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Standard Guide for Irradiation of Finfish and ~~Shellfish~~ Aquatic Invertebrates Used as Food to Control Pathogens and Spoilage Microorganisms[1]

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INTRODUCTION

The purpose of this guide is to present information on the ~~irradiation~~ use of ~~finfish and shellfish to eliminate~~ ionizing radiation for eliminating or ~~reduce, or both,~~ reducing the numbers of ~~certain~~ pathogenic microorganisms and parasites~~,~~ and ~~to extend the refrigerated shelf-life of seafood by~~ for reducing the numbers of ~~certain~~ spoilage microorganisms ~~present.~~ on finfish and aquatic invertebrates. Information on the handling of finfish and ~~shellfish~~ aquatic invertebrates before receipt by the irradiation facility and after shipment from the facility is also provided.

This guide is intended to serve as a set of recommendations to be followed when using irradiation technology where approved by an appropriate regulatory control authority. It is not to be construed as setting forth rigid requirements for the use of irradiation. While the use of irradiation involves certain essential requirements to attain the objective of the treatment, ~~there are~~ some parameters ~~that~~ can be varied in optimizing the ~~process. Hence, this document should be regarded as a guide rather than a rigid code of practice.~~ process.

This guide ~~has been prepared from~~ is based on a guideline published by the International Consultative Group on Food Irradiation (ICGFI) at the initiation of the Joint Food and Agricultur~~al~~e Organization/International Atomic Energy Agency Division of Nuclear Techniques in Food and Agriculture, which serves as the Secretariat to the ICGFI.

1. Scope

1.1 This guide outlines procedures and ~~requirements~~ operations for the irradiation of raw, untreated, fresh (chilled), or frozen finfish and aquatic invertebrates, while ensuring that the irradiated product is safe and wholesome.

1.1.1 Aquatic Invertebrates include molluscs, crustacea, echinoderms, etc.

1.1.1.1 Molluscs include bivalve shellfish, such as clams, mussels, and oysters; snails; and cephalopods, such as squid and octopus.

1.1.1.2 Crustacea include shellfish such as shrimp, lobster, crabs, prawns and crayfish.

1.1.1.3 Echinoderms include sea urchins and sea cucumbers.

1.2 This guide covers absorbed doses used to reduce the microbial and parasite populations in ~~shellfish~~ aquatic invertebrates and

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finfish. Such doses typically are below 10 kGy **(1)** .[2]

1.3 The use of vacuum reduced-oxygen packaging (vacuum or modified atmosphere, and including products packed in oil) with irradiated, raw seafood product is not covered by this guide. The anaerobic environment created by redusced-ofxygen packaging provides the potential for outgrowth of, and toxin production from, *Clostridium botulinum* spores which can grow in the anaerobic environment created by vacuum packaging. spores.

1.4 This guide does not cover the irradiation of smoked or dried fish to reduce microbial load or to control insect infestation.

1.5 *This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety and health practices and determine the applicability of regulatory limitations requirements prior to use.*

2. Referenced Documents

2.1 *ASTM Standards:* [3]

E 170 Terminology ies Relating to Radiation Measurements and Dosimetry[2]

Annual Book

[2] The boldface numbers in parentheses refer to the list of ASTM Standards, Vol 12.02. references at the end of this standard.

[3] For referenced ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For *Annual Book of ASTM Standards,* Vol 15.09. volume information, refer to the standard's Document Summary page on the ASTM website.

E 1204 Practice for Dosimetry in Gamma Irradiation Facilities for Food Processing[2]
E 1261 Guide for the Selection and Application of Dosimetry Systems for Radiation Processing of Food[2]
E 1431 Practice for Dosimetry in Electron and Bremstrahlung Irradiation Facilities for Food Processing[2]
E 1539 Guide for Use of Radiation-Sensitive Indicators[2] Dosimetry
F 1416 Guide for the Selection of Time-Temperature Indicators
F 1640 Guide for Selection and Use of Packaging Materials for Foods to be Irradiated

2.2 *ISO/ASTM Standards:*[3]

51204 Practice for Dosimetry in Gamma Irradiation Facilities for Food Processing
51261 Guide for the Selection and Application of Dosimetry Systems for Radiation Processing
51431 Practice for Dosimetry in Electron and Bremsstrahlung Irradiation Facilities for Food Processing
51539 Guide for Use of Radiation-Sensitive Indicators

2.3 *Codex Alimentarius Commission Recommended International Codes and Standards:*[4]

Codex Stan 1 General Standards for the Labelling of Prepackaged Foods
Codex Stan 19 Recommended International Code of Practice for the Operation of Irradiation Facilities for the Treatment of Food
Codex Stan 106 Codex General Standard for Irradiated Foods
CAC/RCP 9 Recommended International Code of Practice for Fresh Fish
CAC/RCP 16 Recommended International Code of Practice for Frozen Fish
CAC/RCP 17 Recommended International Code of Practice for Shrimps and Prawns
CAC/RCP 18 Recommended International Code of Hygienic Practice for Molluscan Shellfish
CAC/RCP 24 Recommended International Code of Practice for Lobsters
CAC/RCP 27 Recommended International Code of Practice for Minced Fish Prepared by Mechanical Separation
CAC/RCP 28 Recommended International Code of Practice for Crabs
CAC/RCP 37 Recommended International Code of Practice for Cephalopods
CAC/RCP 20 Code of Ethics for International Trade in Food
CAC/RCP 42 Sampling Plans for Prepackaged Foods (AQL 6.5)

3. Terminology

3.1 *Definitions*—Other terms used in this guide may be defined in Terminology E 170.

3.1.1 *absorbed dose*—the quantity of energy from ionizing radiation absorbed by a quantity per unit mass of food. specified material. The special name for the SI unit for absorbed dose is the gray (Gy). The former name for the unit of absorbed dose was rad (1 rad = 0.01 Gy). One gray is equal to one joule of absorbed energy per kilogram of specified material. Formerly, the unit of absorbed dose was the rad (1 rad = 0.01 Gy).

3.1.1.1 *Discussion*—A commonly used standard definition of absorbed dose appears in Terminology E 170.

3.1.2 *dose distribution*—the variation in absorbed dose within a product unit exposed to ionizing radiation.

3.1.3 *product unit*—one or more containers of product collectively transported through the irradiator as a whole, for example, a box, tote, pallet, or carrier.

3.1.4 *shellfish*—includes molluscan bivalves, cephalopods, and crustacea.

3.1.5 *transport system*—the conveyor or other mechanical system used to move the product to be irradiated through the irradiator.

4. Significance and Use

4.1 Irradiation at

4.1 Absorbed doses of or below 1 kGy can inactivates some parasites, such as the broad fish tapeworm (*Diphyllobothrium latum*Dibothrocephalus latus) **(1)(2)**.

4.2 Irradiation, at absorbed

4.2 Absorbed doses below 10 kGy, can reduces or eliminates vegetative cells of pathogenic sporeforming and non-sporeforming microorganisms, such as *Clostridia* spp., spp., *Vibrio* spp., *Salmonellae*, *Listeria monocytogenes*, or *Staphylococcus aureus*, that may be present in fresh or frozen seafood, making these products safer for human consumption.

4.2.1 Doses product.

4.2.1 Absorbed doses below 10 kGy may can reduce the numbers of some spores, but are not adequate to reduce the potential health risk from microbial spores or toxins **(23)**.

4.3 Irradiation, at absorbed

4.3 Absorbed doses below 10 kGy, can reduces or eliminates the vegetative cells of sporeforming and non-sporeforming microorganisms, such as *Bacillus* or or *Pseudomonas* species, that cause spoilage of fresh seafood products, product, thus extending the refrigerated shelf life of the fresh seafood in many cases **(34)**.

[4] Available from Joint FAO/WHO Food Standards Program, Joint Office, Food and Agriculture Organization of the United Nations, Via delle Terme di Caracalla, 00100 Rome, Italy.

5. Harvest/Raw Material

5.1 Follow relevant Recommended International Codes of Practice (RCP) and Standards of Good Manufacturing Practice of the Codex Alimentarius Commission (CAC) in for maintaining the initial quality of the fresh or frozen seafood product during handling from the time of harvest through the time of sale to the consumer **(4)**. See CAC/RCP 9, CAC/RCP 16, CAC/RCP 17, CAC/RCP 18, CAC/RCP 24, CAC/RCP 27, CAC/RCP 28, CAC/RCP 37, and CAC/RCP 20.

5.2 In handling, preparing, freezing, storing, and thawing finfish and shellfish intended for irradiation, take precautions at all times to minimize microbial contamination and outgrowth. Use standards as high as those applied in the processing or preparation of seafood for the frozen or fresh markets.

5.3 Deliver seafood to the irradiation facility without delay, such that irradiation occurs as close to the time of harvest as possible. Seafood approaching the end of its shelf life should not be irradiated in an attempt to extend that shelf life. Irradiation can improve seafood from a public health aspect, only through its effect by reduction of the microbial population within the product. However, there are mechanisms other than microbial action (for example, oxidative degradation) that cause seafood to spoil that need to be considered **(5)**. See CAC/RCP 9, CAC/RCP 16, CAC/RCP 17, CAC/RCP 18, CAC/RCP 24, CAC/RCP 27, CAC/RCP 28, CAC/RCP 37, and CAC/RCP 20.

5.2 In handling, preparing, freezing, storing, and thawing finfish and aquatic invertebrates intended for irradiation, take precautions at all times to minimize microbial contamination and outgrowth. Use standards of hygiene as high as those applied in the processing or preparation of product for the frozen or fresh markets.

5.3 Deliver product to the irradiation facility without delay, such that irradiation occurs as close to the time of harvest as possible. Products approaching the end of their shelf life should not be irradiated in an attempt to extend that shelf life.

NOTE 1—While irradiation can improve finfish and aquatic invertebrates from a public health aspect by reducing the microbial and parasite populations within product, chemical reactions (for example, oxidative degradation) that cause product to spoil also need to be considered when assessing the appropriateness of radiation treatment **(6)**.

6. Packaging

6.1 Packaging seafood product prior to irradiation is one means of preventing post-irradiation contamination.

6.1.1 Pack seafood using

6.2 Use packaging materials suitable to the product considering any planned processing (including irradiation) and consistent with any regulatory requirements.

6.1.2 The irradiation procedure will be facilitated if the product packages are geometrically well defined and uniform. With requirements (see Guide F 1640).

6.3 With certain irradiation facilities, it may be necessary to limit use to particular package shapes and sizes. See ISO/ASTM Practices E 1204 51204 and E 1431.

6.2 The size, shape, or product loading configuration of a product unit used to hold seafood for irradiation is determined largely by certain design parameters of 51431. Irradiation can be optimized if the irradiation facility. Critical parameters include the characteristics of product transport systems packages are geometrically well defined and of the radiation source as they relate to the dose distribution obtained within the product unit. Minimum and maximum dose limits may also affect the size, shape, or product loading configuration of the product unit (see 8.2). uniform.

7. Pre-Irradiation Product Handling

7.1 Inspect finfish and shellfish intended for irradiation product as soon as it is received arrives at the radiation processing facility to determine that they have it has been properly handled prior to receipt.

7.1.1 The arrival.

7.2 *Temperature Control of Product* :

7.2.1 The temperature of fresh seafood, product, excluding unshucked, live molluscan shellfish, received in the chilled state should be maintained as close to 0°C (32°F) as possible in accordance with good manufacturing practice (GMP) at all times. practices (GMPs). Care should be taken not to allow prevent freezing of the product. Pre-irradiation storage at the irradiation facility should be short; less than one day is recommended.

NOTE 1—Fresh seafood 2—Fresh product is usually stored and transported under crushed, melting ice. Where the cooling energy is provided by When refrigeration machinery (for example, reefers), is used, the risk of freezing exists.

7.12.2 The temperature of unshucked, live molluscan shellfish, received in the chilled state should be maintained between 4°C (39°F) and 7°C (45°F) in accordance with good manufacturing practice (GMP) at all times. GMPs. Pre-irradiation storage at the irradiation facility should be short; less than one day is recommended.

NOTE 23—To maintain unshucked molluscan shellfish in the live state, the storage temperature should be above 4°C (39°F).

7.12.3 The surface temperature of seafood product received in the frozen state should be maintained below − 18°C (0°F) at all times. below −18°C (0°F).

NOTE 34—Freezing does not provide an unlimited shelf life without loss of quality, and the pre-irradiation storage period should therefore be minimized. The effect of frozen storage on product quality will be a function of time, temperature, and amount degree of temperature fluctuation.

7.12.4 Handling and storage of seafood differently from the procedures that differ from those described in Sections 5 and 6, especially holding under refrigeration for an unduly long time, does do not constitute GMP. Such treatment may result in excessive bacterial growth and undesirable changes in the products. Irradiation can neither reverse these undesirable changes nor reverse the effects of GMP violations.

7.2 Inspect products.

7.3 Inspect all shipping documents arriving with the shipment to verify that they are complete and in order.

7.2.1 The accurate.

7.3.1 The documents should include a lot number or other means of traceability (see 12.1).

7.34 Use appropriate means, such as physical barriers, to keep non-irradiated and irradiated product separated at all times while at the irradiation facility. This is necessary because it may not be possible to distinguish non-irradiated from irradiated product by inspection.

NOTE 45—Radiation-sensitive indicators (RSIs), such as labels, papers, or inks that undergo a color change or become colored when exposed to ir radiation in the pertinent dose range are commercially available. The purpose of these These indicators is to determine visually may be useful within the irradiation facility as a visual check for determining whether or not a product has been irradiated, rather than exposed to measure the absorbed dose received by the product. These indicators radiation source. They are not dosimeters intended for measuring absorbed dose and must not be used as a substitute for proper dosimetry. Information about dosimetry systems and the proper use of RSIs is provided in Guides E 1261 51261 and E 1539, 51539, respectively.

7.45 Plan preparatory operations for irradiation, such as, but not limited to, dosimeter placement, label placement, and reconfiguration of product in the product unit, to permit expeditious handling of consecutive batches such that batches. These preparatory steps, in addition to the placement of the product on the transport system and the time required for the irradiation treatment are all within contribute to the cumulative time and temperature range exposure that will prevent influence the extent of deterioration by chemical or microbial biological mechanisms or the development of microorganisms of public health significance (see Practices E 1204 51204 and E 1431 51431, and Guide E 51261).

7.5.1 The size, shape, and product-loading configuration of a product unit used to hold product for irradiation are determined largely by certain design parameters of the irradiation facility. Critical parameters include the characteristics of product transport systems and of the radiation source as they relate to the dose distribution obtained within the product unit. Pre-determined minimum and maximum dose limits may also influence the choice of size, shape, and product-loading configuration of the product unit.

8. Irradiation

8.1 *Scheduled Process*—Irradiation of food should conform to a scheduled process. A scheduled process for food irradiation is a written procedure that is used to ensure that the absorbed-dose range and irradiation conditions selected by the radiation processor are adequate under commercial processing conditions to achieve the intended effect on a specific product in a specific facility. The scheduled process should be established by qualified persons having expert knowledge in of the irradiation requirements specific for the food and the processor's irradiation facility **(67)**.

8.2 *Radiation Sources*—The sources of ionizing radiation that may be employed in irradiating seafood products food are limited to the following (see Codex Stan 106):

8.2.1 *Istopic Sources*—Gamma rays from the radionuclides ^{60}Co (1.17 and 1.33 MeV) or ^{137}Cs (0.66 MeV);

8.2.2 X-rays generated from machine sources operated at or below an energy level MeV), and

8.2.2 *Machine Sources*—X-rays and accelerated electrons.

NOTE 6—The USA, other governments, and the Codex Alimentrius Commission currently limit the use of x-rays with energies not to exceed 5 MeV; and

8.2.3 Electrons generated from machine sources operated at or below an energy level MeV and the energies of electrons not to exceed 10 MeV.

8.3 *Absorbed Dose*—Food irradiation specifications usually may include minimum and maximum absorbed dose limits, a. A minimum necessary absorbed dose may be specified to ensure that the intended effect is achieved, and a maximum absorbed dose may be based on government regulations resulting from a safety assessment or be stipulated to prevent product degradation. For a given application, one or both of these limits may be prescribed by regulation. It is therefore necessary, prior to the irradiation of product, to determine the capability of a specific establish an irradiation protocol to provide an that will ensure that the absorbed dose within these limits. Once this capability requirements can be satisfied. This is e accomplished through absorbed-dose mapping to determine the magnitudes and locations of the minimum and, maximum absorbed doses in the product units at the time of actual processing. It is necessary to monitor identify and record the actual absorbed dose absorbed-dose extremes for each production run. For more information on these dosimetric procedures, see Practices E 1204 51204 and E 1431 51431 and Guide E 1261. 51261.

NOTE 57—In general, irradiation of the same product more than once is not recommended. See Codex Stan 106.

8.4 *Product Temperature*—During irradiation, maintain the temperature of unshucked, live molluscan shellfish between 4°C (39°F) and 7°C (45°F). Maintain the temperature of all other fresh seafood product below 4°C (39°F) at any time. (39°F). Maintain frozen product below −18°C (0°F) at all times during processing.

NOTE 68—Absorbed doses up to 2 kGy are not lethal to unshucked molluscan shellfish. Therefore, temperatures during irradiation should be kept between 4°C and 7°C to maintain their viability **(7,8)(8,9). The upper limit of 4°C for fresh seafood product other than unshucked, live molluscan shellfish was developed with regard to** *C. botulinum* **Type E which (***C. botulinum* **may grow below that temperature, 4°C , but not produce toxin over the shelf life of the product. Therefore, the** *C. botulinum* **hazard is not likely to occur for products covered by this standard (see 1.3). Usually, the heat capacity of chilled or frozen seafood product is large enough to maintain the product temperature, even at the surface, during the relatively short time needed for irradiation.**

8.4.1 In cases where seafood product is irradiated while in melting ice, provisions should be made to collect and discard the drip from the melting ice for sanitation and prevention of facility contamination.

9. Post-Irradiation Handling and Storage

9.1 Handle and store irradiated seafood products product in the same manner as nonirradiated seafood products, non-irradiated product, that is, in accordance with GMPs, to avoid recontamination. For fresh seafood, product, excluding unshucked, live molluscan shellfish, received in the chilled state, maintain the post-irradiation temperature as close to 0°C (32°F) as possible at all times. possible. For unshucked, live molluscan shellfish irradiated in the chilled state, maintain the post-irradiation temperature between 4°C (39°F) and 7°C (45°F) at all times. (45°F). For all frozen seafood, product, maintain the temperature below −18°C (0°F) at all times. below −18°C (0°F).

NOTE 79—Some chill rooms may not be designed to cool seafood products product but only to maintain their the temperature after they have it has been cooled by ice or other means.

9.2 Use appropriate means, such as physical barriers, to keep irradiated product separated from non-irradiated product at all times while at the irradiation facility. This is necessary because it may not be possible to distinguish irradiated product from non-irradiated product by inspection. Radiation Sensitive indicators may be useful (see Note 5) as an additional means for indicating that product has passed through the irradiation zone.

10. Criteria for Assessing Irradiation Efficacy

10.1 An irradiation protocol should be designed to accomplish specific goals, such as reduction of pathogens or extension of shelf life of seafood products. product. Proper dosimetric procedures should be followed to ensure that the absorbed dose necessary to accomplish those goals has been delivered to the product. The following criteria may be used to aid in the design of the irradiation protocol:

10.1.1 *Irradiation for Control of Pathogenic Bacteria* —The numbers of pathogenic bacteria that can result in an infectious product vary with the specific bacterial strain and the susceptibility of the consumers involved. The adoption of criteria, such as criteria analogous to those used for heat pasteurization of milk or sterilization of low-acid canned food scheduled processes is the most reasonable approach in the absence of microbiological end product point criteria for expected pathogenic bacteria **(9, 10)(10,11).**

10.1.2 *Irradiation for Inactivation of Parasites*—Generally, the criterion for parasites should be that the uncooked, irradiated product be noninfectious/ or noninvasive for the parasites to be inactivated.

NOTE 810—The absorbed dose needed to ensure the inactivation of *Anasakis* spp. may be above the maximum absorbed dose tolerated by some fishery products, thus resulting in unacceptable organoleptic changes in those products **(34)**.

10.1.3 *Irradiation for Reduction of Spoilage Microorganisms for Shelf-Life Extension*—Generally, the criterion for assessing shelf-life extension should be the aerobic plate count for psychrotrophic seafood microorganisms. Various species of bacteria may be responsible for spoilage; their significance depends, in part, on the species and the harvest location and conditions. R The degree of reduction in levels or specification of absolute levels as final criteria for specifying shelf-life extension cannot be specified established unless local conditions and requirements are known that permit establishment of a base line level of spoilage microorganisms.

10.2 Failure to meet the established criteria should direct attention to the entire processing and distribution chain, and the reestablishment, if necessary, of GMP. Such failure should not serve as the sole basis for regulatory action. GMPs. The hazard analysis critical control point (HACCP) system or another similar product control system should be applied to the processing and distribution chain **(112,123)**.

11. Labeling

11.1 *General Considerations*—Because some consumers may wish to choose between irradiated and non-irradiated foods, many governments have adopted labeling requirements (see section 5.2, Codex Stan 1) **(134)**. Labeling should not only identify the food as irradiated, but should also serve to inform the purchaser of the purpose and benefits of the treatment. An increasing number of Some countries are adopting the internationally recognized "Radura" symbol as a means of labeling (see Fig. 1). In some countries, the symbol must be accompanied by a statement, such as "treated by irradiation" or "treated by ionizing energy," and may also contain a statement explaining the purpose of the treatment, such as, "to extend refrigerated shelf life" or "to eliminate pathogenic bacteria."

11.2 *Unshucked, Live Molluscan Shellfish* :

11.2.1 To facilitate tracing molluscan shellfish from the retail dealer through the original shipper to the harvester and harvest area, a system of documentation is frequently used. For example, each container of unshucked shellfish could be accompanied with

FIG. 1 Radura Logo (Green)

a dealer's tag, containing all information needed to trace the shellfish back to a specific harvester and harvest area. ~~Do not remove these~~ These tags must not be removed from containers to be ~~irradiated. They should~~ irradiated and must remain attached until the container is empty.

11.2.2 Each individual package of shucked shellfish should include a "Sell By" date and a "Date Shucked" date on the principal display panel.

NOTE ~~9~~11—The U.S. recommendations for labeling of shellfish ~~are~~ is provided in the National Shellfish Sanitation Program Manual of Operations.[5]

12. Documentation

12.1 The irradiation facility should establish records of its operation to enable verification of the irradiation ~~treatment. Ensure that~~ treatment.

12.1.1 Identify each lot of ~~seafood~~ product that has been irradiated ~~is identified~~ by a lot number or other means, that allow it to be traced to its origin. Use this identifier on all documents.

12.1.~~1~~2 Record and document the date the product arrives at the facility, the date the lot is irradiated, the starting and ending times of the irradiation, the date the product leaves the facility, the name of the operator, and any special conditions that could affect the irradiation process or the irradiated product.

12.1.~~2~~3 Record and document all dosimetry data associated with product absorbed-dose mapping and routine processing **(1~~4~~5,15~~6~~)**. See also Practices ~~E 1204~~ 51204 and ~~E~~ 51431.

12.1.~~3~~4 Record and document any deviation from the normal radiation treatment run, including extended periods of time that the product may spend on the transport system, and any increase in temperature beyond the allowable limit.

NOTE 1~~0~~2—~~T~~Application of time-temperature indicators ~~are~~ is one means of measuring the combined time and temperature history of a product (see Guide F 1416).

12.2 Audit all documentation periodically to ensure that records are accurate and complete. If deficiencies are found, ensure that corrective action is taken and documented. The person making the audit should sign the documentation. All deficiencies should be made the subject of a separate file for examination by a regulatory authority.

12.3 Retain all records ~~about~~ for each lot irradiated at the facility for the period of time specified by relevant authorities and have them available for inspection as needed.

12.4 Documentation accompanying the shipment of irradiated product should include the name of the product owner; the name and address of the irradiation facility; a description of the product irradiated, including the lot number or other identifier (see 12.1); the irradiation date; and any other information required by the product owner, irradiator, or government authority.

13. Keywords

13.1 aquatic invertebrates; bacteria; crustacea; echinoderms; finfish; irradiation; labeling; microorganisms; molluscs; packaging; parasites; pathogens; processing; shellfish

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~~[5] The boldface numbers in parentheses refer to~~

[5] Available from the ~~list of references at the end of this standard.~~ U.S. Food and Drug Administration, Shellfish Sanitation Branch (HFS-407), 200 C St. SW, Washington, DC 20204.

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