

NOV - 3 2006



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November 3, 2006

I-69

Patricia N. Daniels, Director
Supplemental Foods Programs Division
FNS – USDA
3101 Park Center Drive, Room 528
Alexandria, VA 22302

RE: Docket No. 0584-AD77; Special Supplemental Nutrition Program for Women, Infants and Children (WIC): Revisions in the WIC Food Packages; Proposed Rule.

Dear Ms. Daniels,

Thank you for the opportunity to comment on FR Docket No. 0584-AD77 Revisions in the WIC Food Packages proposed rule. The USA Rice Federation is a national trade association representing all segments of the U.S rice industry. Through our domestic programs, we conduct consumer education activities to help consumers achieve healthy diets, and to create awareness of the role of rice in healthy eating.

We commend USDA for undertaking a comprehensive review of the supplemental WIC food packages and for its proposed revisions to align with the 2005 *Dietary Guidelines for Americans*, to provide WIC participants with a wider variety of food, and to provide WIC State agencies with greater flexibility in prescribing food packages to accommodate participants with cultural food preferences. We support USDA's decision to add whole grain products to the list of products that may be purchased through the program, and specifically we support the inclusion of brown rice.

In response to the proposed rule, USA Rice Federation offers comments related to the following areas:

1. The addition of whole grains provides a great contribution toward improving public health by ensuring a wide variety of nutrient-dense, culturally appropriate and cost neutral choices are available to the WIC population;
2. In order to realize the public health intent of the revised food package, whole grains such as brown rice, bulgar, oatmeal, whole-grain barley and other whole grains should be *primary* food package options;
3. The importance of brown rice as a primary gluten-free grain option for WIC participants;
4. All women should be allowed whole grain options and at least as much whole grains as children.
5. Allowable amounts of whole grains should harmonize with available package sizes;
6. Education at State and local WIC clinics to increase understanding and application of the new WIC food package will ensure that expanded food options, including whole grain options, are offered to WIC participants;
7. Public-private partnerships to educate States and local WIC clinics and participants will maximize implementation of the proposed expanded WIC Food Package.

1. Addition of whole grains provides a great contribution to improving public health by ensuring a wide variety of nutrient-dense, culturally appropriate and cost neutral choices are available to the WIC population. The proposed substitutions for whole grain bread to include brown rice, bulgur, oatmeal, and whole-grain barley will help improve access to whole grains, and hopefully increase consumption to help WIC participants follow the guidelines to *make half your grains from whole*.

Brown rice is a nutrient rich food, and rice is the primary staple for more than half the world's population (United Nations FAO, 2004). As the US population ethnically diversifies, so does the WIC population, bringing along with them important rice traditions and customs. In fact, the Institute of Medicine stated that marked demographic changes have occurred, and Hispanics now make up the largest share of WIC participants (IOM, 2005). The UN Food and Agriculture Organization has said it is significant that almost every culture has its own way of eating rice and that these different recipes are part of the world's cultural heritage (UN FAO, 2004).

In order to maximize the potential public health impact of adding a variety of whole grains to the WIC food package, it will be important to meet WIC participants "where they are" and introduce whole grains in a stepwise manner to match cultural customs and acceptance. The addition of brown rice is an important step in recognizing cultural diversity among WIC participants. However, in order to match participants' cultural expectations, an incremental approach to whole grains may be necessary to increase consumption. White rice is a frequently consumed grain among this population (ARI, Cultural Access Group, 2004). Therefore it will be important to educate WIC participants about *how to make half your grains whole* using familiar ingredients, such as white rice. Health professionals have successfully introduced consumers to the idea of whole grains by encouraging a mix of brown rice with white rice to encourage incremental changes. This approach may be useful in educating WIC participants *how* to increase their consumption of whole grains. It may also help participants sustain improved diet quality once they "graduate" from the WIC program and are "on their own."

2. For WIC participants to realize the public health intent of the new food package, USDA should formalize the proposed rule by including brown rice, bulgar, oatmeal, and whole-grain barley as primary sources of whole grains. While the USA Rice Federation strongly supports the addition of whole grains, we also urge USDA to consider brown rice, bulgar, oatmeal, and whole-grain barley as primary sources of whole grain in the WIC food package – rather than as substitutions – in the same manner that whole grain bread is listed. Providing additional primary sources of whole grains will better serve the intent of the IOM, USDA and the National WIC Association (IOM 2005, USDA 2006, NWA, 2003) to provide flexibility in prescribing culturally appropriate food packages.

Including brown rice and other whole grains as substitutes rather than as primary sources may prove to be a limiting approach. Indeed the proposed rule indicates that states may limit or completely eliminate substitute food options if needed to control food costs (USDA p. 44828, 2006). Eliminating whole grain options will greatly reduce the stated goals of the USDA to align the WIC food package with the *Dietary Guidelines* to address public nutrition-related issues (USDA p. 44784, 2006). Research shows that rice consumption among WIC-eligible women and children is associated with overall more healthful dietary habits than non-rice eating WIC-eligible women and children (see Attachment) (Fulgoni, 2005).

3. Importance of Rice as a Gluten-free Option for WIC Participants. In addition to its association with more healthful dietary habits, a key reason to consider brown rice as a primary option is the increasing prevalence of celiac disease in the population. For people diagnosed with

celiac disease, the only treatment is a life-long prescription for a gluten-free diet, which means avoiding wheat, barley, rye and oats. Rice, including brown rice, is one of the few grains tolerated among this population and should be made easily accessible to WIC participants who must adhere to a gluten-free diet. According to the National Institutes of Health (NIH), studies have shown that celiac disease is very common in the U.S. Recent findings estimate about 3 million people have celiac disease (about 1 in 133 people). Untreated celiac disease may lead to vitamin and mineral deficiencies, including nutrients important to the WIC population such as iron, calcium, phosphorus, folate, B12, and fat-soluble vitamins. Untreated celiac disease can result in complications and risks for pregnant women including miscarriage and congenital malformation of the baby, such as neural tube defects, because of nutrient absorption problems, and osteoporosis due to poor calcium absorption (NIH, 2004). The NIH Celiac Disease Awareness Campaign's current outreach to the medical community will no doubt result in further awareness and diagnosis of celiac disease in the near future. It is estimated that an additional 15% or more of the population, while not celiac, are gluten-intolerant and seek gluten-free alternatives.

4. All women participating in WIC should be allowed whole grain options and at least as much whole grains as children. While the current proposed rule allows whole grain options for a majority of participants, it denies whole grain options for postpartum women (up to 6 months postpartum – food package VI). However, the Dietary Guidelines recommends *all* Americans get *half your grains from whole*. Therefore, we recommend that *all* women in the WIC program should have the same whole grain benefits with the same whole grains options. We also recommend that *all* women be allowed at least as much whole grain as children.

5. Allowable amounts of whole grains should harmonize with available package sizes. It is vital for prescriptive amounts of foods offered through WIC match what is available in the marketplace to ensure access and variety of options for WIC participants. As currently written, the proposed rule specifications allow 2 pounds of whole grain bread or other whole grain options including brown rice, bulgar, oatmeal, whole-grain barley for children and 1 pound of whole grain bread or other whole grain options for women. Unlike other foods such as canned goods, rice packaging is not standardized by size and type. Rice is typically sold in one and two pound packages or 14 or 16 ounce boxes. We recommend that specifications for brown rice should be up to or equal to 2 pounds for children and women.

6. Education at State and local WIC clinics will ensure expanded whole grain options are offered to WIC participants. Successful implementation of dietary guidance is an ongoing issue. It is well documented that only 1 percent of children between 2 and 19 years old meet the Food Pyramid recommendations for grains, vegetables, fruits, meats, and dairy foods. Sixteen percent of children met none of the recommendations (Muñoz, et al, 1997; Nicklas, 2003). This insight makes clear that education of State and local WIC providers is vital to ensure implementation of the new proposed food package. USDA identifies the need for training of personnel to readily identify newly eligible WIC foods. Specifically, it will be important to educate about the cost and nutrient value of various whole grain substitutions – including brown rice – in order to maximize this important option in the new package. Untrained WIC educators may be unfamiliar with potential barriers to consumption of important whole grain substitutions, and may therefore eliminate these important options. Helping WIC participants learn how to include acceptable whole grain choices that best match their cultural tradition will be vital to the success and public health intent of the new proposed food package.

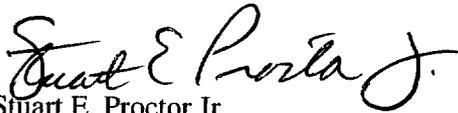
Rice is easy to prepare, versatile, and can be incorporated into familiar meals, such as lunch, breakfast or dinner, and in everything from soups to salads, entrees, side dishes, and even

desserts. In addition, research from the Whole Grains Council among health professionals indicates that incremental introduction of whole grains - by mixing white and brown rice - are improves acceptability, palatability and consumption of whole grains

7. Public-private partnerships to educate WIC providers and participants will maximize implementation of the expanded Food Package. USA Rice Federation stands ready to work together with USDA, the National WIC Association and State and local WIC centers to help translate the new whole grains choices in the WIC food package into actions. USA Rice has a history of educating consumers on how to increase overall whole grain consumption, including brown rice. Our education efforts are consistent with the *Dietary Guidelines for Americans* recommendation to *make half your grains whole*, and the rest from refined grain sources. Our Scientific Advisory Panel of nationally known nutrition experts guides the Federation's nutrition education program to ensure all consumer and health professional communications are grounded in the latest science. Our program materials include a backgrounder, *Brown Rice Basics* with science-based information about brown rice and health for dietitians and health professionals to use as they educate consumers. Our *Whole Grain Goodness* brochure provides tips to help consumers easily achieve three one-ounce equivalents of whole grains each day. And our *Healthy Rice Bowls* education tool shows consumers how to translate *Dietary Guidelines* recommendations into meals, and includes brown rice recipes and cooking and preparation tips.

Again, we commend USDA for its commitment to improving the WIC supplemental food program. Thank you for the opportunity to provide our comments.

Sincerely,



Stuart E. Proctor Jr.
President & CEO



Anne Banville
Vice President, Domestic Promotion

Attachment

Rice. A World of Great Ideas

MEMBERS: USA Rice Producers' Group • USA Rice Millers' Association • USA Rice Council • USA Rice Merchants' Association

ATTACHMENT - *Research Findings*

Rice Consumption is Associated with Better Nutrient Intakes in WIC-eligible Individuals

Research shows that rice consumption among WIC-eligible women and children is associated with greater intakes of nutrients and food groups important among this population* Adult women of childbearing age (18-45 y/o), who are WIC eligible and who eat rice have overall more healthful dietary habits than non-rice eating WIC-eligible women in that they

- Have diets more consistent with the National Academy of Sciences (NAS), Institute of Medicine (IOM) WIC Food Package recommendations to get more fiber (1.9g or 14.6% more/day), vitamin C (17.7mg or 20% more/day), magnesium (26.4 mg or 10% more/day), iron (1.9mg or 13% more/day), folate (87 mcg or 22.5% more/day); and vitamin B6 (.2 mg);
- Consume greater quantities of protein (5.7g/day), zinc (0.8mg/day), and niacin (2.6 mg or more/day). All of these nutrients play an important role in growth and development during pregnancy and maintaining proper nutrition for a breastfeeding mother;
- Consume less total fat (7.6 grams/day) and less saturated fat (3 grams/day);
- Are more likely to meet IOM recommendations to consume more whole grains and legumes. WIC-eligible women consume more total grains per day and more servings of legumes per day.

In addition, research shows that adult women of childbearing age who are WIC eligible and eat rice appear to have better overall health including a lower risk for being overweight or obese, and lower risk for other health factors related to chronic disease than non rice-eating women. WIC-eligible women

- Have lower BMIs than non-rice eating women (27.1 compared to 28.7) and a significant difference in weight - 5 kg (11 lbs) lower weight than non-rice eaters;
- Have smaller waist circumference (88.5 cm among rice-eaters compared to 92.3 cm). Waist circumference has been linked to increased incidence of chronic illness related to weight, and
- Have lower total cholesterol and lower C-reactive protein, health indicators for heart disease.

Also, children (1-4 y/o) meeting WIC eligibility criteria (age and income) who eat rice show positive healthy eating habits that are consistent with the IOM WIC food package recommendations in that these kids:

- Consume less saturated fat, less total fat than non-rice eating kids;
- Consume less discretionary fat and added sugar than non-rice eating children;
- Consume more magnesium, folate, vitamin B6, and niacin, all of which are important nutrients essential for normal growth and development and for optimal health.
- Do not over consume sodium with intakes below adequate intake recommendations, an important WIC requirement.

* Fulgoni, V. *Evaluation of Rice Consumption on WIC Eligible Individuals: Analysis of NHANES (1999-2002)*. Nutrition Impact, LLC, November 28, 2005



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Supplemental Foods Programs Division
FNS – USDA
3101 Park Center Drive, Room 528
Alexandria, VA 22302

RE: Docket No. 0584-AD77; Special Supplemental Nutrition Program for Women, Infants and Children (WIC): Revisions in the WIC Food Packages; Proposed Rule.

Dear Ms. Daniels,

Thank you for the opportunity to comment on FR Docket No. 0584-AD77 Revisions in the WIC Food Packages proposed rule. The USA Rice Federation is a national trade association representing all segments of the U.S rice industry. Through our domestic programs, we conduct consumer education activities to help consumers achieve healthy diets, and create awareness of the role of rice in healthy eating.

We commend USDA for undertaking a comprehensive review of the supplemental WIC food packages and for its proposed revisions to align with the 2005 *Dietary Guidelines for Americans*, and specifically we are pleased to see the inclusion of whole grains. In a separate letter we responded in support of including whole grains and gave specific details with respect to whole grain brown rice.

The purpose of this letter is to express our concern that **using the whole grains health claim imposes severe limitations for processed whole grain foods that would affect the flexibility of WIC.** The whole grain health claim requires manufacturers to prove that foods contain at least 51% whole grain by the presence of a certain level of fiber in the whole grain. This level is set at 11%; therefore, foods must have an overall fiber level of at least 5.6% (51% x 11%) to qualify for the whole grains health claim.

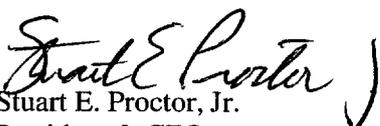
Grains vary widely in fiber content. In fact, many popular and common whole grains, such as brown rice, have less than 11% fiber yet they *are* whole grains. It is widely accepted in the scientific literature that whole grains offer many health benefits related to a wide variety of nutrients found in grains, not just fiber. Rice and corn are widely used grains in cereal and **any standard adopted for WIC should give manufacturers incentive to use whole grain corn and brown rice.**

We urge USDA to consider use of a more useful definition of whole grains, and one that would allow for the use of grains like brown rice and corn. USA Rice Federation endorses the Whole Grain Council's recommendation for using the USDA/FSIS 8 grams of whole grain standard from the guidance for labeling whole grains. This 8 grams standard provides one half serving of the three servings recommended in MyPyramid and would be an easily understood way of promoting whole grain use for WIC and other consumers. In fact, some

cereals on the market today are already describing their cereals using this criteria, with 8 grams of whole grain described as a good source and those with 16 grams an excellent source of whole grain per serving.

Thank you for the opportunity to provide our comments.

Sincerely,


Stuart E. Proctor, Jr.
President & CEO


Anne Banville
Vice President, Domestic Promotions

Rice. A World of Great Ideas

MEMBERS: USA Rice Producers' Group • USA Rice Millers' Association • USA Rice Council • USA Rice Merchants' Association

U.S. Tuna Foundation

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BY HAND DELIVERY

Patricia N. Daniels
Director, Supplemental Food Programs Division
Food and Nutrition Service
U.S. Department of Agriculture
Room 528
3101 Park Center Drive
Alexandria, VA 22302

Re: Proposed Rule To Revise The WIC Food Packages (RIN 0584-AD77)

Dear Ms. Daniels:

The U.S. Tuna Foundation (USTF) is pleased to submit comments in response to the proposed rule that would revise regulations governing the food packages provided through the Special Supplemental Nutrition Program for Women, Infants and Children (the "WIC program"). 71 Fed. Reg. 44,784 (August 7, 2006). The USTF was established in 1976 to be the representative voice of the U.S. canned tuna industry - including the U.S. tuna fleet and the U.S. canned tuna processors Star-Kist Foods, Bumble Bee Foods, LLC and Chicken of the Sea International. The USTF speaks for the industry on numerous issues from fishing access arrangements and federal and state regulations, to national legislation and domestic marketing.

The tuna industry has a long-standing interest in the WIC program. As the Food and Nutrition Service (FNS) knows, canned tuna is the only fish product authorized by the program. In particular, tuna is authorized for breastfeeding women that receive Food Package VII, and has helped supplement the unique nutritional needs of this segment of the WIC population. Our comments focus on the following aspects of the proposed rule: (1) the increase in the amount of canned tuna authorized; (2) extending the availability of canned tuna to partially breastfeeding women; (3) clarification that tuna packed in foil pouches is WIC-eligible; and (4) the exclusion of albacore tuna.

Before turning to our specific comments, USTF congratulates the agency on proposing a rule that would help the WIC food packages better conform to the *Dietary Guidelines for Americans* ("Dietary Guidelines"). Most of the current food packages are nearly thirty years old, and both nutrition science and eating habits have changed significantly over the last few decades. The proposed rule would make a number of changes to the food packages that would help ensure that the program can supplement the diet of program participants in a manner that is consistent with the

Dietary Guidelines. The Dietary Guidelines, of course, recognize the benefits of tuna by recommending the consumption of two eight-ounce servings per week of food rich in omega-3 fatty acids. According to USDA's own statistics, tuna has some of the highest levels of omega-3 fatty acids of fish commonly consumed in the United States.

Increase In Amount of Canned Fish For Fully Breastfeeding Women (Food Package VII)

Current Food Package VII authorizes up to 26 ounces of canned tuna per month. 7 C.F.R. § 246.10(c)(vii). Providing canned tuna through this food package has helped the program supplement the unique nutritional needs of breastfeeding women. As recommended by an April 2005 report from the National Academies' Institute of Medicine (IOM), FNS has proposed to increase the amount of canned tuna authorized to 30 ounces per month.¹ Proposed 7 C.F.R. §§ 246.10(e)(7)(ii) and 246.10(e)(10). USTF supports the proposed increase, as it is both consistent with the recommendations of the Dietary Guidelines and would help the WIC program encourage and promote breastfeeding.

One of the overarching criteria used in developing the proposed food package revisions is a desire to align the WIC food packages with the *Dietary Guidelines for Americans*. The Dietary Guidelines, of course, encourage the consumption of fish because of evidence of a strong link between the "consumption of fatty acids in fish and reduced risks of mortality from cardiovascular disease for the general population." *Dietary Guidelines for Americans 2005* at 30. Increasing the amount of tuna available through Food Package VII would help meet the guidance provided in this area. FNS is also seeking to use the proposed food package changes to promote and support breastfeeding in the WIC program. For example, the proposed changes would increase the market value of the food packages for a breastfeeding woman and her infant during the first year after birth. At the same time, the proposal would decrease the relative value of the food packages for fully formula feeding participants. The desired result is that participants would see an economic benefit to fully breastfeeding their infants. Increasing the amount of tuna available in Food Package VII is an integral component of this effort.

Provide Canned Tuna To Partially Breastfeeding Women

A concern that has been often raised about the existing food packages is that while they do a good job of generally addressing the different nutritional needs of fully breastfeeding and fully formula feeding women, they do not accommodate women that partially breastfeed their infants. In other words, there is no middle ground -- under the existing food packages a woman is generally considered either fully breastfeeding and receives a food package for breastfeeding women (e.g.,

¹ The proposed rule would also expand the types of fish authorized to include canned salmon and canned sardines.

Food Package VII) or she is considered fully formula feeding and receives a food package designed accordingly (*e.g.*, Food Package VI). The proposed rule would rectify this situation by creating different feeding categories for women (and their infants) that recognize the reality of the different feeding options a mother can choose to utilize.

Canned tuna was originally included in Food Package VII because it is both an economical and efficient way to address some of the unique nutritional requirements of breastfeeding women. In particular, it was included “due to its wide availability, ease of apportionment, anticipated participant acceptance, ease and versatility in preparation, and nutrient content.” 57 Fed. Reg. 56,231 at 56,235 (Nov. 27, 1992) (Final Rule establishing Food Package VII); *see also*, 57 Fed. Reg. 9,505 at 9,508 (March 19, 1992) (Proposed Rule to establish Food Package VII). As discussed in the previous section, the amount of canned tuna authorized would be increased under the proposed rule, in part, to increase the perceived market value of the fully breastfeeding food package as incentive to support breastfeeding. USTF suggests that the agency authorize canned tuna for partially breastfeeding women (*e.g.*, Food Packages III and V) for the same reasons.²

It stands to reason that women that are partially breastfeeding have similar nutritional needs as those that have chosen the option of fully breastfeeding their infants. Likewise, a perceived difference in the value of the food packages provided to partially breastfeeding women and fully formula feeding women could affect the decision of whether or not to breastfeed. USTF knows that the agency strongly supports breastfeeding of infants over full formula feeding. There will always be women who will not choose the fully breastfeeding option, and under the proposed rule those recipients would fall under either the fully formula feeding option or the partially breastfeeding option. The agency should use the food packages to encourage these women to choose the partially breastfeeding option, just as it is using the food packages to promote the fully breastfeeding option.

In order to ensure that the nutritional needs of these participants are met as well as to encourage election of the partial breastfeeding option, USTF recommends that FNS authorize canned tuna for partially breastfeeding women. Of course, it may not be necessary to authorize the same amount of canned tuna that is proposed for fully breastfeeding women, and USTF recommends that the agency authorize 18 ounces per month. This is slightly more than half the amount proposed for fully breastfeeding women (30 ounces per month), and would be easy to implement. The most common and widely available packaging size for canned tuna is 6-ounce cans; thus a recipient's monthly benefits could be redeemed for three whole cans.

² We would support the inclusion of canned salmon and canned sardines as well to be consistent with Food Package VII.

Importantly, this change would not increase the administrative burden on local WIC agencies. Under the proposed rule, women and their infants would already have to be placed into one of the three feeding categories. Accordingly, extending the availability of canned tuna to partially breastfeeding women does not require local agency staff to do anything different. Rather, it simply adds to the list of products these recipients would be authorized to receive.

Clarification That Fish Packed In Shelf Stable Foil Pouches Is WIC-Eligible

USTF is pleased that the proposed rule would clarify that tuna packed in shelf stable foil pouches is a WIC-eligible product. 71 Fed. Reg. 44,801 and *proposed* 7 C.F.R. § 246.10(e)(12) Table 4, footnote 6. Compared to its canned counterpart, foil-packed tuna is a relatively new packaging medium, and it is appropriate that the proposed rule provides clarity on this issue so that a nutritionally identical product is not arbitrarily excluded from the WIC program.

Exclusion of Albacore Inconsistent With EPA/FDA Advisory and Recent IOM Guidance

USTF would like to address the proposed exclusion of albacore tuna from the WIC program entirely. USTF believes that what the agency has proposed is entirely inconsistent with the health advisories it purports to implement and recent guidance issued by IOM. For those reasons the prohibition should *not* be adopted.

The proposed rule would exclude albacore tuna in an effort to provide fish products that “do not pose a mercury hazard, as identified by federal advisories of the Food and Drug Administration and the U.S. Environmental Protection Agency. . . .” 71 Fed. Reg. 44,784 at 44,801. The proposed rule, however, contradicts those advisories. First, albacore tuna has not been identified as a “hazard” as the Federal Register notice states. Second, the Food and Drug Administration (FDA) and the Environmental Protection Agency (EPA) *have not* suggested that pregnant or breastfeeding women avoid eating canned albacore. In fact, the agencies have said pregnant and breastfeeding women “may eat up to six ounces (one average meal) of albacore tuna per week.” FDA and EPA Revised Consumer Advisory on Methylmercury in Fish (March 19, 2004) *available at* www.fda.gov/bbs/topics/news/2004/NEW01038.html (Enclosure #1). In other words, these agencies have not called for a prohibition on the amount of albacore, and were clear that women can consume the product safely.

To be sure, FDA and EPA are clear when they believe a product should not be consumed at all. In the same advisory, for example, they clearly state “[d]o *not* eat Shark, Swordfish, King Mackerel, or Tilefish” *Id.* (emphasis supplied). It is also important to note that the FDA and EPA advisory is based on a ten-fold safety factor. This means that if pregnant and nursing women follow this advice they will be consuming levels of mercury in fish that are at least ten times lower than the lowest level for any known subclinical risk.

The underlying science does not support the proposition that mothers who eat canned albacore when they are pregnant put their babies at risk. Activist groups have chosen to distort data in an effort to scare the public rather than engage in sound and meaningful policy development. In fact, every scientific study that has been conducted has found that no one in United States has mercury levels in their system that would come close to affecting their health. The Centers for Disease Control and Prevention (CDC) has found that mercury levels in women and children are significantly below levels that would cause any adverse health effect. These studies, importantly, measured total mercury levels from all sources – not just canned tuna.

Moreover, excluding albacore contradicts and is inconsistent with recent guidance from the Institute of Medicine (IOM) of the National Academy of Sciences. In mid-October, the IOM released a new report on seafood consumption entitled “Seafood Choices: Balancing Benefits and Risks.” Available online at www.nap.edu/catalog/11762.html. A copy of the summary of this report is enclosed. (Enclosure #2). The National Oceanic and Atmospheric Administration (NOAA) requested the report, and specifically asked IOM to review the benefits and risks associated with seafood consumption and recommend guidance for consumers in making appropriate seafood selections. The guidance IOM developed that is applicable to WIC participants does not prohibit the consumption of albacore. For females who are or may become pregnant or are breastfeeding, the IOM guidance says they can consume up to 6 ounces of albacore per week. Similarly, IOM notes that children can consume up to 6 ounces of albacore per week.

FNS should remove the prohibition on albacore from any interim and/or final rule it issues because it is inconsistent with the FDA and EPA advisory and IOM’s recommendations. By “banning” a certain product for alleged safety concerns FNS would also be telling recipients, in essence, that they should not consume albacore tuna at all. That is certainly not consistent with what FDA and EPA have said in their advisory. Perhaps equally as important, it sends a conflicting and incorrect message to WIC recipients about the safety of tuna in general that could scare them away from purchasing any tuna at all – with either program benefits or other resources. This would be a disservice to WIC recipients because they would be forgoing the nutritional benefits of a product that is an excellent source of lean protein and omega-3 fatty acids. While USTF is certain that breastfeeding women could safely consume the full 30 ounce canned tuna allowance by eating albacore tuna, it would not oppose a limit of 24 ounces a month, which would be consistent with the FDA/EPA advisory and IOM guidance, both of which recommend up to six ounces of albacore a week.

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Conclusion

Thank you again for the opportunity to comment on the proposed regulation. The agency has done an excellent job at developing suggested improvements to the WIC food packages, which we believe will only be improved by our suggestions.

Sincerely,



Anne Forristall Luke
President

Enclosures (2)



U.S. Department of Health and Human Services
and
U.S. Environmental Protection Agency



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News

FOR IMMEDIATE RELEASE
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FDA Press: 301-436-2335
EPA Office: 202-564-4355
Consumer Inquiries: 888-72

FDA and EPA Announce the Revised Consumer Advisory on Methylmercury in Fish

The Food and Drug Administration (FDA) and the Environmental Protection Agency (EPA) announced today their joint consumer advisory on methylmercury in fish and shellfish for reducing the exposure to high levels of mercury in women who may become pregnant, pregnant women, nursing mothers, and young children. This unifies advice from both FDA and EPA and supersedes FDA's and EPA's 2001 advisories. The FDA and EPA want to emphasize the benefits of eating fish - consumers should know that fish and shellfish can be important parts of a healthy and balanced diet. They are good sources of high quality protein and other essential nutrients; however, as a matter of prudence, women might wish to modify the amount and type of fish they consume if they are planning to become pregnant, pregnant, nursing, or feeding a young child. By following these three recommendations for selecting and eating fish or shellfish, women will receive the benefits of eating fish and shellfish and be confident that they have reduced their exposure to the harmful effects of mercury.

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.

"This revised advisory is a culmination of months of hard work by both agencies," said FDA Deputy Commissioner Lester M. Crawford, D.V.M., Ph.D. "By following this advice, we're confident that women and young children can safely include fish as an important part of a healthy diet."

In July 2002, FDA's Food Advisory Committee met and made several recommendations to FDA on how to revise its 2001 consumer advisory on methylmercury in fish with special concern for pregnant women, nursing mothers, women who may become pregnant, and young children. One recommendation was for

FDA and EPA to coordinate mercury advisories on commercial fish and recreational fish and say something specific about canned tuna.

In December 2003, FDA's Food Advisory Committee met again to be updated on the progress FDA had made in responding to their recommendations. At that time the committee recommended listing in the advisory fish that are low in mercury. Since the December 2003 meeting and the period of time between the two meetings, FDA and EPA have been working together toward the goal of providing an updated consumer advisory in response to the recommendations from the Food Advisory Committee. This work has included conducting ongoing interagency meetings, conducting field assignments which provided additional testing of mercury in fish for which there were low sample sizes, sampling over 3400 cans of tuna, undertaking exposure assessments using these new data and conducting focus group testing on the revised advisory.

"Our guidance allows consumers to make educated dietary choices for fish they catch or buy," said EPA's Acting Assistant Administrator for the Office of Water Benjamin Grumbles. "With a few simple adjustments, consumers can continue to enjoy these foods in a manner that is healthy and beneficial."

As part of announcing the revised consumer advisory, FDA and EPA plan to launch a comprehensive outreach and educational campaign. Additional information can be found at: www.cfsan.fda.gov or the EPA website at www.epa.gov/ost/fish.

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[FDA-EPA Advisory: What You Need to Know about Mercury in Fish and Shellfish \(March 2004\)](#)

[Mercury Levels in Commercial Fish and Shellfish \(March 2004\)](#)

[Mercury in Fish: FDA Monitoring Program \(1990-2003\)](#)

[FDA-EPA Backgrounder \(March 19, 2004\)](#)

[Fish is an Important Part of a Balanced Diet by Lester M. Crawford, D.V.M., Ph.D. \(March 2004\)](#)

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Free Executive Summary

Seafood Choices: Balancing Benefits and Risks

Committee on Nutrient Relationships in Seafood:
Selections to Balance Benefits and Risks

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Summary

Seafood (refers to all commercially obtained fish, shellfish, and mollusks, both marine and freshwater) is a nutrient-rich food source that is widely available to most Americans. It is a good source of high quality protein, is low in saturated fat and is rich in many micronutrients. Seafood is also a rich source of the preformed long-chain polyunsaturated omega-3 fatty acids eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA), which are synthesized in limited amounts by the human body from alpha-linolenic acid (ALA), a fatty acid found in several vegetable, nut, and seed oils (e.g., walnut and flaxseed oils). In the past several years, research has implicated seafood, particularly its contribution of EPA and DHA to various health benefits identified for the developing fetus and infants, and also for adults, including those at risk for heart disease. Contamination of aquatic food sources, however, whether by naturally-occurring or introduced toxicants, is a concern for US consumers because of adverse health effects that have been associated with exposure to such compounds. Methylmercury can accumulate in the lean tissue of seafood, particularly large, predatory species such as swordfish, certain shark, tilefish, and king mackerel. Lipophilic compounds such as dioxins and polychlorinated biphenyls (PCBs) can be found in the fatty tissue of some fish. High levels of particular microbial pathogens may be present during certain seasons in various geographic areas, which can compromise the safety of products commonly eaten raw, such as oysters. Additionally, some population groups have been identified as being at greater risk from exposure to certain contaminants in seafood.

In consideration of these issues, the US Department of Commerce, National Oceanic and Atmospheric Administration (NOAA) asked the Institute of Medicine (IOM) of The National Academies to examine relationships between benefits and risks associated with seafood to help consumers make informed choices. The expert committee was asked to prioritize the potential for adverse health effects from both naturally-occurring and introduced toxicants in seafood; assess evidence on availability of specific nutrients in seafood compared to other food sources; determine the impact of modifying food choices to reduce intake of naturally-occurring and introduced toxicants on nutrient intake and nutritional status within the US population; develop a decision path for US consumers to weigh their seafood choices to obtain nutritional benefits balanced against exposure risks; and identify data gaps and recommend future research.

The committee concentrated primarily on seafood derived from marine (saltwater) sources and included freshwater fisheries when appropriate to the discussion. Further, the committee recognized that these sources vary greatly in their level of contamination depending on local conditions, and that individual states have issued a large number of advisories based on assessment of local conditions. Although the committee was not asked to consider questions or make recommendations about environmental concerns related to seafood, it recognizes that the impact of changes in seafood production, harvesting, and processing have important environmental consequences.

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To address the task of assessing benefit/risk trade-offs, the committee took a three-step approach. The steps that framed this analytical approach were: 1) analysis and balancing of the benefits and risks (including attention to characteristics that distinguish target populations as well as substitution predictions); 2) analysis of consumer perceptions and decision-making (understanding decision contexts and their variability, and assessing consumers' behavior regarding how they perceive and make choices); and 3) design and evaluation of the decision support program itself (including format and structure of information, media, and combination of communication products and processes). The aim of the analysis in step 1 is to assess the overall effect of seafood selections rather than the assessment of reduction in a specific risk or enhancement of a specific benefit.

ANALYSIS OF THE BALANCING OF BENEFITS AND RISKS OF SEAFOOD CONSUMPTION

The scientific assessment and balancing of the benefits and risks associated with seafood consumption is a complex task. Diverse evidence, of varying levels of completeness and uncertainty, on different types of benefits and risks must be combined to carry out the assessment required as a first step in designing consumer guidance. In light of the uncertainty in the available scientific information associated with both nutrient intake and contaminant exposure from seafood, no summary metric adequately captures the complexity of seafood benefit/risk trade-offs. Thus, the committee developed a four-part qualitative protocol adapted from previous work (IOM, 2003) to evaluate and balance benefits and risks. Following the protocol, the committee considered consumption patterns of seafood; the scope of the benefits and risks associated with different patterns of consumption for the population as a whole and, if appropriate, for specific target populations; and changes in benefits and risks associated with changes in consumption patterns. It then balanced the benefits and risks to come to specific guidance for healthy consumption for the population as a whole, and, as appropriate, for specific target populations.

Consumption of Seafood in the US

Seafood consumption has increased over the past century, reaching a level of more than 16 pounds per person per year in 2003. The ten types consumed in the greatest quantities among the US general population (from highest to lowest) are shrimp, canned tuna, salmon, pollock, catfish, tilapia, crab, cod, clams, and flatfish (e.g., flounder, sole). The nation's seafood supply is changing, however, and this may have a significant impact on seafood choices in the future. The preference among consumers for marine types of seafood is leading to supply deficits, and seafood produced by aquaculture is replacing captured supplies for several of these types.

While seafood is recognized as a primary source of the omega-3 long-chain polyunsaturated fatty acids EPA and DHA, not all seafood is rich in these fatty acids. Among types of seafood, shrimp and canned light tuna are the two most commonly consumed, and they are not especially high in EPA and DHA. Eggs and chicken, although not particularly rich sources¹, may contribute to the EPA and DHA content of the US diet because of their frequent consumption. Relative to other foods in the meat, poultry, fish, and eggs group, however, seafood is generally lower in

¹ Because of changes in feed composition the current levels of EPA/DHA in chicken and eggs may be less than that reported in food databases

saturated fatty acids and higher in EPA, DHA, and selenium, all of which have been associated with health benefits.

Primary Findings

1. Average quantities of seafood consumed by the general US population, and by several specific population groups, are below levels suggested by many groups including levels recommended by the American Heart Association for cardiovascular disease; and
2. For many ethnic and geographic subgroups, there are insufficient data to characterize the intake levels of seafood, EPA, DHA, and other dietary constituents and assess the variability of those intakes.

Benefits Associated with Nutrients from Seafood

The high nutritional quality of seafood makes it an important component of a healthy diet. While protein is an important macronutrient in the diet, most Americans already consume enough and do not need to increase their intake. Fats and oils are also part of a healthful diet, but the type and amount of fat can be important, for example, with regard to heart disease. Many Americans consume greater than recommended amounts of saturated and trans fat as well as cholesterol from high-fat protein foods such as beef and pork. Many seafood selections are lower in total and saturated fats and cholesterol than some more frequently selected animal protein foods such as fatty cuts of beef, pork, and poultry and are equivalent in amount of fat to some leaner cuts of meat. Since it is lower in saturated fats, however, by substituting seafood more often for other animal foods, consumers can decrease their overall intake of both total and saturated fats while retaining the nutritional quality of other protein food choices.

Seafood is also a primary source of EPA and DHA in the American diet. The contribution of these nutrients to improving health and reducing risk for certain chronic diseases in adults has not been completely elucidated. There is evidence, however, to suggest there are benefits to the developing infant, such as increasing gestational length, improved visual acuity, and improved cognitive development. In addition, there is evidence to support an overall benefit to the general population for reduced risk of heart disease among those who eat seafood compared to those who do not, and there may be benefits from consuming EPA and DHA for adults at risk for coronary heart disease.

Primary Findings

1. Seafood is a nutrient-rich food that makes a positive contribution to a healthful diet. It is a good source of protein, and relative to other protein foods, e.g. meat, poultry, and eggs is generally lower in saturated fatty acids and higher in the omega-3 fatty acids EPA and DHA and selenium;
2. The evidence to support benefits to pregnancy outcome in females who consume seafood or fish oil supplements as part of their diet during pregnancy is derived largely from observational studies. Clinical trials and epidemiological studies have also shown an association between increased duration of gestation and intake of seafood or fish oil supplements. Evidence that the infants and children of mothers who consume seafood or EPA/DHA supplements during pregnancy and/or lactation may have improved developmental outcomes is also supported largely by observational studies;

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3. Observational evidence suggests that increased seafood consumption is associated with a decreased risk of cardiovascular deaths and cardiovascular events in the general population. Evidence is insufficient to assess if this association is mediated through an increase in EPA and DHA consumption and/or a decrease in saturated fat consumption and/or other correlates of seafood consumption;
4. Evidence is inconsistent for protection against further cardiovascular events in individuals with a history of myocardial infarction from consumption of EPA/ DHA-containing seafood or fish oil supplements. The protection evidenced by population (observational) studies has not been consistently observed in randomized clinical trials; and
5. Evidence for a benefit associated with seafood consumption or fish oil supplements on blood pressure, stroke, cancer, asthma, type II diabetes, or Alzheimer's Disease is inconclusive. Whereas observational studies have suggested a protective role of EPA/DHA for each of these diseases, supportive evidence from randomized clinical trials is either non-existent or inconclusive.

Risks Associated with Seafood

The safety of seafood in the US has increased in recent decades, although there are still a number of chemical and microbial hazards that are present in seafood. Whether a contaminant poses a health risk to consumers depends on the amount present in the food and the potential outcome from exposure. Consumers are exposed to a complex mixture of dietary and non-dietary contaminants. However, most studies of the risks associated with seafood focus on one contaminant at a time rather than a mixture. The extent to which such co-exposures might affect the toxicity of seafoodborne contaminants is largely unknown. Similarly, few data are available on the extent to which beneficial components of seafood, such as selenium, might mitigate the risks associated with seafoodborne contaminants. The evidence reviewed indicates that the levels of different contaminants in seafood depend on several factors such as species, size, location, age, and feed source. Levels of some contaminants in seafood vary substantially due to their geographic localization; these tend to be mostly freshwater sources.

Consumption of aquatic foods is the major route of human exposure to methylmercury (MeHg). The seafood choices a consumer makes and the frequency with which different species are consumed are thus important determinants of methylmercury intake. Exposure to MeHg among US consumers in general is a concern because there is uncertainty about the potential for subtle adverse outcomes. Since the most sensitive subgroup of the population to MeHg exposure is the developing fetus, intake recommendations are developed for and directed to the pregnant woman rather than to the general population.

Persistent organic pollutants (POPs), including dioxins and polychlorinated biphenyls (PCBs), can be found in the fatty tissue of all animal-derived foods, including seafood. Exposure to these compounds among the general population has been decreasing in recent decades. The greatest concern is for population groups exposed to POPs in seafood obtained through cultural, subsistence, or recreational fishing, because of reliance on fish from locations that may pose a greater risk.

In contrast to heavy metal contaminants and POPs, reported illnesses from seafoodborne microbial contaminants have remained steady over the past several decades. Exposure to vibrio and norovirus infections are still a concern, however, because they continue to be associated with consumption of raw molluscan shellfish. Strategies for minimizing the risk of seafoodborne illnesses are, to some extent, hazard-specific, but overall include avoiding types of seafood

identified as being more likely to contain certain contaminants, and following general food safety guidelines, which include proper cooking.

Primary Findings

1. Levels of contaminants in seafood depend on several factors, including species, size, harvest location, age, and composition of feed. Methylmercury is the seafoodborne contaminant for which the most exposure and toxicity data are available; levels of MeHg in seafood have not changed substantially in recent decades. Exposure to dioxins and PCBs varies by location and vulnerable subgroups (e.g. some American Indian/Alaskan Native groups living near contaminated waters) may be at increased risk. Microbial illness from seafood is acute, persistent, and a potentially serious risk although incidence of illness has not increased in recent decades;
2. Considerable uncertainties are associated with estimates of the health risks to the general population from exposures to methylmercury and persistent organic pollutants at levels present in commercially-obtained seafood. The available evidence to assess risks to the US population is incomplete and useful to a limited extent.
3. Consumers are exposed to complex mixtures of dietary and non-dietary contaminants whereas most studies of risks associated with seafood focus on a single contaminant.
4. Few data are available on the extent to which beneficial components of seafood such as selenium might mitigate the risks associated with seafoodborne contaminants.

Balancing Risks and Benefits

From its review of consumption, benefits, and risks, the committee recommends that:

Recommendation 1: Dietary advice to the general population from federal agencies should emphasize that seafood is a component of a healthy diet, particularly as it can displace other protein sources higher in saturated fat. Seafood can favorably substitute for other high biologic value protein sources while often improving the overall nutrient profile of the diet.

Recommendation 2: Although advice from federal agencies should also support inclusion of seafood in the diets of pregnant females or those who may become pregnant any consumption advice should stay within federal advisories for specific seafood types and state advisories for locally-caught fish.

Recommendation 3. Appropriate federal agencies (the National Oceanic and Atmospheric Administration [NOAA], the US Environmental Protection Agency [EPA], and the Food and Drug Administration of the US Department of Health and Human Services [FDA]) should increase monitoring of methylmercury and persistent organic pollutants in seafood and make the resulting information readily available to the general public. Along with this information, these agencies should develop better recommendations to the public about levels of pollutants that may present a risk to specific population subgroups.

Recommendation 4: Changes in the seafood supply (source and type of seafood) must be accounted for—there is inconsistency in sampling and analysis methodology used for nutrients and contaminants that are published by state and federal agencies. Analytical data is not consistently revised, with separate data values presented for wild-caught domestic, and imported products.

Drawing on these recommendations and its risk-benefit assessment protocol, the committee identified four population groups for which the data support subgroup-specific conclusions. In the committee's judgement, the variables that distinguish between these populations facing different risk-benefit balances based on existing evidence are (1) age, (2) gender, (3) pregnancy or possibility of becoming pregnant, or breast-feeding, and (4) risk of coronary heart disease, although the evidence for a benefit to adult males and females who are at risk for coronary heart disease is not sufficient to warrant inclusion as a separate group within the decision-making framework. The groups and appropriate guidance are listed in Box S-1 below:

To balance the benefits and risks, the recommendations, as they apply to the target population groups 1-3, are arrayed in a decision pathway (shown in Figure S-1) that illustrates the committee's resulting analysis of the balance between benefits and risks associated with seafood consumption.

BOX S-1 Population Groups and Appropriate Guidance

1. *Females who are or may become pregnant or who are breast-feeding:*
 - a. May benefit from consuming seafood, especially those with relatively higher concentrations of EPA and DHA;
 - b. A reasonable intake would be two 3-ounce (cooked) servings but can safely consume 12 ounces per week;
 - c. Can consume up to 6 ounces of white (albacore) tuna per week;
 - d. Should avoid large predatory fish such as shark, swordfish, tilefish, or king mackerel.
2. *Children up to age 12:*
 - a. May benefit from consuming seafood, especially those with relatively higher concentrations of EPA and DHA;
 - b. A reasonable intake would be two 3-ounce (cooked), or age-appropriate, servings but can safely consume 12 ounces per week;
 - c. Can consume up to 6 ounces of white (albacore) tuna per week;
 - d. Should avoid large predatory fish such as shark, swordfish, tilefish, or king mackerel.
3. *Adolescent males, adult males, and females who will not become pregnant:*
 - a. May reduce their risk for cardiovascular disease by consuming seafood regularly, e.g., two 3-ounce servings per week;
 - b. Who consume more than two servings a week should choose a variety of types of seafood to reduce the risk for exposure to contaminants from a single source;
4. *Adult males and females who are at risk of coronary heart disease:*
 - a. May reduce their risk of cardiovascular disease by consuming seafood regularly, e.g., two 3-ounce servings per week;
 - b. Although supporting evidence is limited, there may be additional benefits from including high EPA/DHA seafood selections;

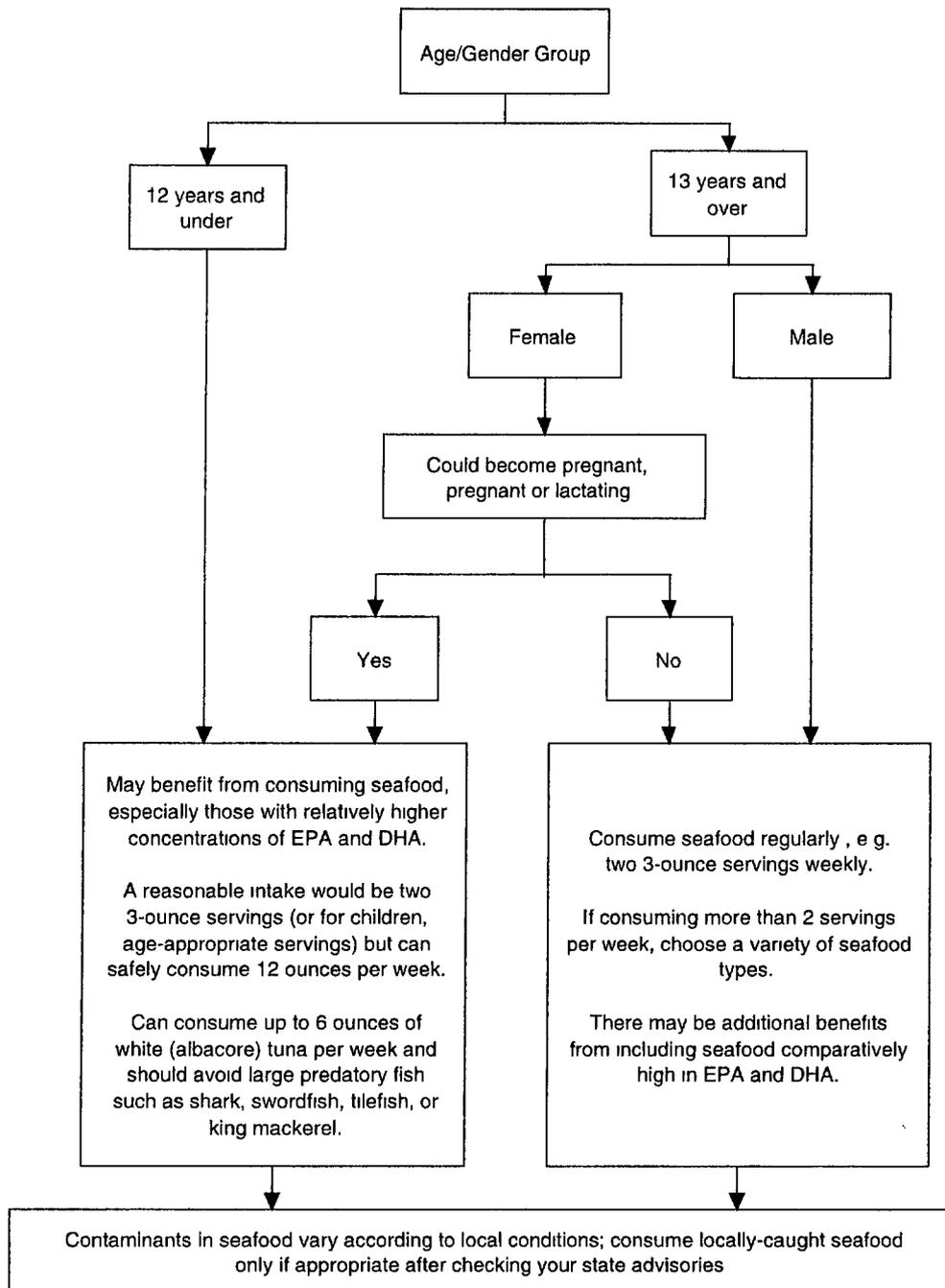


FIGURE S-1 The committee’s decision pathway derived from the balance between benefits and risks associated with seafood consumption. The diagram highlights the variables that group consumers into target populations which face different benefits and risks and should receive tailored advice.

NOTE: The wording in this figure has not been tested among consumers. Designers will need to test the effects of presenting information on seafood choices in alternative formats.

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UNDERSTANDING SEAFOOD CHOICES FOR THE DESIGN OF CONSUMER GUIDANCE

The second step in the approach to balancing benefits and risks associated with seafood consumption is developing an understanding of the context within which consumers make seafood choices. Receiving new information, such as dietary guidance, does not automatically lead consumers to change their food consumption patterns. Food choice is influenced by a complex information environment that includes taste, availability, and price as well as guidance, point-of-purchase information, labeling, and advice from health care providers. In the context of this environment, specific pieces of guidance may have limited impact, although evidence suggests that this impact varies significantly and in many instances is not well measured or understood. There are several factors that mitigate against current advice having the intended consequences in terms of consumer choice. Increased understanding of the individual, socio-cultural and environmental factors that influence consumer choice is necessary for the design of consumer guidance, especially where the intent is to communicate balancing of benefits and risks associated with seafood consumption.

Seafood choices, like all consumption choices, entail value trade-offs; some individuals will choose high risks to achieve what they value as high benefits (e.g., consume raw seafood because of its pleasurable taste), while others may prefer to “play it safe.” Individual differences in tastes; preferences; beliefs and attitudes; and situations complicate the task of informing and supporting benefit-risk trade-off decisions. Audience segmentation and targeting, therefore, is essential for effective communication, because decision objectives, risk attitudes, and people’s knowledge about and interest in decision-making vary. Guidance in making seafood choices should allow consumers to access information in a clear and easy-to-understand format. It should also be structured to support decision making, and allow consumers to access additional layers of information when they want them.

BALANCING CHOICES: SUPPORTING CONSUMER SEAFOOD CONSUMPTION DECISIONS

The third design step for developing specific support for seafood consumption decisions is production and evaluation of the information itself, including ways to integrate the risk and benefit considerations in mock-up examples of how such information might be provided. It is apparent in any discussion of seafood consumption that “one size does not fit all” and that messages about consumption often have to be individualized for different groups, such as subsistence fishers, pregnant women and children, and native populations, to mention a few. The committee’s balancing of the benefits and risks of different patterns of seafood consumption for different subpopulations is illustrated in Figure S-1. Different subpopulations could be used by federal agencies as the basis for advice to consumers on seafood consumption. Resulting communication products should be tested empirically. Through a brief set of questions, a decision pathway can segment and channel consumers into relevant benefit/risk subpopulations in order to provide benefit and risk information that is tailored to each group. The inclusion of alternative presentations of benefit/risk advice and information in the design of consumer advice recognizes that while some consumers prefer to follow the advice to given them by experts, others want to decide on the benefit- risk trade-offs for themselves.

One of the challenges in supporting informed consumer choice is how governmental agencies communicate health benefits and risks to both the general population and to specific subgroups

or particularly vulnerable populations. Developing effective tools to disseminate current and emerging information to the public requires formal evaluation, as well as an iterative approach to design. The use of tailored messages and community-level involvement on an ongoing basis is likely to improve the effectiveness of communication between federal agencies and target populations.

Primary Findings

1. Advice to consumers from the federal government and private organizations on seafood choices to promote human health has been fragmented. Risks have been addressed separately from benefits; portion sizes differ from one piece of advice to another. Some benefits and some risks have been addressed separately from others for different physiological systems and age groups. As a result, multiple pieces of guidance—sometimes conflicting—simultaneously exist for seafood;
2. Given the uncertainties present in underlying exposure data and health impact analysis, there is no single summary metric that adequately captures the complexity of balancing benefits and risks associated with seafood for purposes of providing guidance to consumers. An expert judgement technique can be used to consider benefits and risks together, to yield specific suggested consumption guidance.

Recommendations

Recommendation 5: Appropriate federal agencies should develop tools for consumers, such as computer-based, interactive decision support and visual representations of benefits and risks that are easy to use and to interpret. An example of this kind of tool is the health risk appraisal (HRA), which allows individuals to enter their own specific information and returns appropriate recommendations to guide their health actions. The model developed here provides this kind of evidence-based recommendations regarding seafood consumption. Agencies should also develop alternative tools for populations with limited access to computer-based information.

Recommendation 6: New tools apart from traditional safety assessments should be developed, such as consumer-based benefit-risk analyses. A better way is needed to characterize the risks combined with benefit analysis.

Recommendation 7: A consumer-directed decision path needs to be properly designed, tested and evaluated. The resulting product must undergo methodological review and update on a continuing basis. Responsible agencies will need to work with specialists in risk communication and evaluation, and tailor advice to specific groups as appropriate.

Recommendation 8: Consolidated advice is needed that brings together different benefit and risk considerations, and is tailored to individual circumstances, to better inform consumer choices. Effort should be made to improve coordination of federal guidance with that provided through partnerships at the state and local level.

Recommendation 9: Consumer messages should be tested to determine if there are spillover effects for segments of the population not targeted by the message. There is suggestive evidence that risk-avoidance advice for sensitive subpopulations may be construed by other groups or the general population as appropriate precautionary action for themselves. While emphasizing tradeoffs may reduce the risk

of spillover effects, consumer testing and messages should address the potential for spillover effects explicitly.

Recommendation 10. The decision pathway the committee recommends, which illustrates its analysis of the current balance between benefits and risks associated with seafood consumption, should be used as a basis for developing consumer guidance tools for selecting seafood to obtain nutritional benefits balanced against exposure risks. Real-time, interactive decision tools, easily available to the public, could increase informed actions for a significant portion of the population, and help to inform important intermediaries, such as physicians.

Recommendation 11: The sponsor should work together with appropriate federal and state agencies concerned with public health to develop an interagency task force to coordinate data and communications on seafood consumption risks, benefits, and related issues such as fish stocks and seafood sources and begin development of a communication program to help consumers make informed seafood consumption decisions. Empirical evaluation of consumers' needs and effectiveness of communications should be an integral part of the program.

Recommendation 12: Partnerships should be formed between federal agencies and community organizations. This effort should include targeting and involvement of intermediaries, such as physicians, and use of interactive internet communications, which have the potential to increase the usefulness and accuracy of seafood consumption communications.

Recommendation 13: Development of an interagency task force may be necessary to coordinate federal data and communications on seafood consumption risks, benefits, and related issues, such as fish stocks and seafood sources.

RESEARCH GAPS AND RECOMMENDATIONS

Seafood Consumption

Recommendation 1: Research is needed on systematic surveillance studies of targeted subpopulations. Such studies should be carried out using state-of-the-art assessment methods to determine the intake levels of seafood, EPA/DHA and other dietary constituents, and the variability of those intake levels among population groups.

Recommendation 2: Sufficiently large analytic samples of the most common seafood types need to be obtained and examined. These samples should be used to determine the levels of nutrients, toxicants, and contaminants in each species and the variability between them, which should be reported transparently.

Recommendation 3: Additional data is needed to assess benefits and risks associated with seafood consumption within the same population or population subgroup.

Pregnant and Lactating Women

Recommendation 4: Better data are needed to determine if outcomes of increasing consumption of seafood or increasing EPA/DHA intake levels in US women would be comparable to outcomes of populations in other countries. Such studies should be encouraged to include populations of high fish-consumers outside the continental

US to determine if there are differences in risks for these populations compared to US populations.

Recommendation 5: Dose-response studies of EPA/DHA in pregnant and lactating women are needed. This information will help determine if higher intakes can further increase gestation duration, reduce premature births, and benefit infant development. Other studies should include assessing whether DHA alone can act independent of EPA to increase duration of gestation.

Infants and Toddlers

Recommendation 6: Research is needed to determine if cognitive and developmental outcomes in infants are correlated with performance later in childhood. This should include:

- Evaluating preschool and school-age children exposed to EPA/DHA *in utero* and postnatally, at ages beginning around 4 years when executive function is more developed and;
- Evaluating development of school-age children exposed to variable EPA/DHA *in utero* and postnatally with measures of distractibility, disruptive behavior and oppositional defiant behavior, as well as more commonly assessed cognitive outcomes and more sophisticated tests of visual function.

Recommendation 7: Additional data is needed to better define optimum intake levels of EPA/DHA for infants and toddlers.

Children

Recommendation 8: Better-designed studies about EPA/DHA supplementation in children with behavioral disorders are needed.

Adults at Risk for Chronic Disease

Recommendation 9: In the absence of meta-analyses that systematically combine quantitative data from multiple studies, further meta-analyses and larger randomized trials are needed to assess outcomes other than cardiovascular, in particular total mortality, in order to explore possible adverse effects of EPA/DHA supplementation.

Recommendation 10: Additional clinical research is needed to assess a potential effect of seafood consumption and/or EPA/DHA supplementation on stroke, cancer, Alzheimer's disease, and depression.

Recommendation 11: Future epidemiological studies should assess intake of specific species of seafood and/or biomarkers, in order to differentiate the health effects of EPA/DHA from the health effects of contaminants, such as methylmercury.

Health Risks Associated with Seafood Consumption

Recommendation 12: More complete data is needed on the distribution of contaminant levels among types of fish. This information should be made available in order to reduce uncertainties associated with the estimation of health risks associated with specific seafoodborne contaminant exposures.

Recommendation 13: More quantitative characterization is needed of the dose-response relationships between chemical contaminants and adverse health effects in the ranges of exposure represented in the general US population. Such information will reduce uncertainties associated with recommendations for acceptable ranges of intake.

Recommendation 14: In addition, the committee recommends more research on useful biomarkers of contaminant exposures and more precise quantitative characterization of the dose-response relationships between chemical contaminants and adverse health effects in the ranges of exposure represented in the general US population in order to reduce uncertainties associated with recommendations for acceptable ranges of intake.

Designing Consumer Guidance

Recommendation 15: Research is needed to develop and evaluate more effective communication tools for use when conveying the health benefits and risks of seafood consumption as well as current and emerging information to the public. These tools should be tested among different communities and subgroups within the population and evaluated with pre- and post test activities.

Recommendation 16: Among federal agencies there is a need to design and distribute better consumer advice to understand and acknowledge the context in which the information will be used by consumers. Understanding consumer decision-making is a prerequisite. The information provided to consumers should be developed with recognition of the individual, environmental, social and economic consequences of the advice. In addition, it is important that consistency between agencies be maintained, particularly with regard to communication information using serving sizes.

CONCLUSION

For most of the general population, balancing benefits and risks associated with seafood to obtain nutritional and health benefits can be achieved by selecting seafood from available options in quantities that fall within accepted dietary guidelines. For the specific subgroups identified by the committee, making such selections requires that consumers are aware of both nutrients and contaminants in the seafood available and are provided useful information on both benefits and risks to inform their choices. The committee has put forward its interpretation of the evidence for benefits and risks associated with seafood and considered the balance between them. Recommendations are made to facilitate development of appropriate consumer guidance for making seafood selections, based on the committee's findings, and research opportunities are identified that will contribute to filling knowledge gaps.

Seafood Choices

Balancing Benefits and Risks

Committee on Nutrient Relationships in Seafood:
Selections to Balance Benefits and Risks
Food and Nutrition Board

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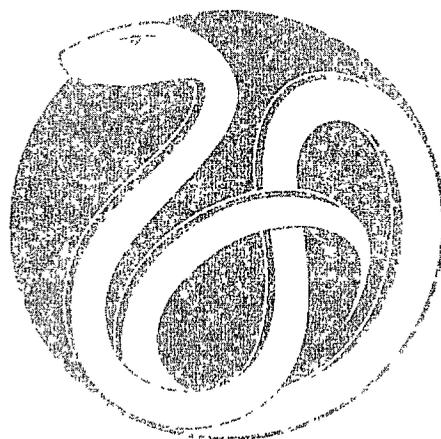
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The serpent has been a symbol of long life, healing, and knowledge among almost all cultures and religions since the beginning of recorded history. The serpent adopted as a logotype by the Institute of Medicine is a relief carving from ancient Greece, now held by the Staatliche Museen in Berlin.

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*"Knowing is not enough; we must apply.
Willing is not enough; we must do."*
—Goethe



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Independent Report Reviewers

This report has been reviewed in draft form by individuals chosen for their diverse perspectives and technical expertise, in accordance with procedures approved by the National Research Council's Report Review Committee. The purpose of this independent review is to provide candid and critical comments that will assist the institution in making its published report as sound as possible and to ensure that the report meets institutional standards for objectivity, evidence, and responsiveness to the study charge. The review comments and draft manuscript remain confidential to protect the integrity of the deliberative process. We wish to thank the following individuals for their review of this report:

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Although the reviewers listed above have provided many constructive comments and suggestions, they were not asked to endorse the conclusions or recommendations nor did they see the final draft of the report before its release. The review of this report was overseen by **Johanna T. Dwyer**, Tufts University School of Medicine and Friedman School of Nutrition Science & Policy and Tufts-New England Medical Center and **Catherine E. Woteki**, Mars, Inc. Appointed by the National Research Council and Institute of Medicine, they were responsible for making certain that an independent examination of this report was carried out in accordance with institutional procedures and that all review comments were carefully considered. Responsibility for the final content of this report rests entirely with the authoring committee and the institution.

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Preface

When I was growing up, fish were considered “brain food”. I was told that eating fish was good for you and would make you smart. Amazingly, there now is some evidence that this old food lore may have some scientific basis, as mothers who consume seafood may provide benefits to the developing fetal nervous system from the fatty acids in the seafood. It is not clear however whether this will make one smarter as an adult.

Seafood is a good source of high quality protein, is low in saturated fat, and is rich in many micronutrients. Seafood is also a major source of the long chain polyunsaturated omega-3 fatty acids, docosahexaenoic (DHA) and eicosapentaenoic acid (EPA), which are synthesized in limited amounts by the human body from alpha-linolenic acid (ALA), an omega-3 fatty acid found in several vegetable oils. Though these fatty acids are found in other foods, some seafood are an unusually rich source. In the past several years, research has implicated seafood and/or DHA and EPA in an array of health benefits for the developing fetus, infants, and also for adults, especially those prone to heart disease. This has led to recommendations by several health authorities to include seafood in a healthy diet.

Seafood is the only animal protein food that is still provided in significant amounts to human diets through capture of wild species. Though our oceans are being depleted of some wild species, and aquaculture has become an important source of seafood, wild capture still provides a significant portion of the seafood we consume. The pollution of our oceans both through natural processes and practices of an increasingly industrialized world raise concern about the contaminants found in our seafood supply. As aquaculture of some species also uses fish meal and fish oil produced from captured wild sources, farmed seafood is not free from potential risks of further reducing ocean stocks or from potential contaminants. As consumption of seafood rises, there has been an increasing awareness of the potential risks of seafood consumption due to the presence of microbial contaminants; persistent organic pollutants; and of heavy metals, especially mercury, in our oceans and inland waters.

Consumers are therefore confronted with a dilemma: they are told that seafood is good for them and should be consumed in larger amounts than current consumption, while at the same time the federal government and virtually all the states have issued advisories urging caution in consumption of fish of certain species or from specific waters. Clearly, it should be an environmental priority to eliminate the sources of contamination of this important component of our food supply so that such a contradiction is avoided.

The National Oceanic and Atmospheric Administration (NOAA) provide federal leadership in marine science and conservation. The seafood industry contributes a large part of the nation's economic health, and as an agency of the US Department of Commerce, NOAA works to advance fisheries management policies and programs to ensure that fishery resources are healthy and sustainable so that they will remain a safe, nutritious and affordable component of the US food supply. In light of these considerations, NOAA recognized the need for an independent

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group to examine the scientific evidence on the nutritional benefits obtained from seafood balanced against potential risks from exposure to contaminants, and ways to guide US consumers to make selections appropriate to their needs. Thus, NOAA asked the Institute of Medicine (IOM) to convene a committee with a diverse background and a broad scope of expertise to address the task put before them.

The committee was charged to identify and prioritize adverse health effects from both naturally-occurring and introduced toxicants in seafood; assess evidence on availability of specific nutrients in seafood compared to other food sources; determine the impact of modifying food choices to reduce intake of naturally-occurring and introduced toxicants on nutrient intake and nutritional status within the US population; develop a decision path for US consumers to balance their seafood choices to obtain nutritional benefits while minimizing exposure risks; and identify data gaps and recommend future research. The committee's report recommends approaches to decision-making for selecting seafood to obtain the greatest nutritional benefits balanced against exposure to potential toxicants, and identifies data gaps and research needs. The Committee concentrated on issues affecting marine species and have not dealt in detail with freshwater fisheries.

The task has not been an easy one. The Committee reviewed the existing literature on benefits of seafood consumption and has attempted to make judgments as to the strength of the evidence. In many cases, we have deemed the evidence for benefit as insufficient or too preliminary. Similarly, the Committee reviewed the data on contaminants and risks they imply. We were surprised at the lack of good data on the distribution of some contaminants in the seafood supply. There is likewise little available evidence as to how beneficial effects of seafood may counteract some of the risks from contaminants.

The Committee also considered how consumers make decisions as to what they eat and tried to advise them on how to approach the task of communicating risks and benefits to consumers. We have not considered it the Committee's task to set specific dietary standards for seafood or EPA/DHA consumption and we have considered our findings in the light of the dietary recommendations of the Dietary Guidelines Advisory Committee as well as other authoritative groups.

The Committee on Nutrient Relationships in Seafood was made up of committed members with widely varied expertise who volunteered countless hours to the research, deliberations, and preparation of the report. Many other individuals volunteered significant time and effort to address and educate our committee members during the first open session, workshop, and through consultations, and we are grateful for their contributions.

The report could not have been produced without the dedicated guidance and expertise of the Study Director, Ann Yaktine, and her colleagues; Cara James, research associate; and Sandra Amamoo-Kakra, senior project assistant. We also thank Geraldine Kennedo for administrative support, Greg Fulco for graphic design and Hilary Ray for technical and copy editing. This project benefited from the support and wisdom of Linda Meyers, director of the Food and Nutrition Board.

Malden C. Nesheim, *Chair*
Committee on Nutrient Relationships in Seafood

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