally occurring to the extent that it is the result of any known human activity or failure to
4 observe “good agricultural or good manufacturing practices” such as the “addition of
5 chemicals to irrigation water applied to soil or crops.” §12501(a)(3)–(4). Even where the
6 chemical is a naturally occurring one, the regulations require that the producer,
7 manufacturer, distributor, or holder of the food at all times utilize measures to reduce the
8 chemical to the lowest level feasible. §12501(b); *See also Nicolle-Wagner v. Deukmejian*
9 (1991) 230 Cal.App.3d 652, 656.

10 83. Reading section 12501 in its context, it is apparent that the drafters were
11 particularly concerned with not exempting chemicals in food that are a result of *known*
12 *human activity*. For example, section 12501(a)(3) provides that “[a]chemical is naturally
13 occurring only to the extent that the chemical did not result from any *known human activity*.”
14 §12501(a)(3) (emphasis added). Subsection (a)(4) states, “[w]here a chemical contaminant
15 can occur naturally in a food, the chemical is naturally occurring only to the extent that it
16 was not avoidable by good agricultural or good manufacturing practices.” §12501(a)(4).

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

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

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

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

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

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

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

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

16 **B. Statutory Purpose**

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

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

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

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

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

18 94. This Court finds that, like methylmercury in tuna, chemicals in food that are
19 the result of both natural and *uncontrollable* human activity are exempt under the "naturally
20 occurring" exception and do not frustrate the purpose of Proposition 65, which is to regulate
21 toxic substances that are deliberately added or put into the environment by human activity.
22 *See* Health & Safety Code §25249 et seq. It would not make sense for the "naturally
23 occurring" exception to be reserved only for those chemicals that are one hundred percent
24 the result of natural sources. Science, by its very nature, allows for some degree of
25 uncertainty. Because science does not demand absolute certainty, the law on science cannot
26 demand anything different. As a result, the "naturally occurring" exception does allow for
27 some flexibility when the business in question has no control over the amount of a chemical
28

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

3 **II. BURDEN OF PROOF**

4 95. The Tuna Cannery have the burden of proof to establish that methylmercury is
5 naturally occurring in canned tuna. TX 2, p. 196 (22 CCR § 12501(b)); Evid. Code §§ 115,
6 500.

7 96. The standard of proof is the preponderance of the evidence. Evid. Code §
8 115; *Baxter Healthcare Corp. v. Denton* (2004) 120 Cal. App. 4th 333, 365-66. The
9 preponderance of the evidence standard requires the trier of fact to believe that the existence
10 of a fact is more probable than its nonexistence. *Lillian F. v. Superior Court* (1984) 160
11 Cal.App.3d 314, 323.

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

17 **III. METHYLMERCURY IN CANNED TUNA IS NATURALLY OCCURRING**

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

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

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

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

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

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

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

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

21 **IV.**

22
23 **ORDER**

24
25 **PREEMPTION**

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

1 which an unlawful business practices claim can be based. Accordingly, the section 17200
2 cause of action must be dismissed. *See People v. Duz-Mor Diagnostic Laboratory, Inc.*
3 (1998) 68 Cal.App.4th 654, 673 (stating that the Unfair Competition Act requires a violation
4 of law, and that a defense to the underlying offense is a defense under the Act).

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

9

10 DATE: May 11, 2006

11



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ROBERT L. DONDERO
Presiding Judge Superior Court

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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 foods² 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

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

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.

Background 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]

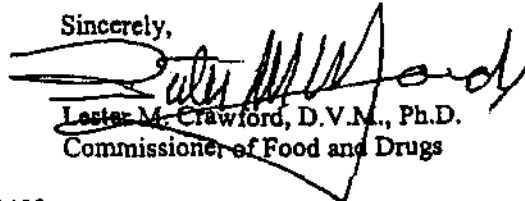
For all of the public health reasons stated above, FDA believes that California should not interfere with FDA's carefully considered approach of advising consumers of both the benefits and possible risks of eating seafood.

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
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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

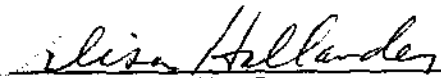
CERTIFICATE OF SERVICE BY MAIL
[Code of Civil Procedure 1013a(4)]

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
Secretary to the Presiding Judge of
the San Francisco Superior Court

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People of the State of California v. Tri-Union Seafoods, et al.
Consolidated Case Nos. CGC-01-402975 and CGC-04-432394
