CITIZEN PETITION TO THE UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION

Division of Dockets Management Food and Drug Administration Department of Health and Human Services 5630 Fishers Lane, Rm. 1061 Rockville, MD 20852

Public Employees for Environmental Responsibility,)	
Petitioners,)))	et No.
Filed With:) Dock)	et No.
Margaret Hamburg)	
In her official capacity as)	
Commissioner of the Food and Drug Administration))	
)	

Public Employees for Environmental Responsibility 2000 P Street, NW Suite 240 Washington, D.C. 20036 (202) 265-7337

SUBMITTED BY:

Christine Erickson Public Employees for Environmental Responsibility 2000 P Street, NW Suite 240 Washington, D.C. 20036 (202) 265-7337

Attorney for Petitioners

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CITIZEN PETITION FOR CHEMICAL TESTING FOR THE PRESENCE OF DISPERSANTS IN GULF SEAFOOD

I. PRELIMINARY STATEMENT

Public Employees for Environmental Responsibility ("PEER") hereby submits this petition under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, and related regulations to request the Commissioner of Food and Drug to begin chemically testing for and monitoring the presence of dispersants in seafood approved for public consumption by the Food and Drug Administration ("FDA").

Following the April 20, 2010 *Deepwater Horizon* mobile offshore drilling unit oil spill, the United States Coast Guard ("USCG"), in consultation with the Environmental Protection Agency ("EPA"), Department of Interior ("DOI"), National Oceanic and Atmospheric Administration ("NOAA"), and the State of Louisiana, granted BP the authorization to use approved dispersants on oil on the surface of the water in an effort to mitigate the shoreline impacts of the spill. Dispersants contain a mixture of solvents, surfactants, and other chemicals, that, when applied directly to the spilled oil, can break down the oil into smaller drops that can sink below the water's surface. Dispersed oil forms a "plume" of oil droplets below the water surface, and mixes vertically and horizontally into the water column.

The FDA, NOAA, and the Gulf states have responded to the spill by testing seafood from the area for contamination by crude oil – conducting sensory tests with teams of human sniffers, as well as chemical tests for the harmful polycyclic aromatic hydrocarbons, or PAHs, found naturally in crude oil.¹ However, neither the FDA nor

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¹ Food and Drug Administration, *Overview of Testing Protocol to Re-open Harvest Waters that were Closed in Response to the Deepwater Horizon Oil Spill* (last updated July 15, 2010), *available at* http://www.fda.gov/Food/ucm217598.htm [hereinafter FDA Overview].

NOAA has begun chemically testing for the presence of oil dispersant in seafood.² According to the FDA:

Based on current science, the dispersants used during the Deepwater Horizon response have a low potential to bioaccumulate in seafood and are low in human toxicity, and therefore there is likely little public health risk associated with consuming seafood that has been exposed to them.³

However, the FDA then stated that:

Nonetheless, as a precaution, the U.S. government will continue to monitor the use of dispersants and test seafood that may have been exposed to them. It is possible for the dispersants to "taint" seafood with a chemical smell. Even though the dispersant "taint" may not be harmful, seafood possessing the chemical smell is considered adulterated and not permitted for sale.⁴

This approach to dispersants raises a clear question: is banning the sale of "tainted" seafood based solely on sensory testing sufficient to protect human health, or should the FDA also be chemically testing for the presence of dispersants in seafood?

Since the spill, BP has unloaded nearly two million gallons of oil-dissolving Corexit 9500 and 9527A dispersants into the Gulf of Mexico.⁵ Despite the USCG's and EPA's directive to keep the use of dispersants to a minimum, BP has been regularly applying dispersants to the Gulf spill at rates of 35,000 to 65,000 barrels per day; in contrast, 250,000 total barrels of dispersants were used in the aftermath of the *Exxon Valdez* disaster in Alaska in 1989.⁶ At one point, BP applied 700,000 gallons in a single

² See Marian Wang, Gulf Seafood Gets Chemically Tested for Oil, Not Dispersant, PROPUBLICA, (July 14, 2010) available at http://www.propublica.org/blog/item/gulf-seafood-gets-chemically-tested-for-oil-not-dispersant; see also Laura Green, Gulf seafood tested for oil but not dispersant, THE PALM BEACH POST NEWS, July 12, 2010, available at http://www.palmbeachpost.com/news/state/gulf-seafood-tested-for-oil-but-not-dispersant-799084.html?viewAsSinglePage=true.

³ FDA Overview, *supra* note 1.

⁴ *Id*.

⁵ Unified Command for the Deepwater BP Oil Spill, Deepwater Horizon Response, available at http://www.deepwaterhorizonresponse.com/go/doc/2931/786995.

⁶ Avery Fellow, *Impact of Oil Dispersants Still Unknown*, *EPA Says*, COURTHOUSE NEWS SERVICE, July 15, 2010, *available at* http://www.courthousenews.com/2010/07/15/28874.htm.

day, which EPA Administrator Lisa Jackson admitted was "an alarming number" at the Senate Appropriations Subcommittee hearing on July 15, 2010.⁷ The sheer volume of dispersants being used in the Gulf is unprecedented. Moreover, approximately 763,000 gallons of dispersant has been injected 5,000 feet undersea at the source of the spill, a technique that has never been used or tested before.

Studies on the long-term effects of dispersant are few and far between, and for deepsea use they are non-existent. Both EPA and FDA have acknowledged that the short and long-term effects of using dispersants by the method and in the quantities employed by BP are entirely uncertain. EPA Administrator Jackson admitted at the July 15 hearing that she did not know of any research focused on the heavy use of chemical dispersants or underwater application of the chemicals. When Senator Lisa Murkowski (R-AK), posed the question "[y]ou're suggesting to me that we haven't done that research anywhere?", Jackson responded "[t]hat's correct senator." When asked about how much research had been done on chemical dispersants since the Exxon Valdez disaster, Jackson said, "there has been significant research, but let me say at the outset, I don't think there has been enough." Jackson also acknowledged in her testimony to the Senate that "there are environmental trade-offs and uncertainties associated with the widespread use of large quantities of dispersants". 11

The FDA has similarly admitted that the current science on dispersants is largely incomplete. "There's not a huge body of research that has been done," Meghan Scott, an

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⁷ *Id*.

⁸ *Id*.

⁹ *Id*.

 $^{^{10}}$ *Id*

¹¹ Testimony of Lisa Jackson, EPA Administrator, Legislative Hearing on use of Dispersants in BP Oil Spill, Senate Committee on Appropriations: Subcommittee on Commerce, Justice, Science, and Related Agencies (July 15, 2010).

FDA spokeswoman, has said. "While we are finding that [dispersant] is harmful to the living fish itself, there's a difference between what it does to a living fish and any harm that it might have for a human consuming a fish that was in or near water with dispersant in it." However, Monica Allen, a spokeswoman with the National Marine Fisheries Service, a division of NOAA, has said that, "work is being done here to develop testing for dispersant. That's ongoing." Thus, until such a test is developed, seafood is receiving the NOAA and FDA stamp of approval and being put on the market in the absence of any chemical testing for the presence of dispersants. This is particularly troubling in light of the fact that, at the July 15 hearing, NOAA Assistant Secretary Larry Robinson stated that:

I think that [testing seafood for dispersants] would be an excellent thing to consider because we've learned from this situation that there are other potentials here, perhaps even from bioaccumulation of dispersants and their by products into seafood. So that's something we have on our list of things we would like to know more about."¹⁴

Existing data overwhelmingly shows that direct contact with the chemicals present in dispersants is extremely dangerous and toxic to human health. The main ingredient of the dispersant chemical, Corexit 9527A, is 2-butoxyethanol, a pesticide deemed highly toxic to humans and wildlife, causing cancer, hemolysis (bleeding), liver and kidney damage, birth defects and other reproductive side effects. In fact, the Material Safety Data Sheet for Corexit 9527A warns with respect to toxicity that, "repeated or excessive exposure to butoxyethanol may cause injury to red blood cells

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¹² Wang, *supra* note 6.

¹³ *Id*.

¹⁴ See YouTube video, Dispersants Hearing: NOAA admits Gulf seafood not tested, yet says toxins may BIOACCUMULATE!, YOuTube, July 15, 2010, available at http://www.youtube.com/watch?v=sU9HyHnd0MM.

¹⁵ http://www.epa.gov/emergencies/content/ncp/products/corex952.htm.

(hemolysis), kidney, or liver." The dispersant also contains arsenic, cadmium, copper, lead and mercury, among other chemicals. To this end, EPA has been urging extreme caution when it comes to human contact with dispersants. Specifically, the EPA website states that:

People working with dispersants are strongly advised to use a half face filter mask or an air-supplied breathing apparatus to protect their noses, throats, and lungs, and they should wear nitrile or PVC gloves, coveralls, boots, and chemical splash goggles to keep dispersants off skin and out of their eyes." ¹⁶

Many scientists also agree that the chemical mixture can enter into the food chain, causing genetic mutations in species and damaging the overall health of the oceans and public safety.

While it is clear that the extent to which dispersants may negatively impact human health and the environment is still largely unknown, there can be no question that, given what is known, the concern over the cumulative and long-term effects is a valid and serious one. The FDA has failed to take a proactive role in ensuring that the use of dispersants in the Gulf will not have an adverse affect on public health through the consumption of seafood from affected areas. The FDA's inaction is putting consumers at risk by ignoring the potential for dispersant-contaminated seafood to negatively impact human health.¹⁷ Adequate tissue and chemical testing should be done before potentially contaminated seafood is put on the market and deemed safe for consumption.

¹⁶ Environmental Protection Agency, *EPA Response to BP Spill in the Gulf of Mexico*, *available at* http://www.epa.gov/bpspill/dispersants.html#qanda2 (last visited June 16, 2010).

¹⁷ Material Data Safety Sheet, COREXIT® EC9527A, *available at* www.deepwaterhorizonresponse.com/.../Corexit_EC9527A_MSDS.539295.pdf (last visited June 16, 2010).

II. ACTION REQUESTED

This Petition seeks FDA action to begin chemically testing and monitoring seafood from the Gulf Coast for dispersants before it is approved for human consumption. In the alternative, Petitioner seeks FDA action in ceasing to certify that seafood from the Gulf is safe to consume until a reliable means of testing for dispersants is developed, and to commit to employ such a test immediately upon its becoming available.

III. STATEMENT OF GROUNDS

One of the greatest unaddressed concerns associated with the Deepwater Horizon oil spill is dispersant contamination of the seafood consumed by the public. Louisiana alone supports a \$2.4 billion a year seafood industry. Thus, it is imperative that the federal agencies responsible for protecting the public from ingesting contaminated seafood are taking all steps necessary to ensure that the short and long term effects of using dispersants in the Gulf does not reach the public.

The FDA is responsible for overseeing a mandatory safety program for all fish and fishery products under the provisions of the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, and related regulations. Adherence to these Acts and their supporting regulations helps ensure that the seafood U.S. consumers purchase is safe to eat. An important element in keeping seafood safe is making sure it is harvested from areas that do not present a chemical or biological hazard. While the NOAA has the legislative authority to close and open federal waters for seafood harvesting, the primary responsibility to test seafood and ensure its safety in the market remains with the FDA.

A. The Presence of Dispersants in Seafood Poses a Risk to Human Health

1. Known adverse effects of dispersants.

The use of dispersants has aptly been called a conscious decision to direct hydrocarbons to one part of the marine ecosystem, "decreasing the risk to water surface and shoreline habitats while increasing the potential risk to organisms in the water column and on the seafloor."

It is undisputed that direct contact with the solvent chemicals contained in dispersants is toxic to humans and other life forms on shore and in the sea. This fact has long been known. Medical professionals have consistently warned that solvents can rapidly enter the human body: they evaporate in air and are easily inhaled, they penetrate skin easily, and they cross the placenta into fetuses. 2-butoxyethanol, in particular, has been deemed a human health hazard because it is a fetal toxin that breaks down blood cells, causing blood and kidney disorders. Moreover, direct long-term exposure in humans is shown to cause central nervous system problems and blood, kidney and liver damage, according to the Centers For Disease Control and Prevention. While many of these diseases and conditions may be immediately evident, others may not appear until years or decades later. In addition, dispersants are shown to kill incubating sea life.

A recent joint Consensus Statement published by a group of expert marine scientists, ocean researchers, and conservation leaders emphasized these known

http://www.cdc.gov/nceh/oil_spill/docs/Oil%20Spill%20Dispersant.pdf.

¹⁸ Committee on Understanding Oil Spill Dispersants: Efficacy and Effects, National Research Council, *Oil Spill Dispersants: Efficacy and Effects*, 2005.

¹⁹ Hazardous Substance Fact Sheet, 2-Butoxy Ethanol, available at

http://nj.gov/health/eoh/rtkweb/documents/fs/0275.pdf.
²⁰ Center for Disease Control and Prevention, *Oil Spill Dispersant (COREXIT EC9500A and EC9527A: Information for Health Professionals*, available at

dangers.²¹ The scientists called for the immediate halt of the use of chemical dispersants in the Gulf of Mexico, due to the already known dangers associated with the chemicals. Among other things, the scientists pointed out that crude oil mixed with dispersants can enter the marine food chain at many points, and can bioaccumulate in animal tissue, potentially impacting marine ecosystems over many years and over a broad geographical area.²²

2. Unknown effects of dispersants.

In addition to the known threats, the majority of current studies on the topic suggest that both bioaccumulation and toxicity in seafood consumed by humans pose potential health risks. Scientists overwhelmingly agree that much more work on dispersants in seafood is required before the federal government should feel confident in deeming it safe to consume.

In its July 15, 2010, "Overview of Testing Protocol to Re-open Harvest Waters that were Closed in Response to the Deepwater Horizon Oil Spill," the FDA stated:

Based on current science, the dispersants used during the Deepwater Horizon response have a low potential to bioaccumulate in seafood and are low in human toxicity, therefore there is unlikely little public health risk associated with consuming seafood that has been exposed to them.²³

However, the FDA failed to cite a single scientific study supporting this assertion and, in fact, later conceded that it did not really know or understand the full effects of dispersants on seafood. FDA has also made the conclusory statement that dispersants "don't concentrate in the edible parts of fish or penetrate fish gills or bodies."²⁴ Yet, NOAA

²¹ Consensus Statement: Scientists oppose the use of dispersant chemicals in the Gulf of Mexico (July 16, 2010).

²² *Id*.
²³ FDA Overview, *supra* note 1.

²⁴ http://marketplace.publicradio.org/display/web/2010/07/14/pm-oil-and-chemicals-in-seafood/

Assistant Secretary Robinson conceded at the July 15 hearing that dispersants may bioaccumulate in fish flesh and humans may be harmed by eating fish with dispersant-soaked flesh.²⁵ The FDA has not conducted any of its own studies on the bioaccumulation of dispersants in seafood and the potential long-term impact of dispersants in the food chain.

The EPA has likewise admitted to not fully knowing and understanding the risks posed to seafood by dispersants, since its analysis of the toxicity of dispersants has focused only on acute effects of exposure, and has not evaluated chronic toxicity or long-term effects.

The majority of studies on the subject suggest that vast quantities of dispersed oil, such as those being used in the Gulf, can enter the marine food chain and bioaccumulate in fish and animal tissue. As plumes of dispersed oil form in the water column, globules of oil and dispersant envelop and kill floating plankton, fish eggs and larvae and everything else at sensitive-life stages. Larger fish such as amber jacks, tuna and grouper and marine mammals are exposed to oil and dispersants by feeding on contaminated fish. The FDA argues that this is not a serious concern because even if the dispersants do bioaccumulate, they are low in human toxicity and therefore not a threat if consumed by humans via seafood. However, the FDA again fails to point to scientific data which supports this position.

In addition, the effects of the interaction between the crude oil and dispersants are particularly unspecified and potentially dangerous. While it is well known that the

²⁵ Testimony of Larry Robinson, NOAA Assistant Secretary of Commerce for Oceans and Atmosphere, Legislative Hearing on use of Dispersants in BP Oil Spill, Senate Committee on Appropriations: Subcommittee on Commerce, Justice, Science, and Related Agencies (July 15, 2010).

²⁶ Consensus Statement, *supra* note 19.

combination of oil and dispersants is more toxic than either alone, the precise magnitude of the resulting danger is still unknown. Many of the chemicals in crude oil and dispersants target the same organs in the human body, increasing the risk and possibly the severity of the harm.²⁷ Dispersants can also increase the dose of crude oil chemicals and movement of chemicals into critical organs. ²⁸ Dr. Susan Shaw, Director of the Marine Environmental Research Institute and co-author of the Consensus Statement, argues that there is a large body of research indicating that crude oil and dispersants are more toxic when they are combined than either oil or dispersants alone. Dr. Shaw explained that "because Corexit contains a petroleum solvent, we're actually putting petroleum solvent on top of a petroleum spill. So it's increasing the hydrocarbons in the water column." Dispersants can work like a delivery system, adding to the toxicity of oil for marine organisms. Dr. Shaw also explained that "dispersed oil enters the body more readily than oil, and it goes into the organs faster." This evidence suggests that the FDA's rationale for failing to test for dispersants is based on a faulty assumption that bioaccumulation is not a concern because the dispersants are low in human toxicity.

Finally, many scientists agree that the worst of the impacts from dispersants on the Gulf are yet to come and will not be apparent for decades.²⁹ Louisiana Wildlife and Fisheries Commission Secretary Robert Barham sounded alarm bells early on stating that the use of sub-sea dispersants complicates the state's efforts to keep fishery products safe. The Commission vehemently objected to the use of dispersant based on their unknown properties and the fact that it would take years before the impact of dispersants on the local food chain, including shrimp, crabs, oysters and fisheries, is truly understood.

²⁷ http://www.sciencecorps.org/crudeoilhazards.htm.

²⁸ *Id*.

²⁹ Consensus Statement, *supra* note 19.

In light of these concerns, it is imperative that the FDA use its authority to take all steps necessary to caution against and prevent harm to the public through chemical dispersant contamination of seafood.

B. <u>The FDA's Current Regime Does Not Include a Reliable Test for Detecting</u> the Presence and Effect of Dispersants in Seafood

In mid-July, the FDA deemed fish in local markets in the Gulf safe to eat. NOAA and the FDA jointly stated that the seafood was safe after testing 400 samples of shrimp, grouper, tuna and other species and finding no concerning levels of crude oil contaminants. The FDA declared that "although crude oil has the potential to taint seafood with flavors and odors caused by exposure to hydrocarbon chemicals, the public should not be concerned about the safety of seafood in stores at this time." ³⁰

While FDA is currently conducting both sensory and chemical analyses of crude oil in fish and shellfish out of the Gulf, it has not yet implemented a program for chemically testing for the presence of dispersants in the tissue of seafood before it reaches the market. Instead, the FDA is relying solely on the sensory test for dispersants, and has stated that it is depending on NOAA to conduct further studies on chemical analyses for dispersants. However, Larry Robinson, Assistant Secretary of Commerce for Oceans and Atmosphere, admitted to the Senate subcommittee that NOAA itself has not tested seafood for dispersant poisoning. Thus, he could not say with certainty whether the fish coming from the Gulf are risk-free and contain no traces of dispersants and could not say when a chemical test for dispersants would be available. FDA's reliance on NOAA to conduct studies and ensure the seafood is safe is misplaced.

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 $^{^{30}\} http://www.fda.gov/Food/FoodSafety/Product-SpecificInformation/Seafood/ucm210970.htm.$

C. Gulf Fisherman Do Not Trust that Gulf Seafood is Safe to Consume

Even the people who make their living off the Gulf seafood industry have raised serious concerns about whether sensory testing ensures that the Gulf's seafood is safe to eat. Louisiana officials and fishing industry groups have voiced concerns that dispersants may lead to a more long-lasting disaster and that the current regime for testing seafood for these effects falls far short of reliable. Shrimpers, for example, are worried that using dispersants at such depths as BP is doing will guarantee that the oil droplets and dispersants spread on the sea floor, where shrimp larvae and other organisms could be affected.31

Likewise, charter fishing captains and commercial crab and oyster anglers have also voiced concerns that FDA's reliance on a sensory test for dispersants is entirely inadequate.³² They argue that fishing should not resume until there is more data and better dispersant testing is devised. In fact, many Louisiana fisherman and groups have proclaimed that they themselves have no confidence in FDA's testing methods and they feel the seafood coming out of the Gulf is not safe to eat.³³

In light of these serious concerns and because of the unprecedented volumes of dispersants being used in the Gulf of Mexico, about which much is unknown-particularly with regard to long-term effects- FDA must take immediate action to safeguard people from the potential dangerous and lasting impacts that dispersants may have in the food chain.

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³¹ http://www.tampabay.com/news/environment/water/fisherman-question-use-of-chemical-dispersants-ingulf-oil-spill/1094257.

32 http://www.nj.com/news/index.ssf/2010/08/dont_trust_eating_seafood_harv.html.

³³ http://www.ni.com/news/index.ssf/2010/08/dont_trust_eating_seafood_harv.html.

IV. CONCLUSION

Petitioners have demonstrated in this Petition that a substantial body of scientific studies, reports and other sources support our position that the pervasive and expanding use of dispersants in the Gulf poses a threat to humans who consume Gulf seafood without adequate testing. Therefore, in the interests of the protection of human health and the overall environment that supports it, Petitioners request that the FDA immediately begin chemically testing seafood from the Gulf for dispersants. Unless and until a method for such testing is developed, seafood from the Gulf should not be deemed safe for human consumption.

Submitted By:

Christine Erickson Staff Counsel Public Employees for Environmental Responsibility 2000 P Street, NW, Suite 240 Washington, DC 20036

Tel: (202) 265-7337