STATEMENT BY CONSUMERS UNION OF U.S., INC. REGARDING FEDERAL DIETARY ADVICE ON METHYL MERCURY IN FISH AND SEAFOOD

At an FDA/EPA "Stakeholders Meeting" College Park, MD, July 30, 2003

Presented by

Edward Groth III, Ph.D. Senior Scientist Consumers Union of U.S., Inc. 101 Truman Avenue Yonkers, NY 10703-1057 USA 914-378-2301 groted@consumer.org

<u>Contents</u>

Page

Introduction	1
I. General Comments (1) Dietary Advice is Essential But Not Sufficient Enforce the Action Level	2 2 2
Consider Lowering the Action Level	3
Control Mercury Pollution	3
(2) Expert Agencies Must Do A Better Job of Speaking With One Voice	2 3 3 3 3
Get on the Same Page on Safety Issues	3
Coordinate Safety and Nutrition Advice	4
(3) Acknowledge Trade-Offs But Keep Your Eye on the Ball	5
Risk-Risk Trade-Offs	5
Risk-Benefit Trade-Offs	5 5
Benefit-Cost Trade-Offs	6
II. Critique of FDA's Current Dietary Advice	7
(1) Advice Should Offer More Choices Than Simply "Eat/Don't Eat"	7
(2) Current Advice Is Not Adequately Protective of Health	8
(3) One Size Advice Does Not Fit All	9
Children	9
High-End Fish Consumers	10
Consumers of Sport Fishing Catches	12
The General Population	12
(4) Silence Is Not Acceptable Advice on Tuna Consumption	13
Fresh Tuna	14
Canned Tuna	14
(5) Better Data Are Needed—But So Is Timely Advice	16
Enlarge the Database	16
Focus More on Low-Mercury Choices	17
Improve Data on Distribution of Mercury Levels	17
Clarify "Species" Criteria	18
Improve Fish Consumption Data	19
III. A Model for Improved Dietary Advice	
(1) How We Developed Our Model Advice	21
Reference Dose	22
Data Sources	23
Serving Sizes	23
Body Weight	24

Attached Materials/Model Dietary Advice

Table 1. Consumers Union's Recent Test Data on Methyl Mercury in Fish

Notes on Table 2

- Table 2. Seafood Species Listed in Descending Order by Mercury Content, With Maximum Number of Weekly Servings for Specific At-Risk Populations
- Table 3A. Consumers Union's Proposed Listing of Fish Species for Purposes of Dietary Advice to Minimize Mercury Exposure
- Table 3B. Consumers Union's Proposed Listing of Fish Species That Are Low In Mercury, for Purposes of Dietary Advice

Appendix A. Mercury Levels in Seafood Species (FDA, May 2001)

STATEMENT BY CONSUMERS UNION OF U.S., INC. REGARDING FEDERAL DIETARY ADVICE ON METHYL MERCURY IN FISH AND SEAFOOD

Presented by Edward Groth III, Ph.D. Senior Scientist

At an FDA/EPA "Stakeholders Meeting" College Park, MD, July 30, 2003

Introduction

Consumers Union¹ (CU) thanks the Environmental Protection Agency and the Food and Drug Administration for arranging and hosting this meeting to get stakeholder input on dietary advice with respect to mercury in seafood. We are pleased to participate and to offer you our perspective on this important topic. As the publisher of CONSUMER REPORTS magazine, CU has been giving consumers advice on food safety issues since 1936. We have tested canned tuna and other seafood choices for mercury content many times over the past 50 years. Our reports on these food categories have often examined the risks of methyl mercury exposure, and offered advice on food choices, consistent with the best currently available scientific knowledge.² Our Washington Office participated in FDA's rulemaking on mercury in seafood in the 1970s, and we have maintained our interest in policymaking on this topic over the years. Jean Halloran, the director of our Consumer Policy Institute, took part in your discussion on methyl mercury policy a year ago as a member of the FDA's Food Advisory Committee. We expect to be actively involved in the process of developing federal dietary advisories on mercury, as your policymaking initiative moves forward from this point. Today we offer you an updated, expanded analysis of appropriate dietary advice on mercury and seafood.

¹ Consumers Union, publisher of Consumer Reports, is an independent, nonprofit testing and information organization serving only consumers. CU is a comprehensive source for unbiased advice about products and services, personal finance, health and nutrition, and other consumer concerns. Since 1936, CU's mission has been to test products, inform the public, and protect consumers. CU's income is derived solely from the sale of Consumer Reports and its other services, and from noncommercial contributions, grants, and fees. CU is online at <u>www.consumersunion.org</u> <<u>http://www.consumersunion.org</u>>.
² See "America's Fish, Fair or Foul?," CONSUMER REPORTS, Feb 2001, pp. 25-31; "Tuna Goes Upscale," with sidebar

² See "America's Fish, Fair or Foul?," CONSUMER REPORTS, Feb 2001, pp. 25-31; "Tuna Goes Upscale," with sidebar on mercury risks, CONSUMER REPORTS, June 2001, p. 17; also, "Right Fish, Least Risk," CONSUMER REPORTS, July 2003, p. 32, for recent examples of CU's dietary advice on mercury in fish.

I. General Comments

(1) Dietary Advice Is Essential But Not Sufficient

Managing the risks associated with dietary exposure to mercury is a complex task and requires multiple strategies. Dietary advice to consumers is one essential component of an effective overall strategy, but dietary advice—which places the burden of managing this risk primarily on the consumer—is not sufficient. Advice reaches those motivated to seek it and able to understand and follow it, and advice may be more or less useful for consumers, depending on the effort level and communication skills of those who offer it. Risk communication per se cannot protect all or even most consumers from exposure, at least occasionally, to excessive doses of methyl mercury in fish.

Our focus here today will be on effective dietary advice. However, in addition to dietary advice, FDA and EPA need to consider additional risk management strategies:

Enforce the Action Level. The FDA Action Level for mercury in fish should be more strictly enforced. CU's tests (see Table 1) and other data indicate that there are far too many fish on the market with mercury levels above the current Action level of 1 ppm. Our tests in 2000 found more than half of 16 swordfish samples exceeded 1 ppm. The maximum level in one sample was 2.45 ppm, and the average methyl mercury level in swordfish we tested was 1.11 ppm. Data on canned tuna published last month by the Mercury Policy Project (MPP),³ show occasional samples of canned white/albacore tuna that exceed the Action Level. MPP tests found methyl mercury levels above 1 ppm in 6 percent (3 of 48 samples) of the white/albacore tuna they tested. Since canned tuna is eaten in much greater quantities than swordfish, this finding urgently needs confirmation, and if validated, is another compelling reason to enforce the Action Level.

In its wisdom, Congress has recently authorized retailers to label any wild-caught fish as "organically" produced. Thus, a swordfish steak containing over 2 ppm methyl mercury may now bear an "organic" label, enticing consumers with its implied promise of lack of harmful contaminants. Unless FDA and other responsible agencies aggressively enforce the legal limit on mercury content, naked commercialism may overwhelm safety limits and the effort to communicate sound dietary choices.

³ "Can the Tuna," Mercury Policy Project, June 19, 2003.

Consider Lowering the Action Level. In a February, 1992 article on seafood quality and safety, CONSUMER REPORTS called on the FDA to lower its Action Level for mercury in seafood.⁴ We argued that the scientific evidence at the time—11 years ago—justified increasing the safety margin against possible adverse effects of dietary mercury exposure. Evidence accrued since then has only reinforced our view that, from the standpoint of health protection, a significantly lower Action Level is justified. In April 1992, Public Voice petitioned FDA to set a lower Action Level for mercury in seafood.⁵ In 2000, the Center for Science in the Public Interest (CSPI) resubmitted the petition, on which FDA had not acted.⁶ We realize that discussion of the Action Level is not on today's agenda, and that such discussion involves weighing various considerations beyond the definition of what is "safe enough." We will defer such a discussion for another time and place. But CU plans to work with FDA, CSPI and other interested parties try to find a sensible resolution on this issue.

Control Mercury Pollution. Although control of mercury discharges into the air and water is also outside the scope of today's discussion of dietary mercury advice, CU also supports EPA's efforts to reduce mercury pollution from sources like coal combustion. Short-term reduction of mercury emissions will not, for biogeochemical reasons, get all the mercury out of oceanic fish, but pollution controls are essential to reduce exposures of specific high-risk local populations, and to interrupt other pathways that contribute to "background" mercury exposure. We urge EPA to redouble its efforts to eliminate all remaining significant sources of mercury emissions.

(2) Expert Agencies Must Do a Better Job of Speaking With One Voice

Get On the Same Page on Safety Issues. When consumers get divergent or conflicting advice from different authorities on a topic like managing mercury exposure, they can become confused and be less motivated to follow either (or any) expert advice on the subject. The dietary advice currently offered by the FDA is out of step with the EPA's Reference Dose for methyl mercury exposure. EPA's risk assessment and definition of

⁴ "Is Our Fish Fit to Eat?" CONSUMER REPORTS, February 1992, pp. 103-114.

⁵ Citizens Petition to Set a Regulatory Limit for Methylmercury in Seafood that Reflects the Risk to Pregnant Women and Children From the Intake of Seafood Containing Methylmercury. Submitted to the Food and Drug Administration by Public Voice for Food and Health Policy, April 7, 1992.

⁶ Letter from Caroline Smith DeWaal, Food Safety Director, Center for Science in the Public Interest, to Dr. Jane Henney, Commissioner, FDA, July 17, 2000.

an acceptable upper intake limit are well grounded in science. FDA's current dietary advice encourages or at least fail to discourage fish consumption choices that are almost certain to result in exposure higher than EPA has defined as without appreciable risk for target populations. Both scientific evidence and the need for clear risk communication demand that FDA and EPA must better harmonize their positions and messages on these issues. The fact that the two agencies are now setting out jointly to develop dietary advice is an encouraging sign.

Efforts also need to be made to coordinate fish consumption advice offered by various state health departments with that offered by responsible federal agencies. States have diverse reasons for issuing mercury/fish-consumption advice. Often their focal concern is a need to warn sport fishermen about the mercury content of fish taken from inland waters. Some states have also tried to guide consumers on the mercury content of and sensible dietary intake limits for some commercially caught fish. To the extent possible, communication programs that address complementary or overlapping aspects of the same general issue, dietary mercury exposure from fish consumption, need to be coordinated. The public should hear the same messages repeatedly from different expert sources, not get a variety of seemingly different and potentially conflicting, confusing advice.

Coordinate Safety and Nutrition Advice. While FDA and EPA collaborate on advice to help consumers manage dietary mercury exposure from fish, many other authorities, including agencies of the Federal government, are urging consumers to eat more fish, for its well established nutritional and health benefits. Agencies with expertise on different inter-related issues need to coordinate their advice. Within FDA, for instance, a proposal is moving forward to permit a wider variety of health claims on food labels. One of the claims being considered has to do with the health benefits of omega-3 fatty acids, found in generous amounts in certain fish. Will those label claims include cautions, where appropriate, that increasing intake of some fish can lead to excessive mercury intake? This is but one of many possible examples of cases where expert agencies could end up working at cross purposes. Agencies that promote nutrition and those that promote food safety (and the different internal offices of those that do both) should work together as closely as necessary to avoid undercutting one another's objectives.

(3) Acknowledge Trade-Offs, But Keep Your Eye On The Ball.

The goal of this process that EPA, FDA and we "stakeholders" are now engaged in is to develop sound dietary advice, to help consumers keep mercury exposure from fish within safe limits. The pre-eminent objective is public health protection. Methyl mercury poses genuine risks to the health and wellbeing of the exposed populations, and government's essential, main mission in this case is to offer scientifically sound guidance to ensure an adequate safety margin for consumers potentially at risk of those effects. We all need to keep that in mind, because any action by government, including risk communication, involves trade-offs. While we must be aware of those trade-offs, we must not lose our central focus on the need to minimize risk of adverse health effects of mercury in fish.

Risk-Risk Trade-Offs. Mercury is just one of many toxic environmental contaminants that bio-accumulate in fish. Some fish accumulate dioxins and PCBs. Some shellfish accumulate arsenic. Some seafood choices entail a higher risk of exposure to bacterial or viral pathogens. Unfortunately, the species that tend to accumulate PCBs are rarely the same as the species that accumulate mercury. In theory, at least, advice that focuses on avoiding mercury alone could steer consumers to fish choices that may increase dioxin exposure, or increase their risk of seafood-borne disease.

The task of developing sound, effective advice on mercury intake from fish consumption is challenging enough for the present. However, attention should soon be turned to better balancing the variety of contaminant-related concerns that should be the subject of advice on fish consumption. Better data should be assembled to make such multiple-factor risk management advice feasible. Until the data needed for such advice have been compiled, interim advice needs to be better than simply "eat a variety of fish." Consumers need at least general guidance on ways to avoid the other pollutants of concern in fish, as well as methyl mercury. While we can recognize the uncertainties and improve this advice as better data become available, it is time to begin addressing these trade-offs.

Risk-Benefit Trade-Offs. Dietary changes to reduce mercury exposure could have some unwanted nutritional effects. Certainly, effective advice to eat certain species less often should reduce consumption of those particular kinds of fish. Whether consumers would eat less fish overall, or would substitute different fish for the ones they were advised to avoid, is easy to speculate about, but could only be established by carefully tracking the dietary choices of a wide cross-section of the public over a long period. Providing a list of positive choices—low-mercury species to choose instead of the higher-mercury fish is an important strategy if the aim is to prevent a decrease in overall fish consumption. If patterns of fish consumption in the population as a whole or in targeted sub-populations were gradually to shift towards lower-mercury species, these changes might also have nutritional impacts. What they might be, and whether they would be positive, negative or both, are difficult to predict and would probably require extensive research to document. In any case, speculation about possible nutritional side-effects of dietary advice should not deflect us from the primary task: Giving consumers clear and useful advice that will help them minimize their mercury intake from fish.

Benefit-Cost Trade-Offs. Dietary advice also has economic consequences. Advice that says "do not eat" certain fish, or that says "limit your intake" of certain other fish, as a risk management strategy for mercury exposure, is likely to reduce sales of the named fish, at least among the populations who are the target of the advice. We have already seen public reports of statements by the tuna industry, for example, that if FDA were to say anything negative about tuna in its dietary advice, the industry could suffer a huge loss in sales with catastrophic economic impacts. Public and political pressures may be brought to bear on the agencies to take no actions, even simple, truthful communication of facts, that could have any adverse impacts on the economic well-being of an already stressed industry.

Consumers Union is sympathetic to some of the industry's arguments. U.S. Consumers enjoy a wide variety of seafood choices, many offered at reasonable prices, and we would neither like to see choices disappear, nor prices rise. But we have a somewhat different perspective from what we perceive the industry's to be on the risks of market effects and the appropriate role for government in this case. Quite simply, EPA and FDA are public health agencies. Your mission is to protect consumers' health, in this case by offering scientifically sound, complete, honest, clear advice on dietary choices that can minimize mercury intake from fish. You must not withhold, distort or hedge that advice to protect against perceived economic impacts, or to avoid angering politically connected seafood producers. You must give consumers facts they need to make sensible, healthy choices and (subject to the caveats above about other possibly needed regulatory actions), let the market sort out the consequences. Industry fears are typically based on unrealistic worst-case assumptions that greatly exaggerate the economic risks. When agencies have taken actions that were associated with such past warnings, actual impacts have almost never proven to be even close in magnitude to the dire forecasts. From a consumer perspective, yes, some parts of the population may eat less of some fish (let's say, tuna.) On the other hand, sound dietary advice should also lead to *increased* consumption of low-mercury fish, such as flounder. In short, some producers would gain while others would probably lose market share, as consumers and the market adjusted to and followed your dietary advice. But it is not the government's job to decide who should win or lose. It's your job to give consumers the facts they need, so they can make informed, sensible choices.

II. Critique of FDA's Current Dietary Advice

Before we prescribe an advisory approach we believe the government should adopt, it is useful to examine current advice, to identify ways it might be improved. We have taken as our baseline for this purpose the FDA's Consumer Advisory on mercury in fish, dated March 2001.⁷ This advisory was aimed at women who are or might become pregnant, and states that it is "prudent" to apply the advice to nursing mothers and young children as well. (What FDA means by "young" children is not defined.)

Several aspects of this current advice need improvement:

(1) Advice Should Offer More Choices Than Simply "Eat/Don't Eat"

FDA's 2001 advice divides all fish species into two categories: Four high-mercury fish (swordfish, shark, tilefish and king mackerel) that at-risk populations are advised not to eat; and all other fish. FDA advises that, except for the four species just named, it is all right to eat as much as 12 ounces per week of any fish, as long as one chooses a variety of fish. FDA also published, in May 2001, a table with the mercury content of various fish species.⁸

⁷ "An Important Message for Pregnant Women and Women of Childbearing Age Who May Become Pregnant About he Risks of Mercury in Fish." Consumer Advisory, Center for Food Safety and Applied Nutrition, US Food and Drug Administration, March 2001.

⁸ Mercury Levels in Seafood Species. Office of Seafood, Center for Food Safety and Applied Nutrition, US Food and Drug Administration, May 2001.

The most serious deficiency with the FDA's current advice is that it is too simplistic. It divides the world of fish choices into two simple categories, "Don't eat at all," and "Eat up to 12 ounces per week." To use the familiar analogy of a traffic light, this is a "Red Light/Green Light" system. It should also include a "Yellow Light" category, applied to fish that contain less mercury than would warrant being included on a "Do not eat" list, but enough mercury to merit cautionary advice, more cautionary than "Consume up to 12 ounces a week of any combination from this list." Advice should include consumption limits for fish with moderate mercury content, with acceptable numbers of servings based on the relative mercury content of each type of fish.

(2) Current Advice Is Not Adequately Protective of Health

Accumulating scientific evidence in recent years has supported a growing consensus that methyl mercury poses risks of toxic effects on the developing nervous system, at lower doses than had previously been recognized. The international Joint Expert Committee on Food Additives and Contaminants (a joint body advisory to the United Nations' Food and Agriculture Organization and World Health Organization) recently recommended that the WHO lower its Provisional Tolerable Weekly Intake by half.⁹ In 2001, the EPA affirmed its Reference Dose (RfD) for methyl mercury of 0.1 μ g/kg–bw/day. A committee of the National Research Council of the National Academy of Sciences advised EPA on the risk assessment on which that RfD was based;¹⁰ there can be little debate that the EPA safety standard is scientifically sound. Many questions about methyl mercury toxicity require further research, and debate persists about adequate margins of safety. But both the emerging epidemiological evidence and prudent public health policy point to an urgent need for improved government advice aimed at managing risks associated with mercury in seafood.

Implicit in such advice is a presumption about "safe" exposure levels. The implicit safe methyl mercury intake embedded in FDA's current advice is not conservative enough to fit recent estimates of the acceptable methyl mercury dose. Based on the EPA RfD of 0.1 μ g/kg-bw/day, the maximum safe weekly methyl mercury intake for a 60-kg woman is 42

⁹ Summary and Conclusions of the Joint FAO/WHO Expert Committee on Food Additives and

Contaminants, 61st Meeting, Rome, 10-19 June 2003. JECFA/61/SC. Geneva, World Health Organization ¹⁰ National Research Council, 2000. Toxicological Effects of Methylmercury. Washington, DC: National Academy Press.

 μ g. FDA says 12 ounces, or 340 grams, is an acceptable weekly intake of fish for all but four highest-mercury fish species. If 340 grams of fish contained just over 0.12 parts per million of methyl mercury, it would provide the RfD of 42 μ g. Eating 12 ounces of any fish that contains more than 0.12 ppm of methyl mercury would therefore expose a 60-kg woman to more than her maximum acceptable weekly dose.

FDA's May 2001 list of mercury in fish species (attached as Appendix A) lists the four species with the highest mercury levels singled out for "don't eat" advice, and 38 other species, which fall under FDA's general advice to "eat up to 12 ounces" of a variety of fish. Of those 38 listed species, 27 (71 percent) contain average mercury levels above 0.12 ppm. FDA's Table 2, titled "Fish and Shellfish with Much Lower Mercury Levels," lists 17 species, of which 11 (65 percent) contain average mercury levels between 0.15 and 0.43 ppm. FDA's published dietary advice therefore steers consumers toward fish varieties that FDA considers "low in mercury," but most of which are likely to contain more mercury than is acceptable, based on the EPA RfD. A much more conservative criterion for the acceptable maximum mercury intake is required to make FDA's advice consistent with current science-based criteria for exposure without appreciable risk.

(3) One Size Advice Does Not Fit All

FDA's advice focuses on women of childbearing age—those who are, or are likely to become, pregnant, the recognized primary population at greatest risk for toxic effects (on the fetal brain) of methyl mercury exposure. However, advice also needs to consider other populations at risk, and to offer more discriminating fish consumption advice, tailored to the specific characteristics of additional, identifiable at-risk groups:

Children. In a single reference to "young children," FDA's current advice states that it is "prudent" for young children not to eat the four fish on the "do not eat" list. Children of all ages are, by implication at least, otherwise covered only by FDA's general advice that one can safely consume up to 12 ounces per week of any other fish, as long as one chooses a variety of different fish.

This advice is seriously flawed and falls far short of providing effective guidance to avoid excessive mercury intake in children. The young child's developing brain is potentially vulnerable to the toxic effects of methyl mercury, and children have much smaller bodies than adults, increasing the relative dose from comparable food servings. A single fish meal would give a 20-kg child three times the dose of methyl mercury, on a body-weight basis, that the same serving would give the child's 60-kg mother. For that 20-kg child to safely eat 12 ounces of fish a week without exceeding the EPA RfD, the fish can contain an average methyl mercury content of no more than 0.04 ppm.

Only six of the 38 fish varieties listed in FDA's 2001 tables contain 0.04 ppm or less methyl mercury; i.e., 32 of the 38 listed fish (84 percent) contain enough mercury that a 20-kg child who ate 12 ounces in a week of any combination of those fish would exceed the RfD. Ten of the 17 fish FDA lists as having "much lower" mercury levels contain more than 0.16 ppm; a single 3-ounce serving of any of these fish would give a 20-kg child more than the EPA RfD. Two additional species on that "low-mercury" list contain more than 0.08 ppm methyl mercury; two servings (six ounces) per week of any of them would exceed the RfD for a small child.

In short, FDA's current advice encourages parents to feed their children fish that contain moderate amounts of mercury. Following that advice will result in far higher doses for a child than for an adult with greater body weight. The FDA's advice is insensitive to risk concerns related to children's intake and urgently needs to be amended.

High-End Fish Consumers. FDA's primary advice is aimed at women of childbearing age, who are urged to eat no more than 12 ounces of fish per week. The 2001 advisory includes a section headed "What if I eat more than 12 ounces of fish a week?" FDA's answer to that question is, "There is no harm in eating more than 12 ounces of fish in one week as long as you don't do it on a regular basis." In fact, it is debatable whether that is sound advice for the target population—women who are or might be pregnant. There are sufficient reasons based on toxicological principles to at least be concerned about spikes of exposure—such as a single week with excessive mercury intake. Such unusual peaks of exposure could have detrimental effects on the fetal brain, if they occur during critical developmental stages. We challenge the scientific basis for FDA's assurance that such "peak exposures" are of no concern as long as they are infrequent, and strongly urge the agencies *not* to include this message in updated advice.

Also in need of re-examination are the unstated assumptions that pregnant women and perhaps children are the only populations at risk from methyl mercury exposure, or that advice designed to protect these most vulnerable populations should adequately protect everyone else. Unfortunately, those assumptions ignore reality. Some consumers eat extraordinary amounts of fish, sufficient to put them at risk of mercury toxicity. This subset—high-end fish consumers—may include some women of childbearing age, but also includes many individuals who are not in that high-risk sub-population.

Some consumers choose seafood as their primary protein source, because they prefer not to eat red meat or poultry. Others choose fish very often because they are aware of the health benefits of fish consumption (benefits that are increasingly the subject of dietary advice from governmental and non-governmental sources alike). Low-income consumers (such as families in the federal WIC program) may consume substantial amounts of fish (especially canned tuna) as a low-cost source of protein. If one considers only people in the highest 1 percent of the U.S. population in terms of their fish consumption, nearly 3 million people fall into in that "extreme" subset.

A recent clinical study¹¹ of patients from a single practice in San Francisco examined 116 people, some of them children, with symptoms of mercury toxicity. Most of the patients habitually consumed far more than 12 ounces of fish per week. The patients had elevated blood mercury levels (89 percent of them had levels above 5 ppb, the EPA's definition of a safe upper limit for body burden), consistent with their symptoms. Most had no known sources of mercury exposure other than their high-seafood diets. This study provides striking evidence that high fish consumption exposes some Americans to doses of methyl mercury within the clinically toxic range.

FDA's current advice seeks to protect high-end consumers by appealing to women of childbearing age to limit long-term average fish intake to 12 ounces a week. FDA seems to have concluded as well that persuading people to limit their total fish consumption is a more effective way to curb high mercury intake, than guiding people to choose fish with lower mercury levels.¹² We urge FDA to reconsider whether this approach is realistic. A significant fraction of the public prefers to eat a lot of fish, receives many messages from health authorities reinforcing that behavior, and will continue to consume large amounts

¹¹ Hightower, J.M. and Moore, D., 2003. Mercury Levels in High-End Consumers of Fish. *Environmental Health Perspectives* **111**(4):604-608.

¹² C.D. Carrington and P.M. Bolger (undated), An Intervention Analysis for the Reduction of Exposure to Methylmercury from the Consumption of Seafood. FDA, College Park, MD.

of fish for a variety of valid reasons. From the discussion above, it is far from clear that limiting consumption to 12 ounces per week would be sufficient to keep mercury intake within safe limits, without further guidance as to species choices. But even if this were an inherently more viable strategy, trying to persuade everyone to eat no more than 12 ounces of fish per week seems unlikely to be effective. To the extent that it did work, it might very well be nutritionally counterproductive. More approaches are needed. More focused and specific advice about mercury in fish should be developed for high-end fish eaters. More effort must be made to alert this sub-population to risks of methyl mercury toxicity associated with unusually high fish consumption, and to provide them with a list of low-mercury (truly low mercury, that is, not moderately high in mercury as on FDA's 2001 list) fish and shellfish choices.

Consumers of Sport Fishing Catches. FDA's current advice calls attention to possible high mercury levels in fish caught from local freshwater lakes and streams, and advises consumers to look for state and local health department advisories to avoid eating fish from specific polluted waters. That advice is sound, but does not go far enough. People who are eating sport-caught fish need to adjust their total fish intake (and especially their consumption of commercially caught mercury-accumulating species) downward so as not to exceed safe limits for total intake. It should not be taken for granted that people will eat either sport-caught fish or commercially caught fish, but not both, in a given week. Some states (e.g., Wisconsin) have developed advice based on the potential for combined mercury intake from fish of both types. FDA and EPA should consult with state health officials and develop methods for similarly integrating state and federal advice.

The General Population. Dietary advice until now has been guided by an assumption that only specific high-risk populations need to be alerted to the risks of mercury in fish: women of childbearing age; people who eat sport-caught fish; and possibly, parents of young children. But that assumption is becoming less tenable as scientific evidence has emerged to suggest that "ordinary" dietary intake of mercury poses some chronic health risks for normal, healthy people.

Evidence has recently been published suggesting that mercury dietary exposure from fish within the bounds of exposure known to occur in North American diets is associated with neurological deficits in adults, similar to those that have been observed in children in the

Faroe Islands study.¹³ Several recent studies have raised the possibility that moderate dietary mercury exposure from fish consumption may increase the risk of cardiovascular disease.¹⁴ A team of EPA scientists has also focused on the likelihood that latent effects of mercury toxicity on the central nervous system, associated with developmental or adult exposure, may manifest as enhanced neuropsychological deficits in old age.¹⁵

In short, emerging evidence has begun to suggest that, in effect, everyone may have some reason to be cautious about the mercury in the fish they consume. The evidence of risks other than developmental neurotoxicity may be too preliminary and incomplete to yield a definition of safe exposure limits for these other effects, at this time. However, the belief that anyone who does not fall into a "high risk" population can eat as much fish as they wish without concern about mercury exposure is no longer sustainable. The top priority should remain on advising high-risk sub-populations, but FDA and EPA should begin to consider the need for more general cautionary advice aimed at all consumers.

(4) Silence is Not Acceptable Advice on Tuna Consumption

Canned tuna is by far the most heavily consumed fish product in the U.S. It constitutes between 25 and 35 percent of all seafood eaten here.¹⁶ Canned tuna is an inexpensive, nutritious, tasty protein source and a popular dietary staple in many households. It is widely consumed by pregnant women, and children eat tuna twice as often as they eat any other fish variety.¹⁷ Tuna are predators that accumulate low to moderate mercury levels. Because of the volume of canned tuna consumed, this fish product is the largest single source of methyl mercury exposure in the U.S. diet, surpassing other fish (such as swordfish) that have far higher mercury levels, but are consumed in far lesser amounts.

¹³ Yokoo, E.M., et al. (2003), Low level methylmercury exposure affects neuropsychological function in adults. *Environmental Health: A Global Access Science Source* **2**(8).

¹⁴ Salonen, J.T., et al. (2000) Mercury accumulation and accelerated progression of carotid atherosclerosis: A population-based prospective 4-year follow-up study in men in eastern Finland. *Atherosclerosis* **148**(2): 265-273. Also, Guallar, E., et al. (2002), Mercury, fish oils, and the risk of myocardial infarction. *N. Engl. J. Med.* **347**(22):1747-1754. Also, Yoshizawa, K., et al. (2002), Mercury and the risk of coronary heart disease in men. *N. Engl. J. Med.* **347**(22):1755-1760.

¹⁵ Rice, D.C., Schoeny, R. and Mahaffey, K (2001), Methods and rationale for Derivation of a Reference Dose for Methylmercury by the US EPA. Written for proceedings of "Children's Environmental Health— Developing a Framework," California EPA, 2001. Accepted for publication in *Risk Analysis* (in press). ¹⁶ MPP. "Can the Tuna." page 6

¹⁶ MPP, "Can the Tuna," page 6. ¹⁷ MPP, "Can the Tuna," page 6.

Despite its impressive resumé as a prominent contributor to mercury exposure, canned tuna fades anonymously into the crowd in the FDA's current dietary advice. Tuna (both fresh and canned) is on FDA's list of "Fish and Shellfish with Much Lower Mercury Levels," covered only by the agency's general advice that pregnant women, children and anyone else can safely consume up to 12 ounces per week of any of these fish. Both this advice and the way it is presented need upgrading in several distinct ways:

Fresh Tuna. FDA's data show clearly that fresh tuna (tuna steak) contains more methyl mercury than canned tuna, on average: 0.32 ppm in fresh tuna, vs. 0.17 ppm in canned tuna. (See further discussion of canned tuna, below.) CU has tested a limited number of samples (24) of fresh tuna, and our results are consistent with FDA's published average (see Table 1). We are also aware of other data (reviewed by the Environmental Working Group¹⁸), which suggest a higher average (0.42 ppm) and a range that includes several samples above 1 ppm. These data consistently show fresh tuna to be a moderately highmercury fish choice. It clearly does not belong on a list of fish that can be consumed in amounts up to 12 ounces per week. For women of childbearing age, fresh tuna should be on a "Yellow-Light" list of fish whose consumption is limited to one 3-ounce serving per week. For young children, fresh tuna belongs on a "do not eat" list.

Canned Tuna. FDA's list lumps all varieties of canned tuna together and indicates an average mercury level of 0.17 ppm. But data from multiple sources indicate that white or albacore tuna contains significantly more mercury than "light" tuna. Averaging data from all varieties obscures this important difference. CU recently tested 12 samples of white/albacore tuna, which had an average methyl mercury level of 0.31 ppm (See Table 1); FDA¹⁹ has reported an average of 0.32 ppm in canned albacore tuna. But recent tests by the Mercury Policy Project²⁰ found an average of 0.51 ppm in canned albacore/white tuna. CU's tests of canned light tuna found an average methyl mercury content of 0.16 ppm (Table 1). MPP tests found an average mercury level of 0.12 ppm in canned light tuna,²¹ and FDA has reported the level in this product to be 0.13 ppm.²²

¹⁸ "Brain Food: What Women Should Know About Mercury Contamination of Fish," Environmental Working Group and The State PIRGs, 2001. Appendic C, Notes on Individual Fish Species, Table 10, page 60.

¹⁹ Carrington and Bolger, op. Cit. (Note 12 supra), Table 1.

²⁰ Can The Tuna, op. Cit., pages 7-8

²¹ Ibid.

²² Carrington and Bolger, op. Cit. (Note 12 supra), Table 1.

Differences in results between CU's, FDA's and MPP's tests with regard to the mercury level in canned white/albacore tuna are intriguing. Such differences may be attributable to sample sizes and sampling strategies. CU sampled the national market and collected samples from cities in several different states, while MPP focused on leading brands and bought samples in a limited number of geographic sites. But MPP's testing seems well designed (replicate samples sent to a second laboratory confirmed the results from the initial lab), and we have no reason to doubt the accuracy of their data. MPP's sample of white/albacore products (48 cans) is four times the size of CU's most recent sample, and may be the best available data set on mercury in albacore tuna. As expected with larger sampling, they found a few cans with quite high mercury levels—including three above 1 ppm—which skewed the average level upward. MPP also report total mercury content, which tends to be 10 to 20 percent higher than methyl mercury (which CU's data report).

Despite the differences between the data sets, CU, MPP and FDA agree that canned white/albacore tuna contains much more mercury than canned light tuna does. The ratio is somewhere between about 2-to-1 and 4-to-1; the exact difference can be better defined by obtaining and examining more extensive data. But the data in hand clearly show that different dietary advice is required for these two types of canned tuna. White/albacore belongs on either a "Red Light" or a "Yellow Light" list for pregnant women. Consumption should be limited to one three-ounce serving a week (based on FDA's or CU's data), or albacore should be on the "do not eat" list, based on MPP's data. As with fresh tuna, canned white/ albacore tuna should be on a "do not eat" list for young children.

Clearly, omitting any mention of tuna varieties and encouraging pregnant women to eat up to 12 ounces of any canned tuna type per week within a variety of seafood choices, the options favored in FDA's current advice, are no longer acceptable alternatives.

Canned light tuna, by contrast, is in a safer category in terms of its mercury content. Its average methyl mercury level of 0.13 ppm (FDA data) makes it acceptable for a pregnant woman to consume up to 9 ounces per week. (But 12 ounces per week would put her over the RfD; high-end consumers of canned tuna among women of childbearing age should be singled out for more focused advice.) For a small child, canned light tuna can safely be consumed in amounts up to 3 ounces per week—about the amount in two tuna

sandwiches. This tuna variety should be on a "Yellow Light" list for children, to keep consumption within that moderate, safe limit.

(5) Better Data Are Needed—But So Is Timely Advice

CU is confident, as we have said, that EPA and FDA have access to ample valid scientific information on which to base dietary advice about mercury in seafood. We ourselves as CONSUMER REPORTS have offered such advice repeatedly over the years, based on the best evidence available at the time. We have also updated and improved our advice several times, as better information became available. And we see this proceeding as one step in exactly such an updating and improvement process for the advice FDA and EPA need to offer to consumers.

The fact that current data are sufficient to support sound advice, however, does not mean the data are perfect. Identifying needs for better data is essential, to focus research and analysis on improving the data, to support better, more refined future advice. In effect, all such dietary advice is provisional, based on facts available now, but subject to revision as more and better data are generated. Recognition of this somewhat tentative nature of scientific knowledge reduces neither the validity of current advice nor the obligation of expert authorities to offer advice based on the best current knowledge.

While we will offer a model for advice FDA and EPA should provide now, we also can recognize several areas in which the existing data are rather "soft," and our advice to the agencies includes recommendations for research and analysis in these areas:

Enlarge the database. FDA (at least in published information) seems to have relatively few data points on mercury levels in some widely consumed fish. For example, mercury levels in FDA's published database for such familiar choices as red snapper, haddock, sea bass and bluefish are based on 10 or fewer samples. To have more confidence that these and other fish varieties are placed in the correct category for dietary intake advice, more extensive sampling is required.

There are also a number of relatively common seafood items that are not on the list, such as mussels, squid, octopus and shad. Clearly, data are most urgently needed on mercury levels in fish varieties most likely to be eaten frequently by large numbers of people. On the other hand, America's cultural and culinary diversity has created a very long menu of seafood choices that large numbers of Americans enjoy, at least occasionally. To be most useful, dietary advice on mercury should include as many of those choices as possible.

There are many other databases on mercury levels in fish, collected by various federal and state agencies, non-government researchers, and private industry. More effort needs to be devoted to integrating and interpreting the data from various sources, both to build the overall database and to ascertain which data, or which combinations of data, can best represent the mercury levels in fish people consume.

FDA also should assemble an integrated database on mercury and other contaminants in fish, so that dietary advice aimed at avoiding one contaminant (e.g., mercury) could be coordinated with knowledge about species that are important sources of other pollutants found in fish (e.g., PCBs).

Focus More on Low-Mercury Choices. It is as important to offer consumers a list of positive choices—fish and shellfish that are very low in mercury, and that can be eaten in significant amounts without concern about mercury toxicity—as it is to warn consumers about higher-mercury species that should be avoided or eaten in limited amounts. And guidance on low-mercury choices should be as firmly grounded in reliable, statistically robust data as warnings about high-mercury fish. Many of the fish varieties that appear to have very low mercury levels are represented in FDA's database by very few samples. More attention needs to be devoted to testing species believed to be low in mercury, so that "eat these fish" advice can be offered with as much sound science and statistical confidence behind it as "don't eat these fish" and "limit intake of these fish" advice.

Improve Data on Distribution of Mercury Levels. Regardless of the average mercury level in a fish species, residues in individual fish (or cans, or other samples) are variable. Mean levels are often skewed by a few samples with very high residues. For now, mean mercury levels are generally used to rank fish for dietary advice purposes. But the data attribute used to characterize a species has important risk management implications, and better data would offer FDA and EPA more sophisticated options in the future.

In regulating pesticide residues, for example, EPA has had access to a huge database (the USDA Pesticide Data Program's results from more than a decade of testing.) EPA has data on residues in, literally, thousands of individual samples of key foods like apples, peaches, or spinach. They can calculate, for example, the residue dose a consumer at the

99th percentile of apple intake would get if they ate an apple containing a residue at the 99th percentile on the distribution of residues of a particular insecticide in apples. This makes it possible to fine-tune exposure assessments and ensure that regulatory actions do not permit exposure above a Reference Dose, where that is the goal.

As far as CU knows, comparable residue data do not exist for mercury in seafood, and FDA cannot calibrate its decisions anywhere near so precisely. Default choices must be made, and each option holds some potential for "errors." For example, advice to limit intake of certain fish, to avoid exceeding a safe weekly intake, might classify fish based on their average mercury level. But sometimes a fish will contain less than the average level, and sometimes it will contain more. How important that is in risk terms depends on whether occasional higher "spikes" of exposure are critical factors in toxicity—and this is a question science cannot yet answer.

When policy choices entail such predictable imprecision, they should err on the side of health protection—which CU believes is entirely appropriate for a public health agency, but which we know upsets some parties. In this specific context, using the *mean* mercury level is somewhat more conservative than using the *median* level. Since means tend to be higher than medians (because of the effects of a few very high residues), the odds that a consumer will get a serving with more than the mean are somewhat less than 50 percent. We think this slight bias in favor of safety is appropriate and have used mean mercury levels, rather than median values, in classifying fish for our model dietary advice, below.

In the long run, more sophisticated approaches that could classify fish based on different statistical indices, such as for example the 90th percentile residue (which would be well justified if "spikes" of exposure are deemed essential to avoid), might be considered. To apply such a statistically-based approach, FDA would need very large data sets on many more fish species. Only a few species have sample sizes that might permit such analysis now. For the present, mean levels offer the soundest basis for classification. But we urge FDA and EPA to pursue larger data sets and to remain open to other approaches as better data make them more feasible.

Clarify "Species" Criteria. FDA's list of mercury in different seafood choices refers to each choice as a "species." Some of the fish on the list may in fact be distinct species, but other listed choices clearly lump several species, or even higher taxa. "Clams," for

example, are an *order*-three taxonomic levels higher than a species. How many species of shark are harvested commercially? How many species fall within "sole/flounder"? On the other hand, FDA seems to have rather detailed data on several species of crabs.

These are not trivial questions. As we saw in the discussion of tuna, above, different but closely related species can have different mercury levels. It may be important to be able to discriminate among the different species now grouped together in FDA's (and CU's) dietary advice charts, and to give consumers more finely-tuned advice.

On the other hand, advice needs to correspond to actual choices consumers face when buying fish. Advice that discriminates finely among shark species would help consumers little if the sign in the fish display case merely says "shark." To know better when such distinctions matter, however, the agencies need more extensive and more discriminating data on differences in mercury levels, especially in fish now listed as "species" that are in fact diverse categories with widely different members.

Improve Fish Consumption Data. There are reasonably adequate data available to estimate how much fish Americans consume, in general. But more detailed and precise information on consumption of individual fish varieties would be useful, especially for guiding dietary advice. When it comes to risk assessment (i.e., estimating the mercury exposure of at-risk populations), the need to estimate fish consumption from imprecise survey data is tempered by the availability of extensive data on blood mercury levels.²³ However, advice to avoid high-mercury species could be targeted more effectively if it were known, for example, who (within demographic and cultural subsets of our diverse population) most often eats which fish. FDA should press the fishing industries to collect more such data and make them publicly available.

This discussion of data needs concerns the future, and generating the basis for refining and improving advice as time goes on. But let's now return our attention to the present, and the need for improved advice based on today's knowledge.

²³ Schober, S.E., et al. (2003), Blood mercury levels in US children and women of childbearing age, 1999-2000. JAMA **289**(13):1667-1674.

III. A Model for Improved Dietary Advice

Consumers Union has followed the approach laid out in Section II, in which we identified needed improvements in FDA's current dietary advice, and developed an approach that we believe is more consistent with the current science and more useful to consumers. We offer it to FDA and EPA as an example of some directions in which we hope your advice will evolve as this process moves forward.

Some caveats are essential. Our Model Advice is incomplete. It is a work in progress. We have created a chart (two versions of it) that classifies fish choices according to their mercury content, and offers guidance as to when and to what extent at-risk populations (women of childbearing age and children) should avoid eating certain species or limit their intake of others.

But we have not, for example, drafted the advisory text to go with these charts. Before reaching that step, we find there are a number of issues that need resolving, which will benefit from a discussion with you, the agencies, and other stakeholders. Later in this process, when we have answered some of these questions, we will offer suggestions, but we are not at that stage yet. In presenting you with our model as it now stands, we will explain its features and how we developed them, and also point out areas where further work is needed.

Our Model Advice is displayed in attached tables. Table 2 presents the information in the most compact fashion. It lists fish species in descending order by mercury content, and provides guidance in terms of the acceptable number of weekly servings for two at-risk populations, women of childbearing age and young children. Table 3 presents most of the same information in a different format. Fish species are listed in the same order and divided into the same categories in terms of acceptable number of servings. Divisions between the categories are delineated more sharply, and more focused advice is offered, but data on mercury levels are not included. We prefer Table 2's approach but present both, as examples of a variety of presentations that might be developed. Also attached are some Notes on Table 2, which explain the data sources and decision criteria used to classify fish into categories for dietary advice.

(1) How We Developed Our Model Advice

We created an advice structured around "Red, Yellow and Green" categories, much as we argued is needed, earlier in these comments. We have not overtly included color-coded references to guide consumers to appropriate fish choices, but FDA and EPA might do that. We have classified fish into categories based on the maximum acceptable number of weekly servings of each fish for each at-risk population, based in turn on each species' mean mercury level. The "Red" category is the list of species for which "0 servings" is acceptable; i.e., a "do not eat" list, where even one serving would exceed the acceptable weekly mercury intake for each population. The "Yellow" category includes fish species with intermediate mercury content, and is broken down into fish that can be eaten 1, 2 or 3 times a week without exceeding a safe mercury dose. The advice here is "Limit intake to no more than the indicated number of servings." The "Green" category includes low-mercury choices that can safely be eaten 4 or more times per week.

In Table 2, all this information is on one page. In Table 3, Table 3A offers lists of fish with limits of 0, 1, 2 or 3 servings, and Table 3B is presented as a separate "positive" list of low-mercury fish and seafood choices.

Note that the listings (and advice) differ markedly for the two target populations, women and young children. Because of the child's much smaller body weight (1/3 that of the adult woman, using our standardized assumed weights), it takes only 1/3 as much of any given fish to provide a comparable dose of mercury. Because of this difference, many more fish are in the "do not eat" category for young children, and most of the rest fall into the "1 serving per week" category. Only six choices (or seven, if flounder and sole are counted separately) fall into the "4 or more servings" category for young children. If advice were being targeted toward older children (which certainly could be considered, and deserves to be discussed), the number of choices available for a child would expand as the age and assumed body weight of the child increased. Fortunately, the choices near the bottom of the list include several that are widely available and likely to appeal to the few children who eat fish four or more times a week.

Our Model Advice does not yet include targeted messages for high-end fish consumers, and this creates some concerns with the "Green" category. Virtually any of these choices might contain enough mercury to exceed the Reference Dose for someone who ate fish and shellfish, say, 10 times a week or more. We believe additional advice, specifically focused on people who consume a great deal of fish, still needs to be crafted. Tables 2 and 3 do not adequately address this identified need.

We also call attention to the way our Model Advice treats different kinds of tuna. We have tuna listed three times—fresh tuna is distinct from canned tuna, and canned tuna is divided into canned white/albacore tuna and canned light tuna. (We might like to divide fresh tuna by species as well, but the data we had did not support that.) We have relied on FDA data on the average mercury level in fresh tuna and canned light tuna. We have listed canned albacore tuna twice, once using FDA data, and once using MPP data (see discussion above in Section II, Part 4). Using either average level puts canned albacore tuna on the "do not eat" list for small children, but for a 60-kg woman, it falls in the "do not eat" category using MPP's average, and in the 1 serving per week group using FDA's average. We expect FDA to list canned albacore tuna once, based on what it determines to be the most appropriate average mercury level for this product.

A few comments are in order on our methodology:

Reference Dose. The goal of our dietary advice is to guide consumers to fish choices that should enable them to keep their mercury exposure within the EPA's RfD, with its nominal 10-fold margin of safety. We recognize that the Uncertainty Factors EPA used to account for inter-individual variability mean some consumers already have a personal "margin of safety" of less than a factor of 10 (while others have a wider personal safety margin). Also, since we have used mean mercury levels to characterize each fish species, a significant fraction of eating experiences would involve above-average levels, further eroding the possible margin of exposure.

Give these expected sources of variability, we judged it most prudent to calculate fish intakes so that, if our advice were followed, the average consumer would not exceed the RfD from fish consumption alone. An advisory focused on fish does not consider other possible sources of mercury exposure (dietary and non-dietary); the average consumer following our advice could "use up" their entire RfD through fish consumption choices, another reason to aim to keep exposures within the RfD. We note that FDA has cited some circumstances when individuals would exceed the RfD, and pointed out that in those cases the margin of safety is reduced from 10-fold to about 8-fold. Implicit is a judgment that 8-fold is still an adequate safety margin. But we have chosen not to erode the nominal 10-fold margin for the average member of the target population.

To calculate acceptable numbers of servings, we used the EPA reference dose, 0.1 μ g/kg-bw/day (or 0.7 μ g/kg-bw/week), as our definition of the safe maximum methyl mercury intake. We strongly urge FDA to do the same. The EPA RfD was developed in concert with a review of the available scientific evidence by an expert committee of the National Research Council. It is as close to a consensus judgment of the U.S. expert community as is ever likely to be achieved. This is neither the time nor the context for scientific turf battles or dueling risk assessments between Federal agencies. The task before you is risk communication. One prerequisite to effectively communicating this risk to the public is that EPA and FDA must agree on the message. CU is comfortable relying on the EPA/NAS risk assessment on this question, and we urge FDA to join us in that decision.

Data Sources. Except for our use of MPP's data on canned albacore tuna, discussed above, the mercury levels indicated in Table 2 are all based on FDA data. Most of the data on average levels in different species were taken from the FDA's May 2001 table of mercury levels in fish. Data on levels in albacore and light canned tuna were taken from Table 1 of Carrington and Bolger's paper, cited in footnote 12.

Our primary goal in this effort has been to demonstrate how advice could be structured, using a coherent data set; at this point, we were not especially concerned with finding the best data to define the mercury level in each species listed. We commented in Section II, Part 5 about the need for better data, and we expect that FDA will pursue better data to the extent it can. We would welcome future discussions where better data are presented and used to refine the placement of particular species in a classification scheme like the one we have developed here.

Serving Sizes. We chose to focus advice on the number of times per week fish could be eaten, i.e. the number of single servings that could be consumed for each species without exceeding safe levels of mercury intake. The serving size choice is a relatively arbitrary decision that is essential for the analysis, and it is worth examining some consequences of the choice we made, as well as some other options. We used three ounces as a standard serving size. While advice could be broken down more finely—into one-ounce intervals, for instance—this would add complexity and probably make the advice harder to follow.

A larger serving size would increase the mercury dose per serving and push more fish varieties into lower (i.e., "0 servings" and "1 serving") categories, making the affected species seem riskier and limiting consumers' choices to fewer options. But on the other hand, larger serving sizes might be more compatible with what consumers really eat. If CU advises that three 3-ounce servings are acceptable and a consumer eats three 6-ounce servings, she could exceed her allowable mercury intake by as much as 100 percent.

We invite discussion on our choice of serving size. We note that FDA's current advice speaks of limiting consumption to *12 ounces* per week, and notes that typical servings of fish are 3 to 6 ounces. Rather than try to define a serving arbitrarily as a single size that may or may not fit consumers' actual eating behavior, our Model Advice might perhaps be revised to say "Limit your consumption to 3, 6, or 9 ounces per week" of the species on each list (rather than 1, 2 or 3 servings per week). The consumer would then have to decide how many servings fit within the designated number of ounces. We solicit other views about the best ways to communicate about portion sizes and safe amounts of fish that can be eaten for fish with different mercury content.

Body weight. In calculating acceptable intakes on a body-weight basis, we used standard assumptions about body size: 60 kg for an adult woman, 20 kg for a child about 3 years old. Obviously, most people weigh more or less than these standardized weights, and the dietary advice might be amended to recognize that. For instance, consumers could be informed that if they weigh significantly less than the indicated standard body size (or if their child is significantly smaller than 20 kg), they should be a bit more conservative in limiting their fish intake. Conversely, if they weigh significantly more than the indicated weights, or their child is older and heavier than the standard 3-year-old, they can eat (or feed their child) somewhat larger portions, or eat fish proportionally more often than the recommended limits. It might also be sensible to communicate weights in pounds, rather than kilograms (or in both units), for ease of comprehension.

Advice also might be tailored to other populations with different body weights, such as children older than 3 years. The more complex the advice becomes, the less likely it is, perhaps, that consumers will effectively use it. However, based on CU's experience, a small but significant fraction of the public are "information seekers"—intelligent, highly motivated individuals who will seek out and use the facts they need to support a decision.

(i.e., the kind of person who uses a Ratings table in CONSUMER REPORTS.) FDA and EPA have a dual challenge: You need to find simple, clear messages that can be propagated in the mass media, and will give average consumers enough balanced information to make sensible choices. But you also need to be prepared to offer more detailed information, on the Internet probably, for those consumers who can absorb and will want more complete advice. That advice might include, for example, charts for adjusting recommendations to suit consumers with different body weights.

In summary, we offer this Model Advice to EPA and FDA as a step forward from the current advice, and to demonstrate an approach we feel would give prudent and useful science-based dietary guidance to consumers. We know we are on a journey and have not reached the destination yet, though we sincerely hope the destination is not far down the road. We look forward to working with the agencies as you carry this effort to its next stages.

TABLE 1. CONSUMERS UNION'S RECENT TEST DATA ON METHYL MERCURY IN FISH

SWORDFISH				
	Maximum MeHg	2.45 PPM		
	Minimum MeHg	0.13 PPM		
	Sample Size	16		
	Average MeHg	1.11 PPM		
	Number of samples >0.5 ppm	11 (8>1 PPM; 7 > 1.5 PPM)		
FRESH TUNA				
	Maximum MeHg	0.68		
	Minimum MeHg	<0.1		
	Sample Size	24		
	Average MeHg	0.25		
	Number of samples >0.5 ppm	1		
CANNED TUNA (all types)				
	Maximum MeHg	0.65		
	Minimum MeHg	<0.1		
	Sample Size	38		
	Average MeHg	0.21		
	Number of samples >0.5 ppm	2		
(White)				
	Maximum MeHg	0.65		
	Minimum MeHg	0.16		
	Sample Size	12		
	Average MeHg	0.31		
	Number of samples >0.5 ppm	2		
(Light)				
	Maximum MeHg	0.46		
	Minimum MeHg	0.1		
	Sample Size	26		
	Average MeHg	0.16		
	Number of samples >0.5 ppm	0		

NOTES ON TABLE 2

Data on mercury levels in fish used to classify species into categories according to the maximum acceptable number of weekly servings were taken from "Mercury Levels in Seafood Species," FDA, May 2001, at <u>http://www.cfsan.fda.gov/~frf/sea-mehg.html</u>, unless otherwise noted.

Data on mercury levels in canned tuna used to classify albacore/white tuna and light tuna are FDA data from Carrington and Bolger's paper (cited in text) and recent test data from "Can The Tuna," by the Mercury Policy Project, June 19, 2003, pp. 7-8. The source of the data is indicated as FDA or MPP where each is used in the tables.

Assumptions and criteria for determining the acceptable number of servings per week:

We used the EPA weekly Reference Dose for methyl mercury, $0.1 \ \mu g/kg$ -bw/day, or $0.7 \ \mu g/kg$ -bw/week. We assumed a standard body weight of 60 kg for a woman of childbearing age, and a standard body weight of 20 kg for a young child (up to age 3). Thus, the maximum safe weekly methyl mercury dose for a woman of childbearing age is 42 μg , and for a young child, it is 14 μg .

We used a standardized serving size of 3 ounces for fish and seafood and considered only increments of whole servings, to limit the number of break points in the dietary advice. (I.e., intake is assumed to fall at 0, 3, 6, 9, or 12+ ounces per week.)

One ounce = 28.35 grams, so the incremental break points in assumed fish intake are:

0 servings = 0 grams/week 1 serving = $3 \times 28.35 = 85$ grams/week 2 servings = $6 \times 28.35 = 170$ grams/week 3 servings = $9 \times 28.35 = 255$ grams/week 4+ servings = $12 \times 28.35 = 340$ or more grams/week

The maximum methyl mercury level that could be present in a single 3-ounce serving of fish without exceeding the RfD for a 60-kg woman is 0.494 ppm. For a 20-kg child, the corresponding upper limit is 0.165 ppm.

The maximum methyl mercury level that could be present in two servings (six ounces) of fish without exceeding the RfD for a 60-kg woman is 0.247 ppm. For a 20-kg child, the corresponding upper limit is 0.088 ppm.

The maximum methyl mercury level that could be present in three servings (nine ounces) of fish without exceeding the RfD for a 60-kg woman is 0.165 ppm. For a 20-kg child, the corresponding upper limit is 0.055 ppm.

The maximum methyl mercury level that could be present in four servings (twelve ounces) of fish without exceeding the RfD for a 60-kg woman is 0.124 ppm. For a 20-kg child, the corresponding upper limit is 0.041 ppm.

Based on these straightforward calculations, fish can be classified into safe consumption categories based on their average mercury content, as follows:

If the mercury content of the fish falls in this range:

above 0.49 ppm between 0.25 and 0.49 ppm between 0.17 and 0.25 ppm between 0.12 and 0.17 ppm 0.12 ppm or lower

The maximum number of servings/week for a 60-kg woman is:

0 servings 1 serving 2 servings 3 servings 4 servings or more

If the mercury content of the fish falls in this range:

0.17 ppm or above between 0.08 and 0.165 ppm between 0.055 and 0.08 ppm between 0.04 and 0.055 ppm 0.04 ppm or lower

The maximum number of servings/week for a 20-kg child is:

0 servings 1 serving 2 servings 3 servings

4 servings or more

TABLE 2. SEAFOOD SPECIES LISTED IN DESCENDING ORDER BYMERCURY CONTENT, WITH MAXIMUM NUMBER OF WEEKLYSERVINGS FOR SPECIFIC AT-RISK POPULATIONS INDICATED

Acceptable number of servings per week for a 60-kg woman	<u>Fish Species</u> and average mercury level	Acceptable number of servings per week for a 20-kg child
0 servings	Tilefish, 1.45 ppm	0 servings
	Swordfish, 1.00 ppm	
	Shark, 0.96 ppm	
	King Mackerel, 0.73 ppm	
	Red Snapper, 0.60 ppm	
	Moonfish, 0.60 ppm*	
	Orange Roughy, 0.58 ppm*	
	Canned Tuna, white/albacore (MPP), 0.51 ppm	
0 servings	Saltwater Bass, 0.49 ppm*	
1 serving	Marlin, 0.47 ppm	
	Grouper (Mycteroperca), 0.43 ppm	
	Freshwater Trout, 0.42 ppm	
	Fresh Tuna, 0.32 ppm	
	Canned Tuna, white/albacore (FDA), 0.32 ppm	
	American Lobster, 0.31 ppm	
	Bluefish, 0.30 ppm*	
	Croaker, 0.28 ppm	
1 .	Sea Trout, 0.27 ppm	
<u>1 serving</u>	Grouper (Epinephelus), 0.27 ppm	
2 servings	Halibut, 0.23 ppm	
	Sablefish, 0.22 ppm	
	Pollock, 0.20 ppm Cod, 0.19 ppm	
	Mahi Mahi, 0.19 ppm	
	Ocean Perch, 0.19 ppm	
	Dungeness Crab, 0.18 ppm	
	Haddock, 0.17 ppm	
2 servings	Blue Crab, 0.17 ppm	0 servings
	Whitefish, 0.16 ppm*	1 serving
	Herring, 0.15 ppm*	
	Tanner Crab, 0.15 ppm	
	Spiny Lobster, 0.13 ppm*	
3 servings	Canned Tuna, light (FDA), 0.13 ppm	
4 or more servings	King Crab, 0.09 ppm	1 serving
	Catfish, 0.07 ppm	2 servings
	Scallops, 0.05 ppm	3 servings
	Flounder/Sole, 0.04 ppm	4 or more servings
	Salmon, ND	
	Oysters, ND	
	Shrimp, ND	
	Tilapia, ND*	
	Clams, ND*	

* Indicates species for which FDA has fewer than 10 samples in its database

TABLE 3A. CONSUMERS UNION'S PROPOSED LISTING OF FISH SPECIES FOR PURPOSES OF DIETARY ADVICE TO MINIMIZE MERCURY EXPOSURE

People who belong to one of the identified populations should limit their consumption of each listed fish to no more than the indicated number of 3-ounce servings per week

0 servings per week (avoid consuming these fish)

Pregnant Women, Women Who May Become Pregnant, and Nursing Mothers

Children up to Age 3 Years

Tilefish Swordfish Shark King Mackerel Red Snapper Moonfish* Orange Roughy* Canned Tuna, Albacore (MPP) Saltwater Bass*

Tilefish Swordfish Shark King Mackerel **Red Snapper** Moonfish* Orange Roughy* Canned Tuna, Albacore (FDA & MPP) Saltwater Bass* Marlin Grouper (Myctoperca) Freshwater Trout Fresh Tuna American Lobster Bluefish* Croaker Sea Trout Grouper (Epinephelus) Halibut Sablefish Pollock Cod Mahi Mahi Ocean Perch **Dungeness Crab** Haddock Blue Crab

* Indicates species on which there are less than 10 samples in the FDA database

TABLE 3A, CONTINUED

Limit consumption to one (1) 3-ounce serving per week

Pregnant Women, Women Who May Become Pregnant, and Nursing Mothers

Children up to Age 3 Years

Marlin Grouper (Myctoperca) Freshwater Trout Fresh Tuna Canned Tuna, white/albacore (FDA) American Lobster Bluefish* Croaker Sea Trout Grouper (Epinephelus) Whitefish* Herring* Tanner Crab Spiny Lobster* Canned Tuna, Light (FDA) King Crab

Limit consumption to two (2) 3-ounce servings per week

Pregnant Women, Women Who May Become Pregnant, and Nursing Mothers

Children up to Age 3 Years

Halibut Sablefish Pollock Cod Mahi Mahi Ocean Perch Dungeness Crab Haddock Blue Crab

Catfish

Limit consumption to three (3) 3-ounce servings per week

Pregnant Women, Women Who May Become Pregnant, and Nursing Mothers

Children up to Age 3 Years

Whitefish* Herring* Tanner Crab Spiny Lobster* Canned Tuna, Light (FDA) Scallops

* Indicates species on which there are less than 10 samples in the FDA database

TABLE 3B. CONSUMERS UNION'S PROPOSED LISTING OF FISH SPECIES THAT ARE LOW IN MERCURY, FOR PURPOSES OF DIETARY ADVICE

People who belong to one of the identified populations can safely consume four (4) or more 3-ounce servings per week of any of the listed fish

Pregnant Women, Women Who May Become Pregnant, and Nursing Mothers

Children up to Age 3 Years

King Crab Catfish Scallops Flounder/Sole Salmon Oysters Shrimp Tilapia* Clams* Flounder/Sole Salmon Oysters Shrimp Tilapia* Clams*

* Indicates species on which there are less than 10 samples in the FDA database