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August 17, 2010

Dr. Margaret Hamburg
Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993-0002

cc: Michael Bolger, Ph.D., Division of Risk Assessment, FDA Center for Food Safety and Applied Nutrition

Re: Gulf Coast Seafood Safety

Dear Commissioner Hamburg:

Thank you for your efforts to ensure the safety of seafood harvested from the Gulf of Mexico following the BP oil disaster. We appreciate the Food and Drug Administration's (FDA's) commitment to working with other federal and state agencies to ensure a uniform procedure for evaluating potential health risks from contaminated seafood.

The FDA should be doing more to protect vulnerable populations, such as pregnant women, children, and subsistence fish consumers from contaminants in Gulf seafood. FDA should revise its seafood risk assessment to protect these groups, work with states and NOAA to make sure that reopening decisions are based on publicly available and robust data, and ensure the adequacy of warnings to vulnerable populations. To that end, we ask that FDA take the following steps:

1) Protect Vulnerable Populations in the Risk Assessment

The protocol for re-opening oil-exposed areas for commercial and recreational fishing relies on an FDA risk assessment for determining "contaminant levels in fish and shellfish tissue that pose

no significant risk.” The assumptions used in this risk assessment fail to adequately account for the increased vulnerability of the developing fetus, young children, and subsistence fishing communities. To protect these populations, the FDA should change the following aspects of the risk assessment:

- **Solely using an adult average body weight of 80 kg (176 lbs) does not adequately protect children, or most women**

The FDA risk assessment uses the assumption that the ‘average American’ bodyweight is 176 lbs. This may be appropriate for adult men, but it will not protect smaller segments of the population. The average body weight of a 4-6 year old child is 47.6 pounds and 50% of American women weigh less than or equal to 155 pounds.¹ Therefore, FDA risk assessment calculations should also be made using female bodyweight and child body weight to assure that each of these population segments is protected.

- **Failing to account for the increased vulnerability of the developing fetus and child puts these populations at risk**

Toxicologic and epidemiologic studies of polycyclic aromatic hydrocarbons (PAHs) have found evidence for the increased vulnerability of the developing fetus and children. In particular, the California Environmental Protection Agency (Cal/EPA) did a comprehensive assessment of early-life exposure and vulnerability to carcinogens.² One of the chemicals examined in its report was benzo(a)pyrene (B(a)P), the PAH of greatest concern in seafood. Cal/EPA found that there was strong evidence of early life vulnerability to cancer from B(a)P, and quantified that extra vulnerability at slightly less than 10-fold greater than adults. The Cal/EPA data are presented in Appendix 1 below.

The Cal/EPA analysis used animal studies and focused on cancer risk; other researchers looked at non-cancer endpoints in humans. For example, researchers at Columbia University have identified statistically significant associations between prenatal exposure to PAHs and low birthweight, decreased infant head circumference, and persistent deficits in child IQ at age 5 years.^{3 4 5} The same researchers compared levels of PAH-DNA adducts (a marker of

¹ McDowell MA, Fryer CD, Ogden CL, Flegal KM. 2008. Anthropometric Reference Data for Children and Adults: United States, 2003-2006. National Health Statistics Reports; no 10, Hyattsville, MD: National Center for Health Statistics.

² In Utero and Early Life Susceptibility to Carcinogens: The Derivation of Age-at-Exposure Sensitivity Measures. California Environmental Protection Agency Office of Environmental Health Hazard Assessment. May 2009, p. 45. [Hhttp://www.oehha.org/air/hot_spots/2009/AppendixJEarly.pdf](http://www.oehha.org/air/hot_spots/2009/AppendixJEarly.pdf).

³ Choi H, et al. International Studies of Prenatal Exposure to Polycyclic Aromatic Hydrocarbons and Fetal Growth. Environ Health Perspect 1744-1750 (2006).

⁴ Perera F, et al. Effects of transplacental exposure to environmental pollutants on birth outcomes in a multiethnic population. Environ Health Perspect 111:201-205 (2003).

⁵ Perera F, et al. Prenatal Airborne Polycyclic Aromatic Hydrocarbon Exposure and Child IQ at Age 5 Years. Pediatrics 124(2):e195-202 (2009).

the potential for genetic damage) in maternal blood and in fetal cord blood; they found that the levels of PAH-DNA adducts were significantly higher in cord blood than in matched maternal blood in two separate study populations, indicating that the fetus is likely to be significantly more susceptible to genetic damage from PAHs compared to the mother.⁶ Therefore, risk assessments must include an adequate adjustment factor to account for the increased vulnerability of early life stages.

- **Using national seafood consumption rates rather than a survey of local conditions likely significantly underestimates risk to Gulf coast residents**

Studies conducted in the wake of other oil spill disasters, such as the *Exxon Valdez*, demonstrated that the use of national consumption rates dramatically underestimated exposure to contaminants in seafood for local populations. National surveys fail to adequately capture local seafood consumption patterns and quantities. A comparison of the finfish consumption rates used in the risk assessment for the *Exxon Valdez* spill and those used for BP disaster reveal that the local rates in the Alaska population were approximately three times those calculated by the FDA for Gulf coast residents using national rates. In addition to subsistence fishing communities that rely solely on Gulf seafood, the cuisine of the Gulf Coast is disproportionately reliant on seafood as compared to national diets. To adequately protect local communities, local consumption rates need to be estimated or adjusted for.

- **Assume at least a ten-year retention period of contaminants in seafood**

Although there are many uncertainties about how long seafood will be contaminated in the Gulf, the quantity of oil released suggests that contamination may persist for some time, and that should warrant precautionary estimates. The risk assessment did not provide a scientific rationale for the choice of a five-year exposure duration. Studies completed after the Exxon Valdez oil spill showed elevated levels of PAHs persisting in oysters for at least 6-7 years after the spill, and a 10-year retention period was used in the fish consumption risk assessment following that much smaller spill.^{7 8} To protect public health, a precautionary exposure duration should be calculated based on the scientific literature for the most highly affected species. At a minimum, the scientific evidence from prior oil spills would support the choice of a 10-year retention period for contaminants.

⁶ Perera F., et al. Biomarkers in Maternal and Newborn Blood Indicate Heightened Fetal Susceptibility to Procarcinogenic DNA Damage. *Environ Health Perspect* 112:1133–1136 (2004).

⁷ Berthou F., Baloet G., Bodennec G., Marchand M. 1987. The Occurrence of Hydrocarbons and Histopathological Abnormalities in Oysters for Seven Years Following the Wreck of the Amoco Cadiz in Brittany (France). *Marine Environmental Research*. 103-133.

⁸ Field, LJ et al. Evaluating and Communicating Subsistence Seafood Safety in a Cross-Cultural Context: Lessons Learned from the Exxon Valdez Oil Spill. Technical Publication of SETAC. 1999.

2) **Include All Oil-Related Contaminants of Concern**

The protocol for re-opening oil-impacted areas relies on chemical analyses of only PAHs despite evidence that other contaminants are in crude oil and in chemical dispersants.

- **Test for metals known to be present in the crude oil**

Cadmium, copper, lead and mercury have all been detected in studies of crude oil.⁹ Given the public health impact of exposures to low levels of these metals and their potential to bio-accumulate in seafood, chemical analyses of seafood should include metals. This monitoring should be initiated as soon as possible to track the risks going forward and enable year-by-year comparisons of contaminant levels.

- **Assess the potential for contamination of seafood by dispersant chemicals**

The BP oil disaster clean-up has involved an unprecedented volume of use of dispersant chemicals. A comprehensive assessment of the potential for dispersant chemicals to contaminate seafood and the degree to which dispersants may enhance the uptake of oil contaminants, such as PAHs is needed.

3) **Ensure that Re-opening of Oil Impacted Areas is Based on Comprehensive Monitoring**

To ensure the long-term safety of, and confidence in, Gulf seafood, there needs to be a robust and comprehensive monitoring program. FDA's decisions on seafood safety rely on monitoring being done to determine where the oil has been. Therefore, the sampling protocols and data being used to evaluate the safety of Gulf seafood ought to be made public. Based on the information now available, we are concerned that the current monitoring program may not be fully capturing oil-exposed areas. These concerns are summarized below and outlined in greater detail in the attached letter to NOAA. The FDA should request the following improvements to the monitoring plan:

- Evaluate the presence of subsurface oil in addition to surface sheens
- Conduct representative sampling that ensures adequate coverage of highly affected areas
- Ensure public disclosure of monitoring data and sampling protocols

4) **Ensure the Adequacy of State Seafood Safety Assessments and Warnings**

Given the large area that was affected by oil and the variety of state and federal jurisdictions governing the re-opening of oil-impacted areas, the FDA should be playing a strong role in

⁹ Osuji LC, Onojake CM. Trace heavy metals associated with crude oil: A case study of Ebocha-8 oil-spill-polluted site in Niger Delta, Nigeria. Chem Biodivers. 2004;1(11): 1708-1715..

ensuring the protection of public health across the Gulf Coast. This entails careful scrutiny of state and local decisions. Inconsistencies among states could quickly erode public confidence in the seafood testing program and put vulnerable populations at risk.

Thank you for your commitment to scientific evaluations of the environmental conditions in the Gulf Coast. We look forward to continuing to work with you to ensure the protection of all communities.

Sincerely,

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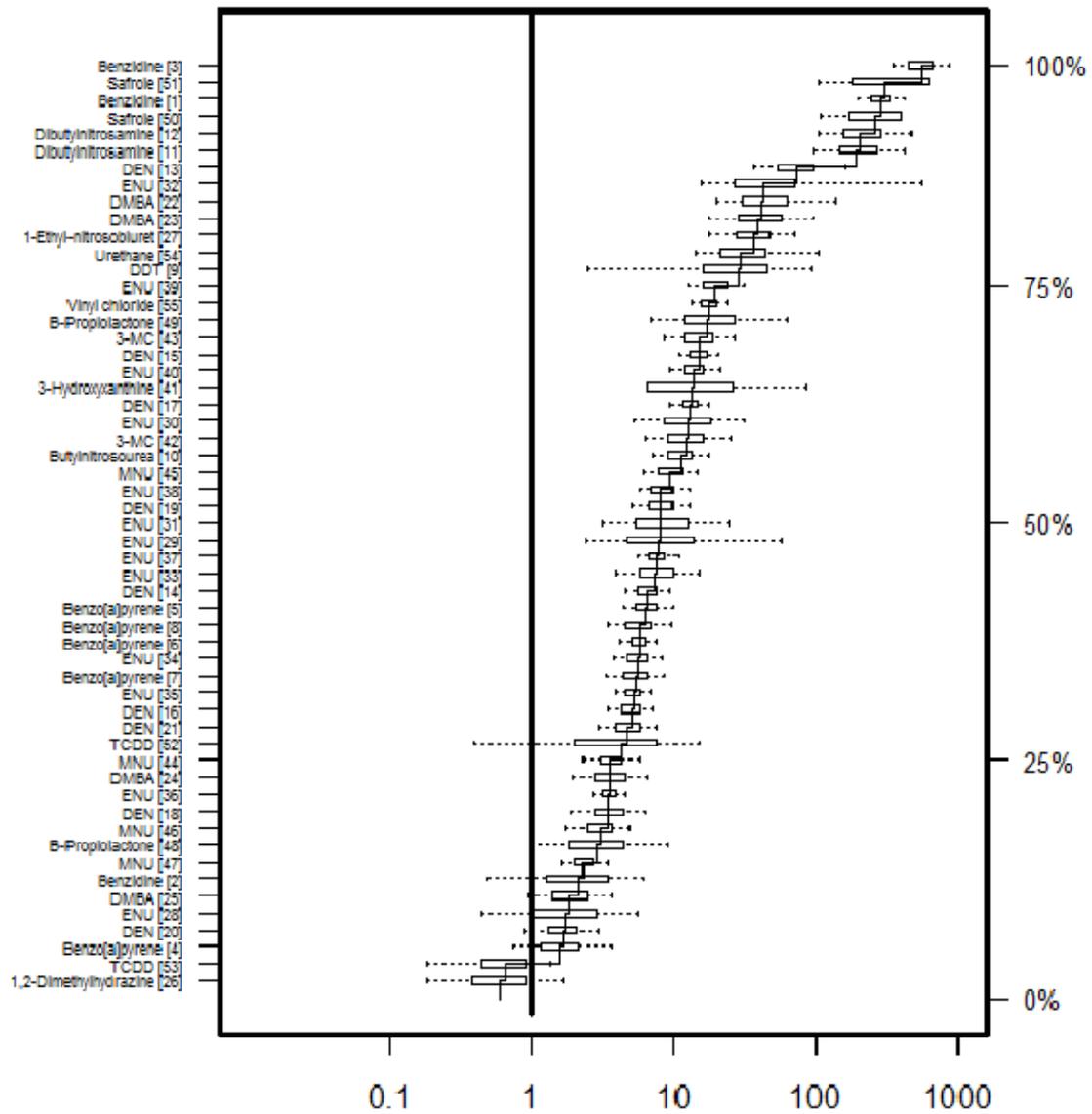
Zion Travelers Cooperative Center, Inc. (ZTTC)

Rev. Tyronne Edwards, Founder/Executive Director

Plaquemines Parish, LA

Appendix 1

Postnatal Age Sensitivity Factors



Source: In Utero and Early Life Susceptibility to Carcinogens: The Derivation of Age-at-Exposure Sensitivity Measures. California Environmental Protection Agency Office of Environmental Health Hazard Assessment. May 2009, p. 45.

http://www.oehha.org/air/hot_spots/2009/AppendixJEarly.pdf