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PROTOCOL FOR INTERPRETATION AND USE OF ORGANOLEPTIC AND ANALYTICAL CHEMISTRY RESULTS FOR RE-OPENING OIL-IMPACTED AREAS CLOSED TO SEAFOOD HARVESTING

INTRODUCTION

Once an oil spill has occurred, Federal and State agencies are faced with the issue of determining when the seafood from the contaminated area may be harvested and processed. NOAA's Office of Response and Restoration (OR&R) publication entitled *Managing Seafood Safety after an Oil Spill (Yender et al. 2002)* provides agencies guidance in such situations. This guidance and other input from both NOAA and the U.S. Food and Drug Administration (FDA) have been used to establish this protocol.

In establishing this protocol it is important to understand the following principles:

- NOAA and the FDA are working with other federal and state agencies to protect consumers from adulterated and unsafe seafood, while minimizing undue economic burden on the recreational and commercial fishing seafood industries.

- Once oil or chemical contaminants are visually observed on the surface, it is recommended that the fishery be closed until testing is completed to confirm that the seafood are palatable, safe and present a negligible risk to human health.

- After the initial fishery closure, the best approach for determining the safety and acceptability of seafood from oil-contaminated areas is one that combines organoleptic analysis of products (i.e. sensory testing) with results from chemical analysis.

Oil contamination presents two kinds of risks: the presence of polycyclic aromatic hydrocarbons (PAHs) that are chemical hazards, and the presence of petroleum taint that render seafood unfit for human consumption. Federal government and state agencies therefore close oil-contaminated harvest areas for health reasons.

Oil-contaminated seafood is adulterated if chemical analysis verifies that the level of PAHs in it exceeds the FDA's opening criteria levels or if the oil contamination (taint) is perceivable by olfaction. Consequently, after an oil spill, seafood suspected of oil contamination can only be brought into interstate commerce when it passes both the chemical-analytical test for PAHs and the organoleptic test for petroleum taint.

The purpose of this protocol is to specify how the results of the organoleptic and chemical analyses will be used in re-opening seafood closure areas. The principles of the protocol are as follows:

Generally:

1. The original closure of the fishery was intended to protect seafood consumers assuming a worst case scenario.
2. Area re-opening will be based on an acceptable reduction of the threat of seafood exposure to the contamination and analyses that assure the safety and edibility of the seafood. Threat of exposure will be based on past observations and the status of the spill and conditions.

3. When the area passes the organoleptic test, seafood will be analyzed from each site and must pass chemical analysis for PAHs before the area may be reopened.

Specific Re-opening Criteria:

1. Threat of exposure – Threat of exposure is sufficiently reduced based on past observations of previous spills, any baseline information collected, and the status of the spill and conditions.
2. Evaluation of oil movement – Confirmation that the closure area is free of sheen by aerial reconnaissance.
3. Assessment of seafood contamination by organoleptic analyses – Determine if the seafood is contaminated by tissue collection for organoleptic analyses. The acceptable condition is that all specimens must pass organoleptic testing conducted by a NMFS sensory panel using the protocol reviewed by the FDA.
4. Assessment of seafood contamination by chemical analyses – Chemical analyses are performed on samples that pass organoleptic analyses to confirm that the measured concentrations are below the maximum permissible levels allowable to protect human health.
5. Opening boundaries will be based on results of analyses (organoleptic and chemical) that demonstrate the product is:
   a. Untainted.
   b. Safe for human consumption.
6. Establish buffer zones between open and closed areas using chemical and organoleptic testing indices.
7. Re-openings may be fisheries specific.

ANALYSIS

1. NMFS organoleptic testing protocol reviewed by FDA.
2. When organoleptic samples are acceptable, verify organoleptic outcomes with chemical analyses performed by the NMFS PAH method.

ONGOING STUDIES

Additional investigation protocols may continue to be designed to assess sediment contamination, ecological injury and other environmental parameters. These investigations are not directly related to or considered a part of this protocol. However, data from these investigations will be reviewed prior to making any decisions to reopen an area or a fishery and may be the basis for requiring additional sampling/analysis as per this protocol. For example, sediment chemical data from fishery areas may be used to identify contaminant “hot spots.”

Water analysis for the identified PAHs may be used to gain an understanding of the effectiveness of the containment and cleanup of the spill. In addition water analysis may be used to determine the amount and effect of the dispersants used as they are also a possible contamination source. Such water analysis will be performed on representative samples of the affected water column. The necessary sampling criteria will be based on many factors including the area of the closure, depth of the water within the closure, and sites and species considered for re-opening of harvest areas or fishery. With regard to inshore fisheries such as molluscan shellfish, sediment samples may also be analyzed.

Surveillance of fisheries should be conducted in response to identified "hot spots" or other relevant changes in environmental conditions (e.g., increases in PAH levels in water, if conducted, or seafood) if warranted, based on the protocol defined.

RE-OPENING PROCESS

NOAA and the FDA will review the data generated as a result of the implementation of this protocol, evaluate the accuracy and quality of the data and assess compliance with the agreed criteria. Based on this assessment, NMFS may re-open federal waters subject to the closure. NMFS will coordinate with State agencies for the re-opening of their waters and to ensure orderly and appropriately enforced re-openings. No partial re-openings will be allowed which are unenforceable, i.e., gear that requires harvesters to segregate their catch and discard catch from fisheries that remain closed.

Organoleptic assessment based on NOAA Technical Memorandum NOS OR&R 9: *Guidance on Sensory Testing and Monitoring of Seafood for Presence of Petroleum Taint Following an Oil Spill* (August 2001) will be utilized. The organoleptic testing will be conducted by a panel of ten expert assessors from NMFS and the FDA. Samples will be examined by organoleptic methods both in the raw and cooked states. If a particular fishery passes the organoleptic testing within a defined sampling area, chemical analyses will commence on that particular fishery within that area. If the chemical analyses pass the risk based assessment criteria for the species in question, that zone will be considered for re-opening. It should be noted that risk assessments for specified species in specific harvest areas may need to be adjusted for different consumption levels. If an area fails organoleptic testing it will be retested in a designated time period.

SELECTION OF TARGET-COMPOUND PAHs

Most petrochemical products such as diesel oil and crude oil contain aromatic components: mono-, bi-, and polycyclic aromatic hydrocarbons (PAHs). Well established liquid chromatography (LC)/fluorescence detection (FD) and gas chromatography (GC)/mass spectrometry (MS) methods are used to separate and quantify these contaminants in seafood.

PAHs are omnipresent in our environment; in addition to sources from petrochemical products they are generated by nearly all pyrolytic processes including forest fires, coffee roasting, and auto driving. Of the large number of PAHs in the environment and in oil products, the EPA has selected a group of representative PAH compounds that adequately characterize the health risk of the matrix that contains them. In 1996, at the North Cape diesel oil spill in Rhode Island, a simplified list of PAHs was generated (**Table I**) that was representative of the aromatics present in oil. These concentrations, while considered safe for human consumption, are likely to be acutely toxic to marine life and thus are unlikely to be exceeded in harvested seafood.

Criteria for Determining Organoleptic Acceptability

A minimum of 6 sub-samples per species from each area under consideration is required. A sub-sample will consist of an individual organism for finfish and multiple organisms for shrimp and shellfish, depending on the intact animal type (e.g. 3 to 6 blue crabs, 6 oysters, 0.4 – 0.5 lb shrimp). The samples will be evaluated by a panel of a minimum of 10 expert assessors in the raw and cooked state.

For a site to pass, all of the following tests must be passed (these criteria are based on past oil spill information and ensure a high confidence level that the seafood is not tainted by oil):

- Seventy percent (70%) of the expert assessors must find NO detectable odor from each raw sample. If any sample fails, the site fails.
- Seventy percent (70%) of the expert assessors must find NO detectable odor from each cooked meat sample. If any sample fails, the site fails.
- Seventy percent (70%) of the expert assessors must find NO detectable taste or flavor in the cooked state. If any sample fails, the site fails.

Chemical Analyses

For crabs: Chemical analysis of edible muscle from a minimum of ten (10) individuals, of legal size if available, will be collected from each sampling site. Tissue samples from individual crabs will be combined to make separate composite samples of the muscle tissue and hepatopancreas. All crabs will be collected from sites selected as commonly used fishing grounds.

For all other seafood: Chemical analysis of a sample of edible tissue from a composite (of at least 200 grams) from a minimum of 10 or more individuals collected at or near the locations specified.

Table 1

Criteria for Re-opening Areas Closed from Oil Spills Based on 160 g/day Seafood Consumption and Concentrations of Chemical Contaminants in Seafood

Chemical[1]	Level of Concern (ppm)	Basis[2]
Napthalene	20	EPA RfD; 70 kg bw; 160 g/day consumption
Fluorene	20	EPA RfD; 70 kg bw; 160 g/day consumption
Anthracene/phenanthrene	150	EPA RfD; 70 kg bw; 160 g/day consumption
Fluoranthene	0.15	10^{-6} Cancer risk estimate = 0.02B(a)P equivalency
Pyrene	0.025	10^{-6} Cancer risk estimate = 0.13B(a)P equivalency
Benz(a)anthracene	0.2	10^{-6} Cancer risk estimate = 0.014B(a)P equivalency
Chrysene	0.25	10^{-6} Cancer risk estimate = 0.013B(a)P equivalency
Benzo(a)pyrene	0.003	10^{-6} Cancer risk estimate = (34ng/p/d)(70/5yr)/160 g seafood/p/d

[1] Includes alkylated homologues, specifically C-1, C-2, C-3, C-4 napthalenes; C-1, C-2, C-3 fluorenes; C-1, C-2, C-3 anthracenes/phenanthracenes; C-1, C-2 pyrenes

[2] With respect to the Basis:

RfD based criteria:	**RfD**
Napthalene:	(0.04 mg/kg/d x 70kg)/0.16kg = 17.5 mg/kg or 20 ppm
Fluorene:	(0.04 mg/kg/d x 70kg)/0.16kg = 17.5 mg/kg or 20 ppm
Anthracene:	(0.30 mg/kg/d x 70kg)/0.16kg = 131 mg/kg or 150 ppm

Criteria for 2- and 3-ring compounds are based on US EPA Reference Doses (RfDs) and the US EPA consumption estimate for a maximally exposed individual. Seafood consumption rate of 0.12 kg taken from the 2-day average 90th percentile intake level of all seafood (NHANES 2005-2006). Consumption levels for all species is considered to be appropriate because a) consumption information on individual species is often limited and not sufficient for detrmined high end intake levels, b) in those circumstance where the 90th percentile can be ascertained for individual species (e.g. shrimp), the estimates are close to that obtained for seafood overall, and c) many consumers eat different species of fish. Alkylated homologues assumed to have similar toxicities to the parent compound. Anthracene and phenanthracene were combined because routine chemical analysis does not distinguish between the analogues of these two compounds.

Cancer risk-(q*)-based criteria:	**q***
Fluoranthene:	[34ng x (70/5)]/[120g x 0.2] = 15ng/g or 0.015ppm
Pyrene:	[34ng x (70/5)]/[120g x 0.13] = 23ng/g or 0.025ppm
Benz(a)anthracene:	[34ng x (70/5)]/[120g x 0.014] = 212ng/g or 0.2ppm
Chrysene:	[34ng x (70/5)]/[120g x 0.013] = 229ng/g or 0.25ppm
Benzo(a)pyrene:	[34ng x (70/5)]/[120g] = 3ng/g or 0.003pm

One-in-a-million increase in the lifetime upper bound cancer risk adjusted to account for exposures which are expected to last longer than 5 years (70/5 yr). For any sample containing fluoranthene, pyrene, benz(a)anthracene, chrysene, or benzo(a)pyrene, the sum of the individual ratios of the detected levels cannot exceed 1.