

\*\*FDA documents provided to NRDC in response to a Freedom of Information Act (FOIA) request\*\*

Part A: Correspondence

(Personal identifiers redacted by NRDC)

Prior to publishing allowable levels for PAHs in seafood in the wake of the BP Oil Spill, FDA's calculations and approach to estimating seafood consumption were critiqued by other agencies. FDA was advised that their numbers would be insufficient to protect Gulf Coast populations. See comment below in an email sent from EPA staff to FDA staff.

-----Original Message-----

From: [REDACTED]@epamail.epa.gov [mailto:[REDACTED]@epamail.epa.gov]

Sent: Saturday, June 12, 2010 2:43 PM

To: [REDACTED]

Subject: Q on Gulf v National Estimates

Importance: High

Hi [REDACTED] - Do we have text already developed that addresses the following (ref the most recent matrix = NHANES data and calculations):

I'm not sure these data capture the population we would be concerned about. I may be wrong, but the data appear to be from a nationwide study of people who reported eating fish/shellfish. Even using the 90th percentile from a nationwide study is likely to underestimate the amount of fish/shellfish that people consume around the Gulf.

I know we have had a few discussions about Gulf v Nationwide estimates, and I know we have discussed the fact that the majority of gulf seafood is distributed via interstate commerce, but do we have language about the resulting level of protection for the higher consumers in the Gulf?

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During the development of the allowable levels for PAHs in seafood in the wake of the BP Oil Spill, FDA staff reviewed multiple values for their risk assessment calculations and found many of them to be legitimate approaches. For example, 10 year contamination duration, 70 kg body weight, and higher rates of seafood consumption rates were all considered valid. See comments below in emails sent between FDA staff.

[REDACTED]

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**From:** [REDACTED]  
**Sent:** Monday, June 14, 2010 11:03 AM  
**To:** [REDACTED]  
**Cc:** [REDACTED]@epa.gov; [REDACTED]@epamail.epa.gov  
**Subject:** Re: Federal and State LOC Tables

I would like to hear from [REDACTED] and [REDACTED]. But I don't think the 10 year duration is a deal breaker. It is very conservative, but with a lot of the oil in the water column (I just returned from Dauphin Island, AL) there will be a lot of sedimentation. If that occurs in shellfish harvest areas then it will extend the closures.

It may be a good idea to have EPA on the State consumption values call.

We are also waiting to hear more from EPA about the frequency adjustment to our original consumption rates (90/120/160). I am still of the opinion that 10/10/43 is too low for high end seafood consumers, but if the NHANES data supports it then it would be hard for me to argue otherwise. BUT, you guys applied the frequency fractile from 1999-2004 NHANES data set to the most recent 2005-2006 NHANES. I don't know how you are mining the data but hope the EPA folks can clarify, finalize and validate the numbers you want to use.

**From:** [REDACTED]@fda.hhs.gov]  
**Sent:** Sunday, June 13, 2010 4:23 PM  
[REDACTED]  
**Subject:** Federal and State LOC Tables

The States use consumption rates of 8/14/32g for shrimp/crab, oysters, and finfish.  
The Feds use consumption rates of 10/10/43 for shrimp/crab, oysters, and finfish.

The States assume 70 kg body weight, 70 yr life expectancy, and 10 year exposure duration.  
The Feds assume 80 kg body weight, 78 yr life expectancy, and 10 year exposure duration.  
[NOTE: if Fed exposure duration is reduced to 5 years then the cancer PAH values will double (2x) but the non-cancer PAH values will remain the same. The CDC references for higher body weight and life expectancy are shown in the Federal LOC document].