

December 16, 2010

Margaret A. Hamberg, M.D.
Commissioner Food and Drugs
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD USA
20992-0002

Dear Dr. Hamberg,

The 2010 Hawaii Seafood Symposium: *Making Sense of Seafood Health Benefits and Risks* convened in Honolulu October 20-22. This 2.5-day symposium concluded that there is an urgent need for the completion of the January 21, 2009 draft FDA Quantitative Risk Benefit Assessment of Commercial Fish Consumption (DOCKET No. FDA-2009-N-0018 <http://www.cfsan.fda.gov:80/~dms/mehgrb.html>).

This is needed in order to provide the public, especially women and children, with the best public health advice currently available regarding the risks and benefits of seafood consumption, based on both the known risks and benefits of seafood consumption.

The current 2004 advisory is widely misunderstood by the public and has resulted in avoidance of fish and shellfish depriving the developing fetus of the vital nutrients they contain that are essential for fetal neurodevelopment and for the health of the mother.

There has been a substantial amount of research on seafood health benefits and risks since the 2004 joint EPA FDA fish consumption advisory was prepared. New research has shown that maternal diets during pregnancy that include more than 2 meals of ocean fish (12 oz) per week were associated with improved cognitive development of the child. This benefit occurs even though all fish contain some amount of methylmercury. The current 2004 advisory limits fish consumption to no more than 2 meals per week during pregnancy. These findings indicate that swift action is needed to make sure expectant mothers are better-informed about the role of fish in a healthy diet.

Since the 2004 advisory, it has become clearer that seafood is highly nutritious, contains nutrients essential for neurodevelopment in children and that any public health advisory for seafood consumption must be based on the evaluation of both benefits and risks, not on the risk of mercury alone. Please consider the findings of this symposium and its recommendation that FDA complete its Risk Benefit Assessment at the earliest time possible and then update the fish consumption advisory.

Sincerely,

John Kaneko, MS, DVM
Symposium Secretariat
Hawaii Seafood Council
1130 N Nimitz Hwy, Ste. A-263
Honolulu, Hawaii 96817 USA

**Michael Crawford, PhD, CBiol,
FIBiol, FRCPATH**, Director
Institute of Brain Chemistry and
Human Nutrition, Imperial
College, London SW10 9NH, UK

Jean Golding, PhD, DSc, FMedSci
Founder and initial Director of the
ALSPAC Study, Centre for Child
and Adolescent Health, School of
Social and Community Medicine,
University of Bristol, Bristol, UK

Michael Morrissey, PhD
Superintendent
Oregon State University
Food Innovation Center
Portland, OR, USA

Nicholas Ralston, PhD
Leader, Health Effects Research
Energy & Environ. Research
Center
University of North Dakota
Grand Forks, ND, USA

Steven Otwell, PhD
Professor & Extension Specialist in
Food Science & Nutrition
Aquatic Food Products Lab
University of Florida
Gainesville, FL, USA

Rachel Novotony PhD, RD
University of Hawaii, CTAHR
Department of Human
Nutrition
Food and Animal Sciences
Honolulu, HI, USA

Marla Berry, PhD
Professor, Cell and Molecular
Biology, JAB School of Medicine
University of Hawaii
Honolulu, HI, USA

Niladri Basu, PhD
Assistant Professor
Environmental Health Sciences
University of Michigan
Ann Arbor, MI, USA

Laura Raymond PhD
Research Manager
Energy & Environ. Research
Center
University of North Dakota
Grand Forks, ND, USA

Doris Hicks, MS
Seafood Technology Specialist
Delaware Sea Grant
University of Delaware
Marine Advisory Service
Lewes, DE, USA

Douglas Stevens, PhD
Director, SKC Environmental Lab,
Department of Life Sciences, Salish
Kootenai College, Ronan, MT, USA

Jon Bell, PhD
Professor
Louisiana State University Ag
Center, Dept. of Food Science
New Orleans, LA, USA

(Symposium speakers above, participants below.)

Steven Arentz, M.D.
San Diego, CA

Paul Bartram
Akala Products
Honolulu, HI

Kyle Boehm
Student
Hawaii Pacific University
Honolulu, HI

Steven Bowman
Commissioner
Virginia Marine Resources
Commission
Newport News, VA

Clayton Ching
Molokai Island Coordinator
Western Pacific Regional Fishery
Council
Kaunakakai, HI

William Coleman
Food and Drug Inspector
Hawaii State Department of
Health
Honolulu, HI

John Corbin
President
Aquaculture Planning &
Advocacy
Kaneohe, HI

Kevin Dietrichs
Guam Community College
Maniglaio, GU

Heidi Hirsh
NOAA NMFS PIRO
Natural Resources Management
Specialist
Honolulu, HI

Mike Jahncke, PhD
Professor
Virginia Seafood Agricultural
Research and
Extension Center
Hampton, VA

Yvette Jensen
Project Administrator
Hawaii Seafood Council
Honolulu, HI

Pierre Kleiber, PhD
Fishery Biologist
Pacific Islands Fishery Science
Center
Honolulu, HI

Amanda Lowrey, PhD
Sanitarian IV
Hawaii Department of Health
Honolulu, HI

Jennifer McGuire, MS, RD
Manager, Nutrition
Communications
National Fisheries Institute
Kailua, HI

Lorraine Medina, MPH
Hawaii Department of Education
Kaneohe, HI

Robert Nakamura, DVM, PhD
Emeritus Professor
University of Hawaii
Aiea, HI

Susan Nakamura
Public Health Nutritionist
Hawaii Department of Health
Kapolei, HI

Thomas Rippen
Seafood Technology Specialist
University of Maryland
Princess Anne, MD

John Tagabuel
Environmental Health Official
Department of Public Health
Saipan, MP

Brooks Takenaka
Assistant General Manager
United Fishing Agency
Honolulu, HI

Cynthia Takenaka
Hawaii Seafood Council
Honolulu, HI

Pamela Tom
Advisor
California Sea Grant
University of California
Davis, CA

Charlotte Yamamoto, MSN,
APRN, NP
Nurse Practitioner
WCCHC, Waipahu Family Health
Center
Waipahu, HI

cc. Michael Landa, Director, CFSAN, FDA
Roberta Wagner, Deputy Director, CFSAN, FDA
Donald Kraemer, Deputy Director, CFSAN, FDA
Phillip Spiller, CFSAN, FDA

**Findings and Recommendations of the
2010 Hawaii Seafood Symposium**
Making Sense of Seafood Health Benefits and Risks
October 20-22, 2010
Honolulu, Hawaii

The following statements, findings and recommendations are based on the current status of scientific knowledge of seafood health benefits and risks presented during this symposium. Information on the symposium program, speakers and their presentations will be available at www.hawaii-seafood.org

Symposium Statement

Seafoods (excluding marine mammals) are among the healthiest foods available. Current scientific evidence indicates that nutrients contained in seafoods enhance neurodevelopment and cardiovascular health. However, appreciation of these health benefits has become lost in statements about potential harm. The well-intentioned US fish consumption advisory: *What You Need to Know About Mercury in Fish and Shellfish, 2004 EPA and FDA Advice For: Women Who Might Become Pregnant, Women Who are Pregnant, Nursing Mothers, Young Children*; now appears to be in urgent need of replacement as the science of the "benefits vs. risks" of seafood consumption has matured. The 2004 guidance that limits seafood consumption to protect the public may be inadvertently causing harm by resulting in the reduced intake of seafood, the primary dietary source of long-chain omega-3 fatty acids (DHA and EPA). Seafood deficiency is currently the most important human health threat concerning seafood consumption. Fish consumption guidance must be based on analysis of health benefits and risks. The current status of scientific knowledge indicates that the accuracy of seafood benefit and risk assessments can be greatly improved by incorporating all of the required variables. The biochemical and epidemiological data have become sufficiently robust to support the inclusion of the cardiovascular, neurodevelopmental and psychiatric effects of omega-3 fatty acids, selenium, methylmercury, and other seafood-related factors associated with benefits and risks into far better informed health assessments than were previously possible. In addition to improved accuracy, assessments that incorporate these variables will enable future studies to identify and evaluate risks and benefits that might otherwise be overlooked.

Symposium Statement (plain language version)

Seafood, including fish and shellfish is an important part of a healthy diet. Seafood in the diet provides a package of nutrients essential for early childhood development and brain and heart health benefits throughout life. The scientific evidence is clear that these health benefits far outweigh the risks. The greatest risk related to seafood consumption is not eating enough. Omega-3's (DHA and EPA) and other nutrients found in seafood are health-promoting. Ocean fish contain rich amounts of selenium that is vitally important for protecting the brain against oxidative damage. Harmful effects of methylmercury can only occur when foods such as pilot whale meats are consumed that contain more methylmercury than selenium. For this reason, any analysis of potential risks associated with methylmercury exposures from eating seafood must include evaluation of selenium. In addition to risks, the beneficial effects of improved dietary intakes of selenium, iodine, vitamin D, and omega-3 fatty acids from increased seafood consumption must also be considered. There is an urgent need to improve the public health guidance and message regarding seafood consumption by adequately weighing the scientific evidence of health benefits against risks. Future guidance must communicate this message clearly and effectively to avoid the unintended consequences of reduced seafood consumption because seafood-deficient diets diminish heart and brain health.

Symposium Findings

- Life evolved in the ocean. Nutrients from seafood have been pivotal in the evolution of the nervous system of all higher life forms and especially in the higher functioning human brain.
- It is clear that seafood consumption improves health. Seafood provides a nutrient-rich package containing essential long-chain omega-3 fatty acids (DHA and EPA), vitamins, protein, and minerals including iodine, iron and selenium.
- Peer-reviewed science has repeatedly demonstrated that the health benefits of eating seafood far outweigh the risks.
- For the expectant and nursing mother, seafood in the diet is the richest source of many nutrients that optimize the development of her baby's brain and nervous system.
- For infants and young children, nutrients contained in seafood are important for their optimal development and social behavior.
- For adults, nutrients in seafood have been shown to prevent or reduce coronary heart disease, stroke, psychiatric disorders, iodine deficiency, adverse effects of heavy metal exposure and possibly some cancers.
- Methylmercury irreversibly inhibits selenium-dependent enzymes that the brain needs to protect itself against oxidative damage.
- Methylmercury exposures in excess of dietary selenium intake are the only way known to impair these vital enzymes, but supplemental selenium is known to prevent this from happening.
- Ocean fish generally contain far more selenium than methylmercury and therefore protect against mercury toxicity rather than contribute to causing it.
- The rich amounts of selenium in ocean fish may explain why there has never been a case of methylmercury poisoning from eating ocean fish that contain naturally occurring background levels of methylmercury.
- The scientific evidence is compelling that seafood-deficient diets are a real and present danger in contrast to consuming too much fish.
- Seafood consumption rates by Americans are among the lowest of all developed nations.
- The omega-3 fatty acid content of American breast milk is among the lowest in the world.
- Scientific evidence does not support the 2004 EPA-FDA fish consumption guidance for pregnant women and young children, which limits fish consumption to 2 meals per week (12 oz).
- The ALSPAC study found that limiting fish consumption to 2 meals a week (12 oz) or less during pregnancy was associated with harm to infants in verbal IQ and other developmental testing.

- The 2004 EPA-FDA fish consumption guidance contains a built-in 10-fold safety (uncertainty) factor that was designed to protect against the adverse effects of methylmercury exposure from mothers that were eating pilot whale meat, not ocean fish.
- The Faroe Islands study found that eating pilot whale meat during pregnancy caused subtle adverse developmental effects in children (loss of ~0.1 IQ point).
- The Seychelles Islands study found that heavy maternal consumption of ocean fish (12 meals per week during pregnancy) was associated with beneficial developmental effects in children.

There is an urgent need to revise the 2004 Joint EPA-FDA fish consumption guidance because:

- The 2004 guidance is outdated, but continues to serve as the basis of health advice for pregnant women currently being given by physicians, dieticians and others.
- The 2004 guidance considered the risk, but not the health benefits of eating seafood.
- The 2004 guidance is no longer based on the best available science. Since 2004 a substantial amount of scientific evidence has emerged documenting the benefits of seafood consumption and the critical role of selenium in determining methylmercury health effects.
- The 2004 guidance requires modification to avoid causing far worse harms than those it was intended to prevent.

Meeting the current and future needs of humankind for the essential nutrients found in seafoods requires multiple coordinated efforts and new thinking because:

- 70% of the planet's surface is ocean. There needs to be an intense investment in the study of the ocean's resources and how to develop this resource rationally to meet the growing nutritional demand of the rising world population.
- There will be a fundamental shift in the seafood supply, from dependence on wild capture fisheries to increasing reliance on aquaculture (fish, shellfish and algae) production.
- There is an immediate need for sustainable management of capture fisheries. These fisheries must be preserved at sustainable levels of harvest.
- Overfishing must be eliminated and overfished (commercially depleted) stocks must be rebuilt. There can be no increase in wild fishery harvests above sustainable limits.
- Environmentally-responsible ocean and land-based aquaculture development has an important role to play in meeting the growing demand for the essential nutrients found in wild seafood.
- The challenge is to develop new sources and formulations of aquaculture feeds that contain the important seafood-derived nutrients, while reducing dependence on feed components produced in wild capture fisheries to sustainable levels.

Symposium Recommendations

- To avoid causing harm, health educators and healthcare providers who play the frontline role communicating seafood consumption risk are in urgent need of clear guidance for seafood consumption that considers both health benefits and risks.
- To hasten this process, the USDA and the FAO/WHO must be encouraged to finalize their draft risk-benefit analyses of seafood in the diet. These analyses are crucial to improving the current seafood consumption guidance that may be causing harm to consumers and their children.
- To develop and disseminate improved guidance, scientists with expertise in the various disciplines involved in seafood benefit and risk analysis must work with public health officials to incorporate the proper variables required for a balanced analysis of benefits and risks.
- States should re-evaluate their processes for developing and issuing fish consumption advisories and consider developing better informed guidelines in multi-state collaborations.
- To protect and improve the health of children, the public and especially expectant mothers, should be encouraged to eat more seafood.

Key Messages from the 2010 Hawaii Seafood Symposium

While many important statements, findings and recommendations emerged from the 2010 Hawaii Seafood Symposium, it is helpful to offer a simple, consistent message on the benefits of fish consumption during pregnancy to offset the fears and confusion currently surrounding the topic.

Eat more seafood, the health benefits far outweigh the risks.

Seafood (ocean fish and shellfish) provides nutrients that are essential for prenatal and early childhood development. Unwarranted fears based on unsupported science about the dangers of eating fish during pregnancy have led women to limit their consumption and thereby deprive their babies of the opportunity for optimal brain and nervous system development.

Nutrients in seafood protect against methylmercury.

Advisories about the dangers of naturally occurring methylmercury in fish have not taken into account the role that nutrients (selenium and omega-3's) play in protecting against any danger from methylmercury. There has never been a case of methylmercury poisoning from eating ocean fish with background levels of exposure.

Current public health advisories are based on studies of pilot whale consumption, not fish.

The current public health guidelines which limit fish consumption for pregnant women and children were based on studies conducted on a North Atlantic population whose methylmercury exposure originated primarily from eating pilot whale meat. Studies involving ocean fish and shellfish (the types of seafood consumed in the US and most of the rest of the world) conducted over 25 years have found significant beneficial effects instead of negative effects.