Overview of FDA's Seafood Sensory Program and Sensory Test Procedure

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Abstract

The Food and Drug Administration (FDA) has the authority to ensure the safety and wholesomeness of fish and fishery products. This authority includes protecting consumers from decomposed seafood (Section 402(a)(3) of the Food, Drug and Cosmetic Act). Sensory analysis (detecting odors of decomposition) is a fundamental tool used by FDA, other government agencies, and the seafood industry, to screen for adulterated product. FDA has developed a system to qualify sensory analysts based on their level of demonstrated expertise and defined criteria. This document provides an overview of the Seafood Sensory Program at FDA, including information on seafood sensory product categories, sensory analyst qualifications, and evaluation of sensory analysts. This document also provides a description of the FDA's sensory testing procedure, including information on collective decision-making, thawing frozen product, and handling of different product forms.

Key Words: seafood decomposition, sensory examination, sensory analyst qualifications, collective assessment, National Seafood Sensory Expert

Overview of the Seafood Sensory Program at FDA

Congress has given the Food and Drug Administration (FDA) the authority to ensure the safety and wholesomeness of fish and fishery products (referred to collectively as seafood for simplicity) that enters U.S. commerce. This includes domestically produced seafood as well as imported seafood products from various foreign processors. This authority includes protecting consumers from decomposed seafood (Federal Food, Drug, and Cosmetic Act, Section 402(a)(3)). The presence of decomposition in seafood can be indicative of undesirable exposure associated with lax harvesting, handling, manufacturing, storage and/or distribution practices that are conducive to microbial contamination, growth, and activity. Reliable detection of decomposition provides an efficient and effective screening of food products that may otherwise contain contaminants that could pose a hazard to consumer's health.

Evaluation of seafood for the presence of decomposition by sensory analysis is a fundamental method used by FDA, other government agencies, and the seafood industry to screen for adulterated product. When chemical analysis of decomposition is conducted in conjunction with sensory analysis, sensory analysis is generally performed first to determine which subsamples might best be analyzed for chemical indicators of decomposition. There are also situations where the agency may conduct chemical testing in the absence of sensory results.

FDA has maintained a cadre of specially trained seafood sensory analysts for regulatory purposes since at least the 1930's, and the agency's seafood sensory capability has become highly respected for its expertise throughout the international community. The

success and integrity of FDA's seafood sensory assessments rest primarily with the care and purposeful attention FDA gives to prepare training samples and materials, to train analysts, and to qualify analysts for making reliable regulatory decisions.

Sensory analysis by qualified analysts is an internationally recognized method used by several government agencies and standards setting organizations inside and outside of the United States including:

- US Food and Drug Administration
- US Department of Commerce, National Oceanic and Atmospheric Administration (NOAA), e.g., NOAA Seafood Inspection Manual (1), US Grade Standard for Fish Fillets (2)
- Canadian Food Inspection Agency
- International Standards Organization ISO 8586:2012 Sensory analysis — General Guidelines for The Selection, Training and Monitoring of Selected Assessors and Expert Sensory Assessors (3)
- Codex Alimentarius CAC-GL 31-1999 Guidelines for the Sensory Evaluation of Fish and Shellfish in Laboratories (4)

It takes many years of experience to properly recognize sensory evidence of decomposition in seafood products, and to distinguish it from other product-related sensory attributes that may be present but are not caused by decomposition. Failing to detect adulterated product can be costly to consumers and, in the case of some seafood products, could present a health hazard. Conversely, incorrect decisions by FDA can be extremely costly to the importer/owner of rejected product. It is essential that analysts are properly qualified and strive to make correct decisions on each subsample.

To ensure FDA's sensory personnel are properly qualified and kept updated on sensory techniques, they are regularly assessed for consistency and accuracy. Reliable detection of decomposition in seafood by sensory analysis at FDA is accomplished by implementation of a rigorous qualification system and the meeting of specific criteria, which include routine training, testing, and evaluation of all sensory analysts. A key component in FDA's sensory training and maintenance objectives is the preparation and presentation of authentic sample packs for examination. Authentic sample packs should be prepared from seafood products with a known history from the time they are captured or harvested and are subjected to controlled spoilage that patterns various commercial exposures. Commercial samples are also used for training purposes to demonstrate sensory attributes that may be present but may be difficult to reproduce. At times, it may be necessary to prepare authentic sample packs in locations throughout the world in order to reproduce natural decomposition attributes common to the fishery product under conditions consistent with the commercial environment in which the products are produced.

Seafood Sensory Product Categories and Terminology

There are six sensory product categories, and they are described in the Laboratory

Manual (5), Volume IV Section 8 Sensory Analysis. That section of the Laboratory Manual also includes definitions of some of the terms used in the sensory analysis of seafood.

Sensory Analyst Qualification

FDA has established criteria to ensure that seafood sensory analysts receive appropriate training and meet standardized requirements, including demonstrable levels of proficiency, to qualify them in a carefully managed and consistent manner. Sensory analysts are qualified at four levels of expertise:

1) Level I Sensory Analyst (Seafood Sensory Candidate)
2) Level II(A) Sensory Analyst
3) Level II(B) Sensory Analyst
4) Level III Sensory Analyst (National Seafood Sensory Expert, or NSSE)

An analyst's qualification status is based on multiple criteria, including the amount of time working side-by-side with more experienced analysts, exposures to an appropriate number of samples overall as well as within specific product categories, and demonstrated proficiency at correctly assessing test samples in the specific product categories.

A Level I Analyst (Seafood Sensory Candidate) is an analyst who has indicated an interest in performing sensory analyses and has read relevant sections of the compliance programs and Laboratory Manual. The analyst is assigned to work side-by-side with one or more of the more experienced sensory analysts. The Level I Analyst participates in the sensory analysis and signs the worksheet in order to gain exposure and experience. However, the analyst's findings are not recognized as official findings for regulatory purposes. The Level I Analyst begins attending national and, when available, in-house seafood sensory training workshops along with more experienced analysts. A Level I Analyst is considered for upgrade to a Level II(A) Analyst in a product category after meeting established criteria. Depending on the intensity of the training exposure and the sensory acuity of the analyst, it takes analysts different lengths of time (typically a year or more) to attain proficiency and meet the criteria for upgrade to a Level II(A) Analyst in the different product categories.

Once an analyst is upgraded to a Level II(A) Analyst in a specific product category, the analyst's findings are recognized as official findings for regulatory purposes. The analyst may examine for the presence of decomposition but can't confirm its presence. Any decomposition identified by the Level II(A) Analyst must be confirmed by a Level II(B) Analyst for that product category or by a Level III Analyst. After meeting the qualification criteria at the Level II(A) Analyst level for a period of time (typically an additional two years or more), the analyst may be considered for upgrade to a Level II(B) Analyst in a product category.

A Level II(B) Analyst in a specific product category may perform a confirmation sensory analysis of samples in that category, to determine if the decomposition assessed by a

Level II(A) Analyst or another Level II(B) Analyst is confirmed. Individuals with Level II(B) Analyst ratings may occasionally be called upon to assist with the training of sensory analysts in national or regional seafood sensory workshops. Individuals with Level II(B) Analyst or higher ratings may also occasionally be called upon to assist with seafood Hazard Analysis and Critical Control Point inspections, HACCP.

A Level III Analyst (NSSE) has typically been performing as a Level II(B) Analyst in all six product categories for at least an additional five years and has accepted a full-time leadership commitment to sensory analysis of seafood at FDA and the preservation of sensory analysis as a reliable analytical instrument at the agency. An NSSE also has considerable experience with sensory issues outside of routine regulatory examinations, and more responsibility for maintaining and enhancing the integrity of the agency's sensory capabilities. An NSSE generally has had significant exposure to industry practices and may occasionally participate in international sensory harmonization activities. An NSSE may be called upon to assist in training analysts from various government agencies and is often required to conduct workshops to train industry personnel (domestically and internationally), as well as analysts from private laboratories that generate sensory findings to be submitted to the agency on behalf of owners of goods. An individual in this category has teaching skills and abilities for training other analysts and is responsible for preparing authentic sample packs for such training and testing.

An NSSE may also be called upon to work with headquarters on assignments and assist with the development of sensory-related policies. In addition, an NSSE may participate in research, and/or provide consultation to researchers, investigating advancements in sensory development or decomposition detection methods. Analysts at this level also actively participate in the assessment and evaluation of the qualification level of other seafood sensory analysts.

Some analysts are more proficient in some seafood product categories than others, and because of this, may qualify for Level II(A) Analyst status in some categories but not in others. For various reasons, some analysts may not advance to Level II(B) Analyst or Level III Analyst (NSSE) levels of sensory expertise. Attending many workshops does not substitute for the knowledge and expertise acquired by routinely examining product and making reliable regulatory assessments.

Evaluations of Analysts

A panel of agency stakeholders evaluate and make final determinations of an analyst's sensory capabilities and qualifications. The panel consists of representatives from three groups within the agency including (1) NSSE(s), (2) a principal(s) from ORTS/DSPC involved with auditing, maintenance, and administration of the agency's seafood sensory field laboratory activities, and (3) DSS technical staff involved in the assessment of decomposition in seafood and seafood decomposition enforcement, policy, compliance, and research programs.

Sensory assessments are susceptible to accusations of subjectivity by owners of goods

that are found violative when they are unfamiliar with the rigors of FDA's development, assessment, and management of its seafood sensory analysts and their capabilities. Respect for, and adherence to, agency protocols regarding analysts' training and qualifications, in addition to sample handling, analysis, and documentation, render FDA's sensory findings reliable. Sensory analysis is a respected and effective analytical tool to protect consumers from decomposed fish and fishery products; it is recognized by industry and governments worldwide, and FDA's seafood sensory analysts are among the best in the world.

FDA's Sensory Test Procedure

A. Products are examined by analysts qualified in the relevant sensory product category.
B. If an analyst believes their sensory acuity is impaired (due to illness, injury, etc.), then the analyst shall immediately contact the supervisor and shall not participate in sensory sample testing until their sensory acuity recovers.
C. Samples shall be analyzed by more than one analyst.
    1. If only two sensory analysts are available to conduct a sensory examination, one analyst is considered to initiate the sensory examination and must be at least a Level II(A) in the product category. The second analyst must be either a Level II(B) in the product category or Level III. As circumstances warrant, the initiating analyst may conduct their examination in isolation, but must be present when the second analyst conducts their examination, and any findings of decomposition must be agreed upon by both analysts.
    2. If three or more sensory analysts participate in a sensory examination, one analyst must be at least a Level II(A) in the product category, and at least one other analyst must either be a Level II(B) in the product category or Level III. If the sample is assigned to a Level I sensory analyst, the analysis cannot proceed unless a minimum of a Level II(A) analyst and Level II(B) analyst are participating in the examination; the Level I analyst may participate along with them.
    3. All the qualified analysts performing the examination will make a collective assessment regarding each subsample in the sample. In order to call a subsample failing, all analysts must reach a unanimous decision. If any qualified analyst disagrees that the subsample fails, then the subsample passes.
D. Level III analysts (NSSEs) are authorized to examine regulatory samples on their own, as circumstances warrant.
E. Prior to issuing a lab classification, i.e., prior to closing out the sample, the following applies:
    1. If lab analysts encounter unusual odors or have questions, they should

consult with an NSSE(s) for guidance. An NSSE(s) may direct that the sample be sent to them for further analysis, or request that an additional sample be collected, as appropriate.

2. When sending a regulatory sample to an NSSE for evaluation, follow guidance in the Laboratory Manual, including sections related to chain of custody and reporting of results.

F. Products are examined by the following methods:

1. Frozen product is typically thawed in running cool water to approximately room temperature. Where necessary, samples such as large fish blocks may be partially or fully thawed under refrigeration in a refrigeration unit suitable for regulatory sample storage. Flesh of the product is broken and brought close to the analyst's nose to detect odors present in the individual piece under examination. This may require breaking the product at more than one location to make a final decision.
    a. Subsamples will be examined individually. In the majority of surveillance samples, between 3 and 24 subsamples will be examined.
    b. For samples such as large shrimp or scallops, a minimum of 1 pound of product as determined by declared count/pound will be examined individually from each subsample.
    c. Generally, approximately 1 pound of product is to be examined from each subsample.
        i. If the subsamples delivered to the lab exceed 1 pound each, remove approximately 1 pound of representative product from each subsample for examination. When the product consists of separate pieces, portions, steaks, etc., the analyst should remain indifferent to the number of pieces that the 1-pound portion yields at the time of drawing product from the subsample to be examined; instead, randomly draw the number of pieces that most closely approximates 1 pound.
        ii. Exceptions to the 1-pound subsample, such as canned/ pouched product, can typically be found in the Compliance Program(s).
        iii. Subsamples consisting of a single piece, e.g., a whole fish, or a loin or fillet from a larger fish, should be examined as collected, even when larger than 1 pound.
    d. Liquid packing media, e.g., water, broth, and oil, will be drained. When necessary, the meat will be rinsed with water.
    e. For breaded or seasoned products, remove the breading or seasoning with water to the extent necessary to conduct sensory examination.
    f. In the case of large frozen blocks of seafood product, remove approximately 5 pounds of product from each block and examine each of these sub-units separately as detailed above.
2. Due to the small size of certain seafood products (raw peeled & de-veined shrimp, cooked and peeled shrimp, etc. that are greater than 50 count per pound) it is necessary to divide a subsample before examining. For a

subsample size of 1 pound, the subsample will be divided into 6 equivalent-sized (handful) portions and analyzed by breaking into each handful. For subsample sizes greater than 1 pound, select approximately 1 pound from the subsample and perform the analysis as detailed above.

3. Cooked ready-to-eat seafood products may be examined by taste as well as odor to detect decomposition.
4. If necessary, the product may be heated or cooked in a microwave oven to facilitate the release of odors and to determine differences in characteristics between uncooked and cooked states, which may aid in determining the presence of decomposition.

G. To prevent olfactory and/or gustatory fatigue, sensory analysts should take breaks as needed to allow these senses to clear.
H. Sensory analysts will wash their hands, or change or wash gloves, as necessary to prevent transfer of odors of decomposition/contamination from one sample portion to another.
I. Sensory results are recorded at the time of analysis on the Analyst Worksheet.

Acknowledgements
The authors would like to thank Terriann Reilly (retired, formerly with NOAA, National Marine Fisheries Service, Seafood Inspection Program) for sharing her knowledge of sensory science and for providing sound scientific guidance.

References

1. NOAA Seafood Inspection Manual, accessed 03 May 2024, https://www.fisheries.noaa.gov/national/seafood-commerce-trade/seafood-inspection-manual
2. US Grade Standard for Fish Fillets, accessed 05 June 2024, https://www.fisheries.noaa.gov/action/advanced-notice-revision-us-grade-standard-fish-fillets
3. ISO 8586:2012, Sensory analysis — General Guidelines for The Selection, Training and Monitoring of Selected Assessors and Expert Sensory Assessors
4. Codex Alimentarius CAC-GL 31-1999 Guidelines for the Sensory Evaluation of Fish and Shellfish in Laboratories
5. Lab Manual, accessed on 16 May 2024, https://www.fda.gov/science-research/field-science-and-laboratories/field-science-laboratory-manual

Supporting Documents

Additional documents are listed in the Laboratory Manual, Volume IV Section 8 Sensory Analysis (Field Science - Laboratory Manual | FDA).

A. CPG Sec. 540.370 Fish and Fishery Products – Decomposition
B. CPG Sec. 540.525 Scombrotoxin (Histamine) – forming Fish and Fishery Products - Decomposition and Histamine
C. CP 7303.842 Seafood Processor, Products, and Importer Inspection Program Part IV, Project 03: Decomposition
D. U.S. Food and Drug Administration Fish and Fishery Products Hazards and Controls Guidance
E. Code of Practice for Fish and Fishery Products CODEX CAC/RCP 52-2003
F. Guidance on sensory testing and monitoring of seafood for presence of petroleum taint following an oil spill. 2001, Reilly, Terriann I. ; York, R. K. Series: NOAA technical memorandum NOS-OR&R 9 (https://repository.library.noaa.gov/view/noaa/22780)
G. ASTM STP 433 Basic Principles of Sensory Evaluation
H. ASTM Committee E-18 on Sensory Evaluation of Materials and Products, 1981. STP 758 – "Guidelines for the Selection and Training of Sensory Panel Members"
I. "Handbook of Seafood and Seafood Products Analysis", 2009, CRC Press, Chapter 26, Sensory Descriptors, by G. Hyldig, pp. 481-497
J. "Sensory Characteristics of Selected Species of Freshwater Fish in Retail Distribution." E. Chambers, IV and A. Robel 1993. Journal of Food Science, vol. 58 pp. 508-512
K. ISO 13300 Sensory analysis – General guidelines for the staff of a sensory evaluation laboratory – Part 2: Recruitment and training of panel leaders
L. LIB 1103 Organoleptic Examination of Frozen Cooked, Peeled, Deveined Tiny Shrimp for Decomposition
M. LIB 1912 Preparation of Authentic Packs of Decomposed Seafood for Training Purposes