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U.S. FOOD AND DRUG ADMINISTRATION DEPARTMENT OF HEALTH AND HUMAN SERVICES

BEFORE THE

COMMITTEE ON HEALTH, EDUCATION, LABOR AND PENSIONS UNITED STATES SENATE

HEARING ON HEALTH IMPACTS OF THE DEEPWATER HORIZON OIL SPILL JUNE 15, 2010

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INTRODUCTION

Mr. Chairman and Members of the Committee, I am Michael Taylor, Deputy Commissioner for Foods at the Food and Drug Administration (FDA or the Agency), an agency of the Department of Health and Human Services. Thank you for the opportunity to discuss FDA's role in helping to protect the American public from negative health impacts 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 spill. This program is important not only for consumers who need to know their food is untainted, but also for the fisheries industry, which needs to be able to sell its products with confidence.

On May 17, FDA established an Incident Management Group (IMG) to oversee and effectively coordinate issues related to the oil spill. The IMG is coordinating activities and monitoring issues that include fish and shellfish safety, protocols for the testing of seafood samples, and requests from federal and state agencies for FDA assistance.

FDA is working closely with the National Oceanic and Atmospheric Administration (NOAA), the Environmental Protection Agency (EPA), other Federal agencies, and state authorities in the regions affected by the oil spill. We are taking a multi-pronged approach to ensure that marketed seafood from the Gulf of Mexico is not contaminated. These measures include the precautionary closure of fisheries, surveillance and testing of seafood products, and FDA's Hazard Analysis and Critical Control Point (HACCP) regulations. Beyond our immediate concern with ensuring that currently-marketed seafood is free of contamination, FDA and NOAA are developing strict protocols for reopening closed Gulf fisheries, in a manner that ensures the safety of product from those areas.

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. FDA is working with both NOAA and the states to ensure that appropriate closures are in place.

On May 2, 2010, NOAA closed to fishing a portion of Gulf waters (3% of the Gulf of Mexico Exclusive Economic Zone (EEZ)) 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. Due to the evolving nature of the spill, NOAA has continued to revise the closed area, which, as of June 14th, encompasses 32.3% of the Gulf EEZ. The states of Alabama, Louisiana and Mississippi have closed portions of their coastal waters to recreational and commercial fishing and the states of Florida and Texas are closely monitoring their waters in conjunction with FDA and other agencies.

SURVEILLANCE

NOAA is collecting a variety of types of seafood samples including finfish, shrimp, crabs, and shellfish from the Gulf for analysis. NOAA is actively monitoring seafood caught just outside of closed federal areas, and testing it for both petroleum compounds and dispersants, to help ensure that NOAA's closed areas are sufficiently protective to prevent the harvest of tainted fish. FDA will be testing seafood collected from state waters by the respective state agencies.

Samples are compared to the baseline samples from unaffected areas, as well as samples taken after Hurricanes Katrina and Rita. These baseline and post hurricane samples demonstrate that Gulf seafood had low levels of polycyclic aromatic hydrocarbons (PAH), a primary contaminant of concern in oil, prior to the spill. They provide a comparative standard for safety in the region following the spill.

FDA is implementing a surveillance sampling program targeting seafood products at Gulf Coast seafood processors. The Agency will be targeting oysters, crabs and shrimp, which could retain contaminants longer than finfish. This sampling will provide verification that seafood on the market is not contaminated from the spill.

TESTING

FDA and NOAA bring considerable technical expertise to this situation in terms of collecting and analyzing seafood. The testing already underway and being planned covers several areas. These include baseline testing of seafood in oil-free areas for future comparisons; surveillance testing to ensure that seafood from areas near to closed fisheries are not contaminated; testing as part of the reopening protocol to determine whether an area is producing seafood safe for consumption; and market testing to ensure that the closures are keeping contaminated food off the market. Results of the testing and sampling times and locations will be made available to the public.

Testing involves two steps — including both a sensory and a chemical analysis of fish and shellfish. The sensory standard for comparison is based on samples of surface water mixed with a combination of oil and dispersants. Sensory experts check the scent and look of raw seafood, and the taste and scent of cooked seafood. Chemical analysis of oil allows scientists to conclusively determine whether contaminants are present in fish or shellfish tissue that would be consumed, and if so at what level, and whether the contaminants are due to the spill or related clean-up activities. The current science does not suggest that dispersants bioaccumulate in seafood. NOAA, however, is conducting studies to look at that issue. FDA will be closely reviewing the results of those studies. If the studies provide new information, that will be taken into consideration in management of the effects of the spill with regard to seafood safety.

FDA has deployed its Mobile Chemistry Laboratory to the Florida Department of Agriculture in Tallahassee, which will be used to run chemical analyses of samples collected by States for select volatile organic compounds. The technique will screen seafood samples for volatile headspace chemical compounds that may be indicative of petroleum taint. Positive results from these tests will trigger further chemical analysis for PAH. FDA has seven employees currently deployed to the Mobile Lab.

FDA's Arkansas Regional Laboratory has begun to test Gulf seafood samples collected by States, while three additional FDA field laboratories and state labs in California, Florida, Arizona and Wisconsin that are members of FDA's Food Emergency Response Network (FERN) continue to work on the implementation of testing protocols and methodology for PAH. These laboratories are expected to be ready to begin running samples by the end of June, and additional state and federal labs are also preparing to assist in the sample analysis.

Samples collected by NOAA from Federal waters for surveillance or associated with re-opening Federal waters will be analyzed by NOAA laboratories or inspection personnel using the same methodology and protocols.

HACCP

The existing framework of FDA's Seafood HACCP program is proving its value in the context of this extraordinary public health effort. These science-based regulations, issued in 1997, initiated a landmark program to increase the margin of safety that U.S. consumers already enjoyed and to reduce seafood related illnesses to the lowest possible levels.

The FDA's seafood HACCP regulation requires processors to identify and control hazards which are reasonably likely to occur. FDA will reissue existing guidance to seafood processors that explains how they can meet their obligation under the regulation to ensure that they are not receiving fish from waters that are closed by federal or state authorities. The Agency is also increasing inspections of facilities that may be processing seafood from affected areas.

REOPENING

FDA and NOAA are working to refine a protocol that sets the health standard for what seafood in the Gulf is considered safe to consume, as well as a process for determining when closed federal waters can be re-opened. Under the protocol, waters impacted by oil will not re-open until oil from the spill is no longer observable and seafood samples from the area successfully pass both sensory analysis by trained screeners and chemical analysis to ensure there are no harmful oil products found in them. With respect to PAH and other possible chemical contaminants, the reopening criteria include quantitative limits that will help ensure that seafood harvested from reopened waters will be as safe as seafood taken prior to the oil spill.

FDA will work with NOAA to facilitate the re-opening of previously closed areas as quickly as possible in order to minimize the impact of closures on the fishing industry and coastal communities. The two agencies have held multiple discussions with state officials from Texas, Louisiana, Mississippi, Alabama, and Florida to discuss the protocol for reopening waters closed in response to the oil spill. We are confident that the protocol used to re-open federal waters can also be used to assess the safety of state harvest waters before they are re-opened by state agencies.

NOAA and FDA have provided a working draft of the re-opening protocol to the affected Gulf Coast states. Along with the protocol, federal agencies are working to provide the States with all of the baseline data from areas where oil from the Deepwater Horizon spill had not yet reached.

Each sample location was selected to represent the spectrum of seafood species and conditions in the Gulf of Mexico.

CONCLUSION

FDA, in close coordination with other federal and state agencies, has been proactive in monitoring this disaster, planning for its impacts, and preparing our personnel and facilities to continue to help ensure a safe food supply. The protocols and approaches we have developed will protect 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.