DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

JUL 28 2010

The Honorable Edward J. Markey
House of Representatives
Washington, D.C. 20515-2107

Dear Mr. Markey:

Thank you for your letter of May 25, 2010, in which you expressed concern about the use of chemical dispersants for crude oil following the explosion and subsequent oil spill involving the Deepwater Horizon drilling rig. Specifically, you expressed concern that because these chemicals were not intended to be used for long durations, and were not intended to be used at such depths, there could be serious and unknown long-term consequences for the marine ecosystem, the food chain, and human health.

The Food and Drug Administration (FDA or the Agency) shares your concern about ensuring the safety of seafood coming from the Gulf of Mexico. We recognize that the spill has significantly impacted the fishing industry in the Gulf, and its recovery will be dependent upon public confidence in the safety of seafood from that region. As you are aware, state and federal authorities have closed waters to fish and fishery product harvesting to prevent the sale and potential consumption of contaminated seafood. Furthermore, FDA, the Environmental Protection Agency (EPA), and the National Oceanic and Atmospheric Administration's (NOAA) National Marine Fisheries Service, working collaboratively with the Gulf Coast states, have agreed on a protocol to determine when closed federal and state harvest waters can be re-opened. FDA is confident that when followed, this protocol will ensure that seafood harvested from the re-opened areas will be fit for consumption. Under the current protocol, harvest waters should not re-open until it is determined that there is no active oil contamination in the area, it is not likely to become oiled in the near future, and the seafood samples from the area successfully pass both sensory analysis by trained experts and subsequent chemical analysis to ensure that they contain no harmful oil residues.

With regard to your specific questions concerning the chemical dispersants, we have restated each question, followed by FDA's response.

1. FDA's webpage states that "available information indicates that dispersants being used to combat the oil spill do not accumulate in seafood." On what basis was this statement made? Please provide all documentation that demonstrates that the sustained long-term use of high volumes of dispersants both on the surface and on the ocean floor does not accumulate in seafood. Does this available information also include evidence that the dispersants being used do not accumulate in plants or un-hatched eggs?

Response: FDA has determined that the chemical dispersants currently used to combat the Deepwater Horizon oil spill, COREXIT® EC9527A and COREXIT® 9500, have a low potential for bioconcentration in seafood species. Our assessment included a review of current scientific literature and the COREXIT® Material Safety Data Sheets (MSDSs), which are required by the Occupational Safety and Health Administration to identify and describe the physical and biological properties of constituents of the finished products. The constituents were reviewed by FDA toxicologists and chemists for potential toxicity, and the ability to bioconcentrate in seafood species. NOAA is conducting further studies on exposure of seafood to dispersants, and if the results indicate a potential for bioconcentration of the dispersants or their constituents, FDA and NOAA have the ability to test for these compounds.

The potential for a chemical to become concentrated in aquatic organisms is described by the bioconcentration factor (BCF). According to EPA guidelines, "the BCF is defined as the ratio of chemical concentration in the organism to that in surrounding water." Bioconcentration occurs through uptake and retention of a substance from water, through gill membranes or other external body surfaces.[1] The scientific community generally accepts the following scale for measuring BCF: a BCF greater than 1000 indicates a high potential for bioconcentration, a BCF between 250 and 1000 indicates a moderate potential, and a BCF below 250 indicates a low potential. For food safety purposes, it is generally accepted that any chemical with a BCF of less than 100 does not pose a public health concern.

The constituents and characteristics of COREXIT® EC9527A and COREXIT® 9500 dispersants are as follows:

- Propylene glycol, a constituent of both COREXIT® EC9527A and COREXIT® 9500, is generally recognized as safe (GRAS) by FDA in 21 *Code of Federal Regulations* (CFR) 184.1666, for use as a direct food additive under the conditions prescribed. Among other uses, it is a moisturizer in medicines, cosmetics and toothpaste. Propylene glycol has a BCF of 3, which is a low order of bioconcentration.

- 2-butoxyethanol, a constituent of COREXIT® EC9527A, is also a primary ingredient of various cleaners, liquid soaps and cosmetics. 2-butoxyethanol has a BCF of 3, which, again, is a low order of bioconcentration. The half-life for 2-butoxyethanol in water is approximately 1-4 weeks, indicating that it is readily biodegradable.

- Proprietary organic sulfonic acid salt, a constituent of both COREXIT® EC9527A and COREXIT® 9500, is reported by the manufacturer to be readily biodegradable, non-bioaccumulative, and moderately toxic to fresh water fish and invertebrates. It has a BCF of 10, which is also a low order of bioconcentration.

- Petroleum distillates, constituents of COREXIT® 9500, are volatile organic solvents produced from crude oil (e.g. mineral spirits, kerosene, white spirits, and naphtha). They are

[1] In the context of setting exposure criteria, it is generally understood that the terms "BCF" and "steady-state BCF" are synonymous. A steady-state condition occurs when the organism is exposed for a sufficient length of time and the ratio does not change substantially.

common in hundreds of consumer products, including lip-gloss and deodorants. Petroleum distillates have BCFs ranging from 60 to 80, indicative of a low potential for bioconcentration.

The low BCFs are due to the fact that the constituent compounds present in the dispersants are of a type which does not penetrate the lipid barrier of the intestinal tract in finfish or shellfish, and thus there is no uptake into the body of the seafood organism.

With respect to the potential for accumulation of dispersants in aquatic plants and eggs, FDA defers to EPA on these issues, as they do not fall directly within FDA's regulatory jurisdiction for the safety of food for human consumption.

In summary, although seafood is exposed to the dispersants, the inherent properties of the dispersants minimize the possibility of their being present in food. Based on current scientific literature and our assessment, the potential for bioconcentration of the constituents in the COREXIT® dispersants in aquatic organisms is low, and thus there is no information at this time to indicate that they pose a public health threat from exposure through the consumption of seafood.

2. How does the FDA monitor whether dispersant chemicals are present in the tissue of fish that are sold for consumption?

Response: Other than the sensory analysis for oil and dispersants conducted pursuant to the FDA-NOAA Gulf Fisheries Reopening Protocol, FDA does not presently monitor for dispersant chemicals in the tissue of seafood because of the dispersants' low bioconcentration potential. This decision is based on our assessment described in the answer to Question 1. However, and as noted in the previous response, NOAA is conducting further studies on seafood exposure to dispersants and if the results show the potential for bioconcentration, NOAA and FDA have the ability to test for COREXIT® dispersant constituents. We have addressed the possibility for such analyses in the NOAA-FDA Gulf Fisheries Reopening Protocol developed in response to the oil spill, and FDA's electronic sensing analyzers have been calibrated for both crude oil and dispersants.

3. What federal standards are in place for how much dispersant (or its constituent chemicals) can be present in seafood consumed by humans?

Response: Bioconcentration of COREXIT® dispersant chemicals in seafood intended for human consumption has not been demonstrated to occur. Therefore, federal standards for the dispersant chemicals in seafood have not been proposed.

4. Would it be necessary for the FDA to be aware of the full chemical composition of the dispersants being used in order to accurately monitor and regulate them? If so, does FDA have this information?

Response: It is necessary for FDA to be fully informed of the complete composition of dispersants in order to scientifically assess their significance to seafood safety as well as to

monitor and regulate them in the event a hazard was identified. FDA is aware of the chemical identities of constituents comprising COREXIT® EC9527A and COREXIT® 9500.

5. How does FDA plan on monitoring the long-term effect that these chemical dispersants have on aquatic life in the Gulf of Mexico and the consequent effect that consumption of seafood from the Gulf has on human health? Will FDA continue to conduct such monitoring to ensure that as these chemicals move up the food chain from plants to fish intended for human consumption, that they don't appear weeks, months, and years after the use of dispersants is halted?

Response: The 2005 National Research Council (NRC) report "Oil Spill Dispersants: Efficacy and Effects," which was reviewed in our assessment, concluded that the potential acute lethal toxicity of chemically dispersed oil is primarily associated with the dispersed oil and dissolved oil constituents following dispersion and not with the current generation of dispersants themselves. FDA does not presently monitor for COREXIT® dispersant chemicals in the tissue of seafood because of their low bioconcentration potential, and the Agency does not have plans for long-term studies of COREXIT® dispersant constituents in seafood. This position is based upon our assessments as described in the answer to Question 1.

FDA is responsible for the human health implications of commercial seafood consumption and will continue to work with our federal, state, and academic partners to identify and characterize contaminants in seafood intended for human consumption. Other federal agencies, including NOAA and EPA, focus more directly on water quality, including impacts to aquatic life from chemical discharges.

6. What actions will FDA be required to take if it is determined that consumption of contaminated seafood is a human health concern?

Response: FDA is working with NOAA and the states to prevent the consumption of contaminated seafood through a series of risk-management approaches. This includes the closure of waters to fish and shellfish harvesting, the elaboration and implementation of a strict protocol to determine when closed harvest waters can safely be re-opened, ongoing surveillance sampling and testing of fish and fishery products for contaminants of concern, and stepped-up enforcement of FDA's existing Hazard Analysis and Critical Control Point (HACCP) regulations, which require that seafood processors identify and address reasonably-expected hazards to the safety of their products. An example of such a hazard would be an assurance that processors not accept seafood from areas that are closed due to contamination. Appropriate regulatory action would be taken against adulterated seafood found in commerce to prevent it from being consumed.

Thank you for sharing your concern with us. If we may be of further assistance, please let us know.

Sincerely,

Jeanne Ireland
Assistant Commissioner
for Legislation