



STATEMENT OF
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BEFORE THE
SUBCOMMITTEE ON ENERGY AND ENVIRONMENT
COMMITTEE ON ENERGY AND COMMERCE
U.S. HOUSE OF REPRESENTATIVES

HEARING ON
DEEPWATER HORIZON OIL SPILL

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INTRODUCTION

Chairman Markey and Members of the Subcommittee, I am Donald Kraemer, Acting Deputy Director of the Center for Food Safety and Applied Nutrition at the Food and Drug Administration (FDA or the Agency), an agency of the Department of Health and Human Services. Accompanying me is Dr. Vicki Seyfert-Margolis, Senior Advisor to the Chief Scientist, in FDA's Office of the Commissioner. We appreciate the opportunity to discuss FDA's role in ensuring the safety of seafood harvested from waters in the Gulf of Mexico in the wake of the Deepwater Horizon oil spill.

FDA is an active and integral part of the federal government's comprehensive, coordinated, multiagency program to ensure that seafood from the Gulf of Mexico is free from contamination as a result of the oil spill. This program is important not only for consumers who need to know their food is safe, but also for the fisheries industry, which needs to be able to sell its products with confidence.

FDA is working closely with the National Oceanic and Atmospheric Administration (NOAA) at the Department of Commerce, the Environmental Protection Agency (EPA), as well as other federal agencies and state authorities in the regions affected by the oil spill. We want to stress the high level of cooperation that we have experienced among these agencies, both at the leadership level and between the technical and scientific staffs that carry out the research, testing and analysis needed to fulfill our statutory mandates. We are taking a multipronged approach to ensure that marketed seafood from the Gulf of Mexico is not contaminated as a result of the oil spill. These measures include the

precautionary closure of fisheries, surveillance and testing of seafood products, and a renewed emphasis on FDA's Hazard Analysis and Critical Control Point (HACCP) regulations. Beyond our ongoing work to ensure that currently marketed seafood is safe, the Agency, in conjunction with NOAA and the Gulf states, has developed a strict protocol for re-opening closed Gulf fisheries in a manner that helps to ensure the safety of product from those areas. We are also planning for additional research into potential hazards to the food supply presented by crude oil and dispersant chemicals.

CLOSURES

The primary preventative control for protecting the public from potentially contaminated seafood is the closure of fishing areas in the Gulf that have been or are likely to be affected by the oil spill. NOAA has the authority to close federal waters to commercial and recreational fishing, and states have the authority to close waters within their state jurisdictional limits. Immediately after the oil spill began, FDA worked with NOAA and the states to ensure that appropriate closures were put in place and to define the conditions under which waters that were closed could re-open.

On May 2, 2010, NOAA closed to fishing a portion of Gulf waters (3 percent of the Gulf of Mexico Exclusive Economic Zone) that were known to be affected by oil, either on the surface or below the surface, as well as areas projected to be affected by oil within 72 hours and a five-nautical-mile safety zone around those areas. As the oil spill evolved, NOAA continued to revise the closed area, which now covers 52,395 miles (or 22 percent) of the federal waters in the Gulf—down from 35 percent at its height.

SURVEILLANCE

Both FDA and NOAA are analyzing a variety of seafood samples, including finfish and shellfish, that have been commercially harvested from Gulf waters for polycyclic aromatic hydrocarbons (PAH), the primary contaminants of concern in oil. This sampling is intended to provide verification that seafood on the market is not contaminated from the spill.

FDA has so far tested for PAH in about 500 animals of a variety of commercially harvested seafood, including shrimp, crab, and oysters, from open state waters. These species, if exposed, are likely to retain PAH contaminants longer than finfish.

The specimens are composited together, so that like species from the same location are analyzed as one unit, for a total of 47 analyses in the case of FDA samples. The results of all samples have shown PAH levels well below the levels of concern, usually by a factor of 100 to 1,000 below those levels, essentially at the same levels as were seen before the spill.

At the outset of the oil spill, the existing reference test for PAH took five to seven days to obtain results. Given the urgent need for testing large numbers of seafood samples as quickly as possible for surveillance testing and to make timely re-opening determinations, FDA worked aggressively to develop an alternative test that is reliable, accurate, and efficient. This new testing method reduced the time needed for analysis from more than a week down to about 48 hours. This rapid test is highly accurate, however, if PAH is

detected or if results are inconclusive, samples will undergo testing using the traditional confirmatory test. However, if PAH is detected below the established level of concern, the results can be used immediately to make decisions regarding the re-opening of waters.

FDA operates a mandatory HACCP program for seafood, in which processors are obligated to identify hazards that are reasonably likely to occur and institute preventive controls to address them. The framework of our seafood HACCP program is proving its value in the context of this extraordinary public health challenge. These science-based regulations, issued in 1997, initiated a landmark program to increase the margin of safety that U.S. consumers already enjoyed and reduce seafood-related illnesses to the lowest possible levels.

Over the past several weeks, FDA has conducted more than 300 inspections of seafood processors in the Gulf region to verify that they are implementing controls to ensure that they receive fish harvested only from waters from which harvesting is permitted.

FDA reminded seafood processors of their HACCP obligations related to environmental contaminants, such as oil, in a letter to the industry dated June 14, and we will assess compliance with those obligations with an additional round of inspections. Additional inspections will be performed as processors that had temporarily closed due to lack of product begin to re-open in the coming weeks.

TESTING FOR RE-OPENING

FDA, NOAA, and EPA worked in close cooperation with state agencies in Louisiana, Mississippi, Alabama, Florida and Texas to establish a single, agreed-upon protocol for re-opening closed fishing waters. The protocol sets the health standard for what seafood in the Gulf is considered safe to consume, including quantitative limits for PAH. Under the protocol, waters impacted by oil will not re-open until: 1) oil from the spill is no longer present in quantities or forms that could contaminate seafood; 2) a sampling plan is agreed upon that identifies the numbers, types, and locations of seafood samples that will be collected from the area to ensure that any contamination that may be present is detected; and 3) all samples from the area successfully pass both sensory and chemical analysis to ensure that they contain no harmful oil products.

Testing involves two steps—sensory (organoleptic) analysis by trained screeners for the presence of petroleum as well as dispersant residues, and chemical analysis of fish and shellfish for PAH. Sensory screeners, a cadre of analysts who have years of training and experience performing carefully controlled organoleptic testing of seafood for a variety of contaminants, were “calibrated” against a sample of oil, dispersant, and seawater mixture collected near the well head, as well as a sample of dispersant alone. Sensory experts check the scent and appearance of raw seafood, and the taste and scent of cooked seafood. Samples that pass sensory testing are sent for chemical analysis of oil, which allows scientists to conclusively determine whether PAH contaminants are present in fish or shellfish tissue that would be consumed, and if so, at what level.

Seafood samples from federal waters are being collected by NOAA. Samples collected in state waters for re-opening purposes are being collected by state personnel. All sensory analyses are being performed at the NOAA laboratory in Mississippi, using a combined team of FDA and NOAA screeners. FDA is utilizing the resources of its laboratories in Arkansas and Cincinnati, and state Food Emergency Response Network laboratories in Connecticut and Minnesota, to perform the necessary analyses of samples collected in state waters. Samples collected by NOAA from federal waters are analyzed by NOAA laboratories. To date, all samples have passed sensory testing for oil or dispersants and, as with the surveillance sampling, the results of all chemical analyses have shown PAH levels well below the levels of concern, usually by a factor of 100 to 1,000 below those levels, essentially at the same levels as were seen before the spill.

RE-OPENINGS

NOAA has jurisdiction over the re-opening of federal waters and to date has re-opened two large sectors of the federal waters. A third area has samples pending analysis.

FDA is working closely with the states to facilitate the re-opening of closed state waters when the evidence indicates it is safe to do so. The states of Alabama, Louisiana, Florida and Mississippi have re-opened closed portions of their coastal waters to recreational and commercial fishing with concurrence from FDA that the criteria under the joint re-opening protocol have been met. Additional re-openings are likely in the coming weeks.

To ensure that an appropriate, representative sampling of seafood is collected, FDA first approves a state's sampling plan for each area to be re-opened. After approval of the

plan, samples are collected by state agencies and tested by FDA. Upon completion of testing, if the results demonstrate that contaminants are below the levels of concern, FDA informs the state, which then re-opens the fishery in question. We are confident that these steps ensure that state waters are appropriately re-opened, and that commercial and recreational harvest can be safely resumed.

As of August 18, nine areas designated by states in their jurisdictional waters have been re-opened to harvesting of certain seafood species, after FDA testing showed that all samples were negative for the presence of oil and dispersants. Nine more—in some stage of sampling and testing—are likely to re-open in the near future. The status of these state areas is listed in the attached Addendum.

ADDITIONAL TESTING AND RESEARCH

The current science indicates there is a low risk that dispersants will bioaccumulate in seafood and are, therefore, unlikely to present a food safety concern. Further, analysis of more than 2,500 sea water samples from throughout the Gulf by NOAA and EPA have shown only one sample with detectable levels of dispersant compounds, and these were located close to the wellhead, not in areas presently open for seafood harvest. However, out of an abundance of caution, and in order to gather additional information, NOAA and FDA are conducting additional studies to reaffirm that dispersants do not accumulate in tissues of fish and shellfish. FDA is refining its ability to test for dispersants by working with NOAA to develop a practical and efficient chemical test for dispersants in edible portions of seafood that can be deployed in federal and state labs to provide rapid yet

reliable results. FDA will continue to study the long-term impacts of chemical dispersants on food safety. We will take any new, relevant information into account and adjust our protocols accordingly.

Additionally, FDA, in partnership with the National Institutes of Health, the Centers for Disease Control and Prevention, and the Agency for Toxic Substances and Disease Registry, has begun to plan for testing of important toxicological endpoints, biological activities, and tissue targets for crude oil, dispersant chemicals, and related mixtures that are appearing in the Gulf. The agencies will conduct studies to include literature evaluations, analytical chemistry activities, and biological, toxicological and toxicity pathway screens to inform and extend our understanding of the hazards presented by these complex materials.

CONCLUSION

The safety of consumers is FDA's highest priority and a responsibility we are taking very seriously. In close coordination with other federal and state agencies, we have been proactive in monitoring this disaster, planning for its impacts, and mobilizing our personnel and facilities to continue to take the steps needed to ensure a safe food supply. Now, in the midst of responding to these unprecedented events, we can see the results of our approach. Gulf waters are being re-opened only as the seafood harvested from those areas is demonstrated to be free of contamination as a result of the oil spill. The protocols and approaches we have developed, in cooperation with our federal and state

partners, are protecting the American people, while minimizing the negative impact on Gulf seafood producers and exporters.

Thank you for the opportunity to discuss FDA's activities with regard to seafood safety.

I look forward to answering any questions you may have.

Addendum

State Waters Re-openings in the Gulf of Mexico as of August 18, 2010

Alabama

- Mississippi Sound, upland out to Dauphin Island—re-opened for finfish and shrimp on August 8, 2010;
- Lower Mobile Bay to state/federal boundary—re-opened for finfish on August 16; samples of shrimp passed sensory testing and are undergoing chemical testing;
- Mississippi Sound, upland out to Dauphin Island—crabs are undergoing sensory testing;
- Lower Mobile Bay to state/federal boundary—crabs are undergoing sensory testing.

Florida

- Western end of state waters off Pensacola—re-opened for finfish fishing on July 31; cleared to re-open for commercial harvest of shrimp on August 13.

Louisiana

- Mississippi Delta to Mississippi State Line—re-opened for finfish and shrimp on July 29;
- Barataria Bay and vicinity—re-opened for shrimp and finfish on August 14;
- Terrebonne and Timbalier Bays and vicinity—re-opened for shrimp and finfish on August 14;

- Mississippi Delta to Mississippi State Line—crabs passed sensory testing;
- Mississippi Sound—Cabbage Reef, Bay Boundreau/Christmas Camp Lake, and Lake Maichais/Lake Fortuna—partial re-opening for oysters.

Mississippi

- Mississippi Sound—re-opened for finfish and shrimp on July 30;
- Barrier Islands out to federal waters—re-opened for finfish and shrimp on August 6;
- Mississippi Sound—oysters passed sensory testing and are undergoing chemical analysis;
- All of Mississippi Sound and Barrier Islands out to federal waters—crabs passed sensory testing and are undergoing chemical analysis.