ehp ENVIRONMENTAL HEALTH PERSPECTIVES
ehponline.org

Seafood Contamination after the BP Gulf Oil Spill and Risks to Vulnerable Populations: A Critique of the FDA Risk Assessment

Miriam Rotkin-Ellman, Karen K. Wong, Gina M. Solomon

http://dx.doi.org/10.1289/ehp.1103695

Online 12 October 2011

NIEHS
National Institute of Environmental Health Sciences

National Institutes of Health
U.S. Department of Health and Human Services

Seafood Contamination after the BP Gulf Oil Spill and Risks to Vulnerable Populations: A Critique of the FDA Risk Assessment

Miriam Rotkin-Ellman[1], Karen K. Wong[2], Gina M. Solomon[1,2]

[1]Natural Resources Defense Council, San Francisco California, USA

[2]Department of Medicine, University of California San Francisco, San Francisco, California, USA

Corresponding Author:

Miriam Rotkin-Ellman MPH

111 Sutter Street, 20th Floor,

San Francisco, CA 94104

Phone: 415-875-6100

Fax: 415-875-6161

mrotkinellman@nrdc.org

Key words: BP oil spill, children's health, Deepwater Horizon, Food and Drug Administration, Gulf of Mexico, polycyclic aromatic hydrocarbons, risk assessment, seafood

Competing financial interests: none

Running Title: Reassessment of PAHs in Gulf Seafood

Abbreviations used in manuscript:

- ADAF, age-dependent adjustment factor
- BaP, benzo(a)pyrene
- FDA, Food and Drug Administration
- GC/MS, Gas chromatography mass-spectrophotometry
- HPLC, High performance liquid chromatography
- LOC, level of concern
- NAS, National Academy of Sciences
- NOAA, National Oceanic and Atmospheric Administration
- OEHHA, Office of Environmental Health Hazard Assessment
- PAH, polycyclic aromatic hydrocarbon
- US EPA, United States Environmental Protection Agency

Acknowledgements

MRE and GMS are employed by NRDC, a nonprofit environmental advocacy group. The authors declare they have no actual or potential competing financial interests.

Abstract

Background: The BP oil spill of 2010 resulted in contamination of one of the most productive fisheries in the United States with polycyclic aromatic hydrocarbons (PAHs). PAHs, which can accumulate in seafood, are known carcinogens and developmental toxicants. In response to the oil spill, the U.S. Food and Drug Administration (FDA) developed risk criteria and established thresholds for allowable levels (Levels of Concern) of PAH contaminants in Gulf Coast seafood.

Objectives: We evaluate the degree to which FDA's risk criteria adequately protect vulnerable Gulf Coast populations from cancer risk associated with PAHs in seafood.

Discussion: FDA's Levels of Concern significantly underestimate risk from seafood contaminants among sensitive Gulf Coast populations by failing to: account for the increased vulnerability of the developing fetus and child; utilize appropriate seafood consumption rates; include all relevant health endpoints; and incorporate health protective estimates of exposure duration and acceptable risk. For benzo(a)pyrene and naphthalene, revised levels of concern are between 2-4 orders of magnitude below the level set by FDA. Comparison of measured levels of PAHs in Gulf seafood with the revised levels of concern, revealed that up to 53% of Gulf shrimp samples were above levels of concern for pregnant women who are high end seafood consumers.

Conclusions: FDA risk assessment methods should be updated to better reflect current risk assessment practices and to protect vulnerable populations such as pregnant women and children.

Introduction

The Gulf of Mexico is a very productive fishery, comprising the majority of domestic shrimp (60%) and oyster (70%) production (Louisiana Seafood Promotion & Marketing Board 2010). During the BP Deepwater Horizon oil spill, over 200 million gallons of oil poured into the Gulf, followed by 1.8 million gallons of dispersants intended to break down the oil into droplets (Repanich 2010).

The US Food and Drug Administration (FDA) is the agency responsible for determining seafood safety. In response to the oil spill, FDA, working with the states and the National Oceanic and Atmospheric Administration (NOAA), initially closed approximately 37% of the Gulf of Mexico (225,290 km^2) to commercial and recreational fishing (NOAA 2010). Re-opening of these areas was conducted on a rolling basis based on a two phase testing regime consisting of organoleptic testing, in which experts sniff pieces of seafood for oil taint and chemical analysis for polycyclic aromatic hydrocarbons (PAHs) (FDA 2010a). PAHs are the main constituent of crude oil that has the potential to accumulate in aquatic organisms and present a health risk via ingestion of contaminated seafood (Yender et al. 2002). Crustaceans and mollusks, such as shrimp, crab, and oysters, are especially likely to be contaminated due to reduced rates of biological clearance of PAHs in these species (Law et al. 2002). FDA tested for the presence of thirteen PAHs selected based on known carcinogenicity or other health effects, including stunted growth, anemia, and kidney disease. The FDA also calculated allowable thresholds – levels of concern (LOC) – for PAHs in each specific type of Gulf seafood.

The FDA allowed most Gulf fisheries to reopen during the summer and fall of 2010 based on measured PAHs in seafood below the LOCs although public confidence in Gulf seafood was slow to rebuild (Marcus 2011). The adequacy of the policy decision to resume commercial fishing hinged on the accuracy of FDAs assumptions in calculating the LOCs and on the rigor of the seafood monitoring program. By critically evaluating FDA's risk assessment and monitoring practices, we aim to both determine the adequacy of public health protection in this particular case, and to identify any broader improvements that may be needed to risk assessment practices and food safety determinations at the FDA.

Objectives

We evaluate the degree to which FDA's procedures for determining the safety of Gulf seafood following the BP oil spill reflect current risk assessment practices and protect vulnerable populations. We focus on cancer risk associated with shellfish consumption, calculate revised levels of concern designed to be protective of vulnerable populations, and compare them with FDA's levels of concern as well as with measured concentrations of PAHs in Gulf shellfish.

Discussion

The FDA Gulf seafood risk assessment contains numerous assumptions that are inconsistent with FDA's own prior practice and with risk assessment guidelines produced by other authoritative entities, including the National Academy of Sciences (NAS), the World Health Organization (WHO), the US EPA, and the California EPA. Each of these assumptions would tend to result in an underestimate of risk for a significant fraction of the exposed population. The questionable assumptions include six main issues that are explained in greater detail in the following sections:

(1) high consumer bodyweight; (2) low estimates of seafood consumption; (3) short exposure duration; (4) failure to adjust for early life susceptibility to PAHs; (5) failure to include a cancer risk assessment for naphthalene; and (6) high cancer risk benchmark. Taken together, these flaws illustrate a failure to incorporate the substantial body of evidence on the increased vulnerability of sub-populations to contaminants, such as PAHs, in seafood.

High Consumer Bodyweight

For derivation of all LOCs, the FDA assumed that the consumer weighs 80 kilograms (kg) (176 pounds). Although the FDA's bodyweight assumption is reasonable for some segments of the population, close to 75 percent of the female population in the U.S. weighs less than 80 kg and the average bodyweight of a 4-6 year old child is 21.6 kg (McDowell et al. 2008). FDA acknowledged in a follow-up risk assessment, conducted for an additional oil spill related contaminant that using a lower bodyweight (60 kg) offered greater health protections (Bolger 2010). US EPA publishes age-group specific bodyweights for use in risk assessments, based on the broad scientific understanding that children have increased susceptibility to ingested contaminants due to their high food intake as a proportion of their bodyweight (NAS 1993). Because acceptable intake of contaminants is calculated as a fraction of bodyweight, using an inflated assumption in a risk assessment is systematically under-protective of the entire population that weighs below the level used in the calculation.

Low Estimate of Seafood Consumption

The FDA assumed that the consumer eats a daily average of 49, 12, or 13 grams of fish, oysters, or shrimp/crab. FDA derived this consumption rate from the 90th percentile reported in the 2005-

2006 National Health and Nutrition Examination Survey (NHANES) for nationwide seafood consumption (FDA 2010a). Populations living along the Gulf Coast have been found to have a rate of seafood consumption that is higher than in the rest of the nation (Mahaffey et al. 2009). For example, surveys of New Orleans residents and recreational anglers in Louisiana found high-end consumers reporting shrimp intakes of 65.1 and 55.5 grams per day respectively – significantly higher than FDA's estimate of 13 grams/day (Anderson and Rice 1993; Lincoln et al. 2010). Federal and International Agencies, including the US Environmental Protection Agency and the World Health Organization, identify the need to protect high-end and subsistence fishing communities from contaminants in seafood by accounting for increased consumption rates. These agencies recommend using local studies and/or the 95th-97th percentile of national consumption surveys, in contrast to the 90th percentile used by FDA (US EPA 2000, WHO 2008). The US EPA recommends fish consumption rates to protect subsistence adult consumers ranging from 142.4 (general population) to 170 (Native Americans) grams/day which is 2.9 to 3.5 times higher than FDA estimate of 49 grams/day (US EPA 2000). Similarly, the 95th percentile fish consumption rate reported in the NAS report, *Seafood Choices: Balancing Benefits and Risks*, is equal to 155 grams/day – 3.2 times higher than the FDA assumption (NAS 2007). FDA also failed to account for the possibility that consumers may eat a combination of various types of seafood and calculated consumption rates and LOCs for shrimp, oysters, crab, and fish separately.

Failure to Consider the Cancer Risk from Naphthalene

Naphthalene was one of the most frequently detected PAHs in Gulf seafood tested after the spill, and was the most prevalent PAH in the oil itself (FDA 2010a and FDA unpublished data).

Despite the fact that naphthalene poses a health risk due to both carcinogenic and non-carcinogenic health effects, the FDA established the LOC in Gulf seafood solely based on non-cancer effects (FDA 2010a). Naphthalene is listed in the National Toxicology Program's 12^{th} Report on Carcinogens (which FDA has endorsed) as *reasonably anticipated to be a human carcinogen* based on dose-related rare nasal and respiratory neuroblastomas and adenomas in male and female rats, and lung tumors in female mice; inhalation has been associated with cancer of the larynx in humans, and ingestion was associated with human colorectal cancer in one study (NTP 2011). Naphthalene is also listed by the State of California as *known to cause cancer* with sufficient evidence to determine a cancer potency factor of 0.12 $(mg/kg\text{-}day)^{-1}$ which defines the relationship between exposures and cancer risk (OEHHA 2005).

The FDA did not assess whether exposures in Gulf seafood could pose an increased risk of cancer from naphthalene. Because PAHs are a mixture of multiple compounds, small exposures to multiple PAHs can add up to significant cancer risks. By omitting naphthalene from its cancer risk assessment, the FDA ignored the potential cumulative effect of exposures to multiple carcinogens.

Failure to Include Early Life Vulnerability

FDA conducted a single risk assessment for adults and did not evaluate potential increased risks to the developing fetus or child, yet exposure to PAHs during pregnancy causes genetic damage to the developing fetus. Most PAHs are lipid soluble and therefore cross the placenta (Calabrese 1978; Shendrikova and Aleksandrov 1974). PAHs have also been demonstrated in human breast milk (Kim et al. 2008; Del Bubba et al. 2005). Animal studies have found that ingestion of PAHs during pregnancy results in much greater genetic damage in the fetus compared to the mother (Harper et al. 1989). Human children exposed prenatally to PAHs have statistically significant increases in DNA aberrations in specific chromosomes, low birth weight, and intrauterine growth restriction (Choi et al. 2006; Dejmek et al. 2000; Perera et al. 2003; Orjuela et al. 2010; Perera et al. 2005).

The increased vulnerability of the developing fetus and child to genotoxins and carcinogens has been widely recognized. In March 2005, the US EPA released the *Supplemental Guidance for Assessing Susceptibility from Early-Life Exposure to Carcinogens*. These guidelines presented age-dependent adjustment factors (ADAFs) which adjust the slope factors to account for differences in carcinogen potency by age groups based on data from animal studies comparing cancer potency in early life stages compared to adult animals (US EPA 2005). The US EPA methods also use different rates of exposure according to age, accounting for the relative difference in intake between children and adults. EPA did not include ADAFs for prenatal exposures but did acknowledge that the available data supports increased prenatal susceptibility (US EPA 2005). In California, the Office of Environmental Health Hazard Assessment (OEHHA), under the California Environmental Protection Agency (California EPA), accounts for childhood exposures in its risk assessment methods, and provides an adjustment factor for prenatal exposures (OEHHA 2009). FDA did not incorporate any of this information into its calculation of the LOCs.

Short Exposure Duration and Less-Protective Cancer Risk Benchmarks

The FDA LOC incorporates a duration of exposure of only five years and an acceptable rate of cancer of 1 cancer in 100,000 people (10^{-5}). However, based on prior experience from oil spills, PAHs are detectable in shellfish for up to thirteen years after oil contamination, and there is evidence of ongoing DNA damage from PAHs in marine life after that time (Bejarano and Michel 2010; Thomas et al. 2007). Although there is considerable variation in the half-life of PAHs, depending on the structure of the compound and the environmental conditions, using an average value recommended by the California EPA for PAHs in soil (570 days), approximately 10% of the contamination would be expected to remain after 5 years and less than 2% would remain after 10 years (OEHHA 2000). FDA risk assessments conducted for prior oil spills, such as the Exxon Valdez, utilized more conservative and health protective values for these parameters: 10 year exposure duration and 1 in a million (10^{-6}) acceptable cancer risk level (Bolger and Carrington 1999).

Revised Risk Assessment and Levels of Concern

We used published sources to estimate exposure scenarios for three populations vulnerable to PAH contamination in Gulf Coast seafood; a woman (or small man), a child (2 -12 years old), and a pregnant woman (prenatal exposure - <10 years old). See Table 1 and Supplemental Material for a description and comparison of the exposure and risk profiles. Using the vulnerable population risk profiles, FDA's LOC equation (adult scenario), and US EPA/California EPA ADAFs and risk calculation methods (child and pregnant woman scenarios), we derived revised LOCs for benzo(a)pyrene (BaP), one of the most potent PAHs, and for cancer risk from naphthalene in individual types of seafood and for a combined cumulative shellfish rich diet.

Consistent with FDA methods, we used toxic equivalencies to translate the LOC for BaP to other (non-naphthalene) carcinogenic PAHs detected in seafood (Supplemental Material and Supplemental Material, Table 1).

Recalculated LOCs, including the factors omitted by the FDA, resulted in significantly lower numbers (Table 2). Most notably, the revised LOCs for naphthalene in shellfish using the pregnant woman scenario are four orders of magnitude smaller than FDA's values. At the LOCs set by FDA, we calculate cancer risks of 4,094 and 20,214 per million people for a combined high shellfish diet for the woman and pregnant woman scenario respectively (Table 3). Although this scenario represents the sum of individual shellfish consumption rates, it is consistent with estimates of high-end shellfish consumption (Supplemental Material, p.4). These risks greatly exceed FDA's risk threshold of 1 in 100,000 or 10 in a million and indicate that the FDA LOCs are too high to be protective of vulnerable sub-populations.

Health risks associated with Gulf Coast shellfish tested after the oil spill

Although the volume of testing was low, government monitoring of PAH levels in Gulf seafood enables a rough calculation of the cancer risk associated with measured levels of PAHs in Gulf shellfish for populations of concern. FDA based the re-opening of coastal (state) waters to commercial shellfish harvesting on a total of 80, 37, and 92 samples of shrimp, oyster, and crab respectively (FDA 2011). NOAA analyzed an additional 122 shrimp samples before re-opening offshore (federal) waters (NOAA 2011). Subsequently, both the FDA and NOAA have conducted follow-up testing of seafood collected in re-opened Gulf waters for shrimp (N=155), crab (N=34) and oysters (N=3).

NOAA initially used gas chromatography mass-spectrophotometry (GC/MS) with low detection limits, but omitted the alkyl naphthalenes; thereby underestimating total naphthalene concentrations. Subsequent NOAA testing and all FDA testing used a more rapid high-performance liquid chromatography with fluorescence detection (HPLC) method with a higher detection limit. We analyzed the data published on the FDA and NOAA websites as of June 10, 2011. In addition, NRDC conducted a shrimp sampling project in Barataria Bay, Louisiana and the Mississippi Sound near Pass Christian in December 2010 using the GC/MS analytical method, but including alkyl naphthalenes. Our project, although covering only two specific locations of concern, collected 4-9 samples per 100 square mile sampling grid, greatly exceeding the sampling density FDA reported for state waters.

We used the revised risk assessment methods to evaluate the levels of carcinogenic PAHs detected in shellfish following the oil spill. For the 7 PAHs with established toxicity equivalents, we calculated total BaP equivalents (BaPe) to enable comparison to the LOC and to calculate total cancer risk. Detection frequencies and concentrations of carcinogenic PAHs varied between the analytes, types of shellfish, testing methods, and agency data sets (Supplemental Material, Table 2). To calculate cancer risks at the levels detected in Gulf shellfish, we combined results generated using comparable analytical methods (FDA and NOAA data sets). To evaluate a worst-case scenario, and in light of high analytical limits of detection, we calculated cancer risks based on detected values and 10 year exposure duration. More information on our data analysis methods is available in the Supplemental Material.

Cancer risks for vulnerable Gulf populations at the mean of the detected values in shellfish were found to be 0.008 and 4.2 in a million due to total BaP equivalent concentrations and 0.5 and 3.9 in a million from naphthalene for the woman and pregnancy scenarios respectively. Combined cancer risk from all PAHs, including naphthalene, was highest for the pregnancy scenario at 8.1 (95% CI 4.3-12.9) in a million (Table 4). Comparing measured (using the HPLC method) PAH levels to the revised LOCs in shellfish using the pregnancy scenario, we found 0 to 27% exceeded the revised LOCs set just for individual (shrimp, crab, or oyster) consumption and 17 to 55% exceeded the LOC for combined shellfish consumption. In contrast, a much smaller number of samples (2-8%) of shrimp had PAH concentrations that exceeded the revised cumulative exposure LOCs for the adult woman scenario (Supplemental Material, Table 3). Levels of naphthalene and BaP equivalents measured in our pilot shrimp sampling project were lower than values reported using the HPLC method in the FDA and NOAA data sets and only 1 out of 13 samples exceeded any of the relevant LOCs (Supplemental Material, Table 3). Notably, the revised LOCs, using revised risk calculations and the pregnancy scenario, for BaP in shrimp and total shellfish are below the limit of detection for BaP using the HPLC method (0.39 ppb). The LOC for naphthalene in shrimp for the pregnant woman scenario is below the limit of quantification of the HPLC method (15.0 ppb) (FDA 2010b).

Taken together, these findings demonstrate that FDA's conclusion that there were no risks to Gulf populations from oil-spill related contaminants in seafood missed some exposures of concern, particularly for high-end seafood consuming pregnant women. Additionally, the use of the HPLC – fluorescence analytical method, while improving the speed of analysis, may have missed low levels of PAH contamination of public health relevance for vulnerable populations.

Conclusions

Environmental risk assessment requires the use of scientifically-founded assumptions and appropriate default estimates about the exposed population, the intensity and duration of exposure, and the dose-response relationship. The risk assessment methods FDA used to set safe exposure levels for Gulf Coast seafood following the oil spill do not incorporate current best practices and do not protect vulnerable populations. FDA conclusions about risks from Gulf seafood should be interpreted with caution in coastal populations with higher rates of seafood consumption and in vulnerable populations such as children, small adults, and pregnant women. Our analysis demonstrates that a revised approach, using standard risk assessment methods, results in significantly lower acceptable levels of PAHs in seafood and identifies populations that could be at risk from contaminants in Gulf Coast seafood. Health advisories targeted at high end consumers would better protect vulnerable populations like pregnant women, women who may become pregnant, and children. Our approach did not address infant exposure to PAHs via maternal seafood consumption/lactational transfer. The NAS found that there is up to 50-fold inter-individual variability in cancer risk, and recommends incorporation of estimates of uncertainty, and population risk distributions, into future risk assessments (NAS 2008). Improved public health protection from contaminants in food will require reforming FDA risk assessment practices.

References

Anderson AC, Rice JC. 1993. Survey of fish and shellfish consumption by residents of the greater New Orleans area. Bull Environ Contam Toxicol 51(4):508-514.

Bejarano AC, Michel J. 2010. Large-scale risk assessment of polycyclic aromatic hydrocarbons in shoreline sediments from Saudi Arabia: Environmental legacy after twelve years of the gulf war oil spill. Environ Pollut 158(5):1561-1569; doi: 10.1016/j.envpol.2009.12.019.

Bolger M and Carrington CD. 1999. Hazard and risk assessment of crude oil in subsistence seafood samples from Prince William Sound: Lessons learned from the Exxon Valdez. In: Evaluating and Communicating Subsistence Safety in a Cross Cultural Context: Lessons Learned from Exxon Valdez Oil Spill. (Field LJ et al. eds). SETAC 195-204.

Bolger M. 2010. Levels of Concern (LOC)s for Select Gulf Seafood. Memo to Don Kraemer Acting Deputy Director Center for Food Safety and Applied Nutrition. http://www.fda.gov/downloads/Food/FoodSafety/Product-SpecificInformation/Seafood/UCM231697.pdf. [Accessed 20 June 2011]

Calabrese E. 1978. Pollutants and High Risk Groups: The Biological Basis of Increased Human Susceptibility to Environmental and Occupational Pollutants. New York, NY: John Wiley and Sons.

Choi H, Jedrychowski W, Spengler J, Camann DE, Whyatt RM, Rauh V et al.. 2006. International studies of prenatal exposure to polycyclic aromatic hydrocarbons and fetal growth. Environ Health Perspect 114(11):1744-1750.

Dejmek J, Solansky I, Benes I, Lenicek J, Sram RJ. 2000. The impact of polycyclic aromatic hydrocarbons and fine particles on pregnancy outcome. Environ Health Perspect 108(12):1159-1164.

Del Bubba M, Zanieri L, Galvan P, Donzelli GP, Checchini L, Lepri L. Determination of polycyclic aromatic hydrocarbons (PAHs) and total fats in human milk. Ann Chim. 2005. 95(9-10):629-641.

FDA (Food and Drug Administration). 2010a. Protocol for Interpretation and Use of Sensory Testing and Analytical Chemistry Results for Re-Opening Oil-Impacted Areas Closed to Seafood Harvesting Due to the Deepwater Horizon Oil Spill.

FDA (Food and Drug Administration). 2010b. Laboratory Information Bulletin: Screen for the Presence of Polycyclic Aromatic Hydrocarbons using LC-Fluoresence.

FDA (Food and Drug Administration). 2011. Gulf of Mexico Oil Spill: Reopening of Closed Waters Information by State. http://www.fda.gov/Food/FoodSafety/Product-SpecificInformation/Seafood/ucm221959.htm. [Accessed 10 June 2011]

Harper BL, Ramanujam VM, Legator MS. 1989. Micronucleus formation by benzene, cyclophosphamide, benzo(a)pyrene, and benzidine in male, female, pregnant female, and fetal mice. Teratog Carcinog Mutagen 9(4):239-252.

Kim SR, Halden RU, Buckley TJ. Polycyclic aromatic hydrocarbons in human milk of nonsmoking U.S. women. Environ Sci Technol. 2008. 42(7):2663-2667.

Law RJ, Kelly C, Baker K, Jones, J, McIntosh, AD, Moffat, CF. 2002. Toxic equivalency factors for PAH and their applicability in shellfish pollution monitoring studies. J. Environ. Monit. 4: 383-388.

Lincoln RA, Shine JP, Chesney EJ, Vorhees DJ, Grandjean P, Senn DB. 2011. Fish consumption and mercury exposure among Louisiana recreational anglers. Environ Health Perspect. 119:245-251.

Louisiana Seafood Promotion & Marketing Board. 2010. Seafood Jobs. Available: http://louisianaseafood.com/seafood_jobs [accessed 25 November 2010].

Mahaffey KR, Clickner, RP, Jeffries, RA. 2009. Adult Women's Blood Mercury Concentrations Vary Regionally in the United States: Associations with Patterns of Fish Consumption (NHANES 1999-2004). Environ Health Perspect. 117:47-53.

Marcus MB. 2011. Gulf Seafood Safety Concerns Consumers. USA Today. 23 May: Fitness and Food.

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.

NAS (National Academy of Sciences) – Committee on Improving Risk Analysis Approaches Used by the U.S. EPA, National Research Council. 2008. Science and Decisions: Advancing Risk Assessment. The National Academies Press. Washington DC.

NAS (National Academy of Sciences) – Committee on Nutrient Relationships in Seafood: Selections to Balance Benefits and Risks. C, Malden C. Nesheim and Ann L. Yaktine, Editors. 2007. Seafood Choices: Balancing Benefits and Risks. The National Academies Press. Washington DC.

NAS (National Academy of Sciences) – Committee on Pesticides in the Diets of Infants and Children, National Research Council. 1993. Pesticides in the Diet of Infants and Children. The National Academies Press. Washington DC.

NOAA (National Oceanic and Atmospheric Administration). 2010. Closure Size and Percent Coverage. Available: http://sero.nmfs.noaa.gov/ClosureSizeandPercentCoverage.htm [accessed 20 June 2011].

NOAA (National Oceanic and Atmospheric Administration). 2011. Deepwater Horizon/BP Oil Spill: Federal Fisheries Closure and Other Information http://sero.nmfs.noaa.gov/deepwater_horizon_oil_spill.htm [Accessed 20 June 2011].

NTP (National Toxicology Program). 2005. 12th Report on Carcinogens.

OEHHA (Office of Environmental Health Hazard Assessment). 2000. Technical Support Document for Exposure Assessment and Stochastic Analysis - Appendix G: Chemical Specific Soil Half-Lives. California: California Environmental Protection Agency.

OEHHA (Office of Environmental Health Hazard Assessment). 2005. No significant risk level (NSRL) for the Proposition 65 carcinogen naphthalene. Naphthalene NSRL. California: California Environmental Protection Agency.

OEHHA (Office of Environmental Health Hazard Assessment). 2009. In utero and early life susceptibility to carcinogens: The derivation of age-at-exposure sensitivity measures. California: California Environmental Protection Agency.

Orjuela MA, Liu X, Warburton D, Siebert AL., Cujar C, Tang D et al. 2010. Prenatal PAH exposure is associated with chromosome-specific aberrations in cord blood. Mutat Res 703(2):108-114; doi: 10.1016/j.mrgentox.2010.08.004.

Perera FP, Rauh V, Tsai WY, Kinney P, Camann D, Barr D et al. 2003. Effects of transplacental exposure to environmental pollutants on birth outcomes in a multiethnic population. Environ Health Perspect 111(2):201-205.

Perera F, D Tang, Whyatt R, Lederman SA, Jedrychowski W. 2005. DNA Damage from Polycyclic Aromatic Hydrocarbons Measured by Benzo[a]pyrene-DNA Adducts in Mothers and Newborns from Northern Manhattan, The World Trade Center Area, Poland, and China. Cancer Epidemiol Biomarkers & Prev. 14:709-714.

Repanich J. 2010. The Deepwater Horizon Spill by the Numbers. Popular Mechanics. Available: http://www.popularmechanics.com/science/energy/coal-oil-gas/bp-oil-spill-statistics [Accessed 30 November 2010].

Shendrikova IA, Aleksandrov VA. 1974. Comparative penetration of polycyclic hydrocarbons through the rat placenta into the fetus. Bull Exp Biol Med 77(2):169-171.

Thomas RE, Lindeberg M, Harris PM, Rice SD. 2007. Induction of DNA strand breaks in the mussel (mytilus trossulus) and clam (protothaca staminea) following chronic field exposure to polycyclic aromatic hydrocarbons from the Exxon Valdez spill. Mar Pollut Bull 54(6):726-732; doi: 10.1016/j.marpolbul.2007.01.009.

US EPA (U.S. Environmental Protection Agency). 2000. Guidance for Assessing Chemical Contaminant Data for Use in Fish Advisories. Volume 2: Risk Assessment and Fish Consumption Limits -Third Edition. EPA 823-B-00-008.

US EPA (U.S. Environmental Protection Agency). 2005. Supplemental guidance for assessing susceptibility from early-life exposure to carcinogens. EPA/630/R-03/003F.

US EPA (U.S. Environmental Protection Agency). 2008. Child Specific Exposure Factors (CSEF) Handbook.

US EPA (U.S. Environmental Protection Agency). 2009. Exposure Factors Handbook: External Review Draft.

WHO (World Health Organization). 2008. Highest Reported 97.5th Percentile Consumption Figures (Eaters Only) for Various Commodities by the General Population and Children Ages 6 and Under. GEMS/Food for the Codex Committee on Pesticide Residues and the Joint FAO/WHO Meetings on Pesticide Residues.

Yender, R. Michel, J., Lord C. 2002. Managing Seafood Safety After an Oil Spill. Seattle: Hazardous Materials Response Division, Office of Response and Restoration, National Oceanic and Atmospheric Administration (NOAA).

Table 1: Parameters to estimate cancer risk due to PAHs in Gulf Seafood: FDA versus vulnerable populations method

Parameter	FDA	Vulnerable Populations				
Risk Scenario	Adult	Woman	Pregnant Woman[a]			Child[b]
Acceptable Risk Level	1 in 100,000	1 in 1,000,000[c]				
Exposure Duration (years)	5	10[c]				
Early Life Age Groups			prenatal	0-<2	2-5	6-<12
Body Weight (kg)	80	60[d]	60[e]	9.6[f]	17.4[f]	31.8[f]
Consumption Rates (g/day)						
Fish	49	155[g]	15.5[h]	16.9[i]	84.4[g]	86.4[g]
Shrimp	13	44[g]	4.4[h]	10.1[j]	24.0[g]	24.6[g]
Crab	13	21[g]	2.1[h]	4.7.[j]	11.2[g]	11.5[g]
Oyster	12	18[k]	1.8[h]	2.4[l]	5.8[l]	10.7[l]
Age Dependent Adjustment Factor (ADAF)						
Child scenario [m]					3	3
Pregnant woman scenario[n]			3	13	5	3

[a]Pregnant Woman Scenario = 3[rd] trimester-9.75 years.
[b]Child Scenario = 2-<12 years old.
[c]Value used in Exxon Valdez risk assessment (Bolger and Carrington 1999)
[d]Value used in FDA risk assessment for dispersant chemicals in Gulf seafood (Bolger 2010)
[e]Prenatal dose calculated based on woman's body weight as per OEHHA (2009)
[f]USEPA (2008) Child Specific Exposure Factors (CSEF) Handbook
[g]NAS (2007) *Seafood Choices: Balancing Benefits and Risks* -95[th] percentile
[h]Fetal PAH exposure assumed to be 10% of maternal based on animal dose studies (Perera et al. 2005)
[i]USEPA (2008) CSEF Handbook – high end fish consumers
[j]Estimated using the EPA CSEF early life total fish consumption distribution and 2-5 year old consumption rates
[k]Louisiana anglers study (Lincoln et al. 2011)
[l]US EPA (2009) Exposure Factors Handbook: External Review Draft – Consumption Rates for Native American Children
[m]US EPA (2005) ADAFs
[n]OEHHA (2009) median Age Sensitivity Factor (ASF)

Table 2: Comparison of FDA's published Levels of Concern (LOCs) for PAHs in Gulf Seafood and revised LOCs calculated for vulnerable populations

PAH/ Seafood Type	FDA LOCs (ppb)	Vulnerable Populations Revised LOCs (ppb)		
		Woman[a]	Child[b]	Pregnant Woman[c] (prenatal exposure)
Benzo(a)pyrene				
Fish	35	0.41	0.10	0.06
Shrimp	132	1.46	0.35	0.17
Crab	132	3.05	0.75	0.36
Oyster	143	3.56	1.06	0.63
Total Shellfish[d]		0.77	0.20	0.10
Naphthalene				
Fish	32,700	25.16	6.07	3.76
Shrimp	123,000	88.64	21.33	10.24
Crab	123,000	185.71	45.67	21.96
Oyster	133,000	216.67	64.48	38.31
Total Shellfish[d]		46.99	11.86	5.91

[a]Adult(FDA equation):LOC=(Risk Level*Body Weight*Averaging Time*Unit Conversion Factor)/(Cancer Slope Factor*Consumption Rate*Exposure Duration)

[b]Child scenario(OEHHA equation):LOC=Risk Level/Cancer Slope Factor*$\{(ADAF_{2-5}*duration_{2-5}*consumption_{2-5})+(ADAF_{6-12}*duration_{6-12}*consumption_{6-12})\}$

[c]Pregnant woman scenario(OEHHA equation):LOC=Risk Level/Cancer Slope Factor*$\{(ASF_{prenatal}*duration_{prenatal}*consumption_{prenatal})+(ASF_{0-2}*duration_{0-2}*consumption_{0-2})+(ASF_{2-5}*duration_{2-5}*consumption_{2-5})+(ASF_{6-<10}*duration_{6-<10}*consumption_{6-<10})\}$

[d]These values reflect LOCs calculated (see Supplemental Materials) assuming combined high-end consumption of shrimp, crab, and oysters.

Table 3: Cancer risks (excess risk per million people) calculated for vulnerable Gulf Coast populations at the LOCs set by FDA for the Gulf Coast following the BP oil spill.

Scenario	Contaminant	Fish	Shrimp	Crab	Oyster	Total Shellfish
	BaPe	85	968	462	40	1470
Woman	Naphthalene	1300	1388	622	614	2624
	Total	1385	2356	10.8	654	4094
	BaPe	351	376	176	13	565
Child	Naphthalene	5389	5767	2639	206	8612
	Total	5740	6143	2815	219	9177
	BaPe	567	784	366	87	1237
Pregnant	Naphthalene	8703	12015	5602	1360	18977
Woman	Total	9270	12799	5968	1447	20214

Table 4: Calculated cancer risks (excess risk per million people) based on mean (95% CI) detected PAH levels* in Gulf shellfish tested after the BP oil spill

Scenario	BaPe	Naphthalene	Total
Woman	0.008 (0.006-0.012)	0.5 (0.1-0.8)	0.508 (0.106-0.812)
Child	2.1 (1.5-3.0)	1.9 (0.5-3.3)	4.0 (2.0-6.3)
Pregnant Woman	4.2 (3.2 -6.2)	3.9 (1.1-6.7)	8.1 (4.3 - 12.9)

*Combined FDA & NOAA testing using the HPLC-fluorescence method