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Congress of the United States
House of Representatives
Washington, DC 20515–2107

April 20, 2012

The Honorable Margaret Hamburg
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Hamburg,

I write to request information relating to the long-term impacts on seafood resulting from exposure to oil and chemical dispersants following the BP Deepwater Horizon disaster. Two years after the explosion aboard the *Deepwater Horizon* drilling rig and the resulting largest oil spill in this country, there continue to be questions raised regarding the long term impacts on seafood caught in the Gulf of Mexico. Recent reports from the Gulf have indicated that market valued species of fish, such as grouper and red snapper and invertebrates, such as shrimp and crab, have increasing occurrences of lesions and deformities including missing eyes[1]. Given the time since the oil spill, these deformities are not thought to be a result of acute toxicity; instead they are believed to be consistent with genetic defects that are now impacting new generations of species born in the Gulf waters.

While the Food and Drug Administration (FDA) and the National Oceanic and Atmospheric Administration (NOAA) continue to assert seafood from the Gulf of Mexico is adequately tested and safe for human consumption, recent analyses have called into question the methods the federal government used to analyze safety. One of these studies claims that the assumptions and criteria that the FDA and NOAA used to determine safety and to open Gulf waters for commercial fishing significantly underestimated the risk to certain populations, including women and children.[2] Other reports contend that the government seafood testing program focused on ensuring the seafood was free of crude oil components and overlooked other harmful chemicals, such as those that were used in dispersants.[3] These studies and reports call into question the methodology FDA used in determining whether seafood from the Gulf was safe for fishing and for eating.

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[1] See for example: http://www.cbsnews.com/8301-205_162-57416414/sick-deformed-fish-spotted-after-bp-gulf-of-mexico-oil-spill/

[2] Rotkin-Ellman M, Wong KK, Solomon GM, 2011 Seafood Contamination after the BP Gulf Oil Spill and Risks to Vulnerable Populations: A Critique of the FDA Risk Assessment. Environ Health Perspect 120(2)

[3] http://www.msnbc.msn.com/id/40494122/ns/us_news-environment/t/panel-challenges-gulf-seafood-safety-all-clear/#.T5BegqEpPcc

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The Gulf of Mexico's economy depends on healthy coastal and ocean ecosystems supporting 13 of the top 20 leading ports in 2009 for seafood tonnage. In 2008 alone, the Gulf region's commercial fishing industry, including fishermen, seafood wholesalers, processors and retailers, generated more than $10.5 billion in sales and more than 200,000 jobs. Continued comprehensive monitoring of seafood is critical for public health, but also vital to maintaining vibrant coastal economies.

Since the *Deepwater Horizon* disaster, scientists across the federal government and in private enterprise have been working diligently to understand the environmental and human health implications of this catastrophe. To better understand the FDA's progress and plans in ensuring seafood safety and protecting public health, I ask for your response to the following questions:

1. Has the FDA conducted any long term impact studies on the seafood in the Gulf of Mexico and the consequent impact on public health? If so, what did the agency find? If not, does the agency have plans to develop a long-term comprehensive monitoring program?

2. Did the agency investigate the reports of increased lesions and deformities in Gulf Seafood? If so, what did the agency find? If not, why not?

3. Would the agency expect that increased lesions and deformities in seafood may impact the safety for human consumption?

4. Now that the immediate Deepwater Horizon disaster is over and all waters in the Gulf of Mexico are open for commercial fishing, what is the agency's role in proactively studying seafood safety in the Gulf of Mexico and determining whether caught seafood remains safe for human consumption?

5. When the agency conducted testing to determine whether Gulf waters were safe for commercial fishing and seafood safe for human consumption did the agency take into consideration (a) subpopulations of women and children, including their smaller body weights? (b) the high consumption rate of seafood from populations living in Gulf Coast states? (c) the cancer-risk associated with the frequently detected polycyclic hydrocarbon known as naphthalene? (d) impacts on pregnant women and developing infants? If so, please describe how each of these factors were incorporated into FDA's assessment and what FDA found specific to each of these items. If one or more of these categories were not taken into consideration, please explain why.

6. Please explain the guidelines the FDA used in developing the assumptions used to assess risk in Gulf of Mexico seafood. If these assumptions are inconsistent with the FDA's own prior practice or with risk assessment guidelines produced by other authoritative entities (i.e. National Research Council, World Health Organization, etc) please explain how they differed. If these assumptions have changed in FDA's current evaluations of seafood safety, please explain.

7. To date, FDA has not set a consistent legal limit for polycyclic aromatic hydrocarbons (PAH) in seafood. Instead, if there is an oil spill emergency FDA comes up with a site specific limit for these toxic compounds found in oil for seafood from that region. Since the health impacts of PAH's don't change from spill to spill, has FDA considered deriving a science derived tolerable nationwide limit on these toxic compounds that can be used for any future oil spills? If so, please explain where FDA is in this process and provide a detailed timeline for finalization of this PAH limit. If not, why not?

8. Given the impact of the recent reports and scientific studies regarding seafood and other wildlife in the Gulf region, what additional work do you think needs to be done to address the human health implications of the *Deepwater Horizon* oil spill?

9. What interaction does FDA have with other federal agencies to ensure the safety of seafood consumption from the Gulf of Mexico?

Thank you for your assistance and cooperation in this matter. I request that you provide a full and complete response within 15 working days or no later than May 11, 2012. Should you have any questions about this request, please have your staff contact Dr. Heidi Geisz or Dr. Avenel Joseph of my staff at (202) 225-2836.

Sincerely,

Edward J. Markey

Edward J. Markey