Interpretation Number: 09-XI-.02-100

National Shellfish Sanitation Program
U.S. Food and Drug Administration
Shellfish Safety Team
Division of Cooperative Programs
Office of Compliance

Date: October 26, 1998
Revised: December 8, 2002

Model Ordinance
Reference: Chapter I.@.02H.(2) (c)-(e)
Chapter XI. 02. A. (2)
Chapter XI. 02. E. (4)

Key Words: Ice, sanitary quality, stored, protected, adulteration

Question: 1) What are the factors affecting the sanitary quality of ice and actions that should be taken when ice is improperly stored, protected or subject to adulteration?

Interpretation:

Ice is a regulated food which is used or intended for use on molluscan shellfish either in-shell or shucked for human consumption. Ice must be protected from adulteration as defined in the Food, Drug and Cosmetic Act §402.

In accordance with the Guide for the Control of Molluscan Shellfish any ice used in the processing, storage or transport of shellstock or shucked shellfish shall be made on-site from potable water in a commercial machine; or received from a facility sanctioned by the appropriate regulatory authority. Ice must be stored in a safe and sanitary manner to prevent its contamination.

The dealer shall use only equipment and utensils, including approved plastic ware which are: (1) constructed in a manner and with materials that can be cleaned, sanitized, maintained or replaced in a manner to prevent contamination of ice and shellfish products; and, (2) free from any exposed screws, bolts, or rivet heads on food contact surfaces. The dealer shall assure that all joints on food contact surfaces: (1) have smooth easily cleanable surfaces; and (2) for stainless steel, are welded. "Item 12 - Ice: approved source, sanitary, protected" is designated as a Swing item and identified as either a Key or Critical deficiency (NSSP Standardized Shellfish Processing Plant Inspection Form (ISSC Form 93-01(A).)

Key Deficiency: Applies when conditions may lead to adulteration of ice.

Critical Deficiency: Applies when the ice is visibly adulterated.

Key Conditions:

The following conditions are representative of Key deficiencies:

- Improperly constructed, maintained, cleaned, and sanitized walk-in coolers, insulated rooms, or other storage containers;
- Improperly constructed, cleaned, sanitized and stored totes, scoops, shovels, or other utensils used in handling ice;
- Ice making machines not maintained or protected (reservoir).

Corrective Actions:

Ice storage unit:

- Discontinue the use;
- Set a correction schedule for cleaning, repair, or replacement

Ice handling equipment:

- Discontinue use, clean and sanitize; or
- Replace with approved equipment

Ice machines:

- Shut down and initiate cleaning and/or repair.

Critical Conditions:

The following conditions are representative of Critical conditions:

- Dirt or other debris such as insulation, or paint chips observed in the ice;
- Ice is observed to be exposed to mold, slime, rust, condensate from cooler evaporator units, or other sources of adulteration.
- Ice exposed to foot traffic and observed to be used in direct contact with product;
- Stored food items in the ice.

Critical deficiency corrective action:

1. Discard ice;
2. Repair or replace ice storage units and equipment which caused the ice to be adulterated, or obtain ice from another source;
3. Destroy all product exposed to ice produced under conditions of adulteration

Where the dealer fails to take the appropriate corrective action as outlined above and required by Chapter I. @02. H. (2) (a), the shellfish Control Authority must initiate decertification procedures, as required by

Chapter I. @02. H. (2) (b), and must ensure that the product is removed from commerce or is processed to eliminate the hazard, consistent with Chapter I. @02. H. (2) (c).

Rationale:

Ice is considered a food when used in direct contact with shellfish. As a food ice must be stored and handled in the same sanitary manner as any other food product. No food product shall enter into commerce that is either injurious to health or is otherwise adulterated. Contaminated ice used in direct contact with shellfish will cause the shellfish to be adulterated. Each shellfish dealer must protect molluscan bivalves and food contact surfaces from adulteration with lubricants, fuel, pesticides, cleaning compounds, sanitizing agents, condensate and other chemical, physical and biological contaminants.

All materials used in equipment, utensils, walk in coolers, or rooms used to make or store ice must meet food contact surface requirements. A preventive or corrective measure should be used to control an identified food safety hazard to ensure that no product shall enter into commerce that is either injurious to health or is otherwise adulterated.

Other References:

1. Food and Drug Administration, "Federal Food, Drug and Cosmetic Act", Government Printing Office, Washington, DC
2. Food and Drug Administration, "1997 Food Code", Washington, DC.
3. 21 Code of Federal Regulations, Part 123 - Fish and Fishery Products, Government Printing Office, Washington, DC
4. 21 Code of Federal Regulations, Part 110 - Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food, Government Printing Office, Washington, DC

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National Shellfish Sanitation Program
U.S. Food and Drug Administration
Shellfish Safety Team
Division of Cooperative Programs
Office of Compliance
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Revised: December 8, 2002

Model Ordinance Chapter XI. 02. B. (1)
Reference: Chapter XI. 02. B. (2)

Key Words: Food contact surfaces, cleaning, sanitizing, equipment construction

Question: 1) What is a **food contact surface**?
2) What constitutes effective cleaning and sanitizing of a food contact surface?
3) What constitutes acceptable construction of shellstock grinders and parts thereof are considered food contact surfaces?

Interpretation:

1) A **food contact surface** means a surface of equipment or a utensil with which food normally comes into contact; or a surface of equipment or a utensil from which food or liquid may drain, drip, or splash into a food; or onto a surface normally in contact with food. Food contact surfaces include, but are not limited to, equipment and utensils such as; shucking knives and handles, shucking hammers and handles, shucking blocks, ice scoops and shovels, ice bins, skimmers, blower tanks, shucking pails, shellstock grinders.

2) Food-contact surface shall be clean to sight and touch. Cleaning and sanitizing shall occur prior to use each day and any time during use when contamination may have occurred. At a minimum, food contact surfaces shall be cleaned and sanitized every four hours. More frequent cleaning may be necessary depending on the characteristics of the equipment and its use and the amount of food residue accumulation. At the end of each day, food contact equipment and utensils shall be washed and rinsed.
Food contact surfaces shall be effectively washed to remove or completely loosen soils by manual or mechanical means such as the application of detergents; hot water; brushes; or high pressure sprays. If washing in sink compartments is impractical such as when equipment is fixed or utensils are too large, washing shall be done using an alternative manual procedure. In such instances, washing shall be facilitated by 1) disassembling equipment as necessary to allow access of the detergent solution to all parts and equipment components and 2) utensils shall be scraped or rough cleaned to remove food particle accumulation.
The cleaning of food contact surfaces shall occur prior to sanitizing in order for the sanitizer to be effective in destroying vegetative bacteria. Sanitizers may be applied by immersion, spraying or

brushing. Sanitizer concentration shall be in accordance with the manufacturer's directions on the label.

3) Parts of a shellstock grinder which are considered food contact surfaces include; the blade, the area behind the blade including the motor shaft from the blade to the motor housing, and the inside surface of the housing or cover surrounding the blade. These food contact parts shall be manufactured from high impact materials that are easily cleanable and non-corrosive. The grinder must be constructed to be easily disassembled and assembled to facilitate inspection, maintenance, cleaning, and sanitizing.

Guidelines for grinder construction:

1. The motor shaft should be of corrosion resistant material.
2. Juncture point where the motor shaft enters the blade chamber must be sealed to reduce dirt and detritus deposition around the shaft.
3. The blade must be made from a single piece of high impact non-corrosive material. Blade teeth must be an integral part of the blade, or if grinding surfaces are used instead of teeth, they must be welded to the face of the blade with all welds ground smooth.
4. The housing around the blade assembly must be constructed of material that is corrosion resistant.
5. Bolts or screws must be constructed of corrosion resistant material to prevent rust and corrosion.
6. The inside surface of the blade housing must be smooth, and if welded ground smooth for easy cleaning.
7. The blade housing must be designed with an easily removable cover that will open up the **entire blade assembly area** to facilitate inspection, cleaning, sanitizing, and maintenance.

Rationale:

Each shellfish dealer is responsible for assuring that all food contact equipment and utensils meet the design, construction, repair, and cleaning requirements of the NSSP, Guide for the Control of Molluscan Shellfish. Food contact surfaces must be cleaned and sanitized at a minimum frequency and in accordance with proper procedures to prevent contamination of shellfish by microbial pathogens and chemicals. Consistent with the FDA Food Code, cleaning and sanitizing shall occur at least every four hours and where necessary more often, depending on the accumulation of food debris or exposure to other contaminants. Under the NSSP Guide for the Control of Molluscan Shellfish and 21 CFR, Part 123, shellfish dealers are responsible for monitoring and maintaining records of the cleaning and sanitizing of food contact surfaces.

Other References:

1. 21 Code of Federal Regulations, Part 110 - Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food, U.S. Food and Drug Administration.
2. 21 Code of Federal Regulations, Part 123 - Fish and Fishery Products, U.S. Food and Drug Administration.
3. 1997 Food Code, U.S. Food and Drug Administration.
4. Food Equipment American National Standard NSF International Standard ANSI/NSF, NSF International, Ann Arbor, MI, 48113.

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National Shellfish Sanitation Program
U.S. Food and Drug Administration
Shellfish Safety Team
Division of Cooperative Programs
Office of Compliance
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Model Ordinance Chapter XV. 03. L. (1) (c)
Reference: NSSP Guidance Documents
Approved NSSP Laboratory Tests

Key Words:

Sample Volume, Fecal Coliform Counts, MPN Table and Count Range

Question:

What sample volume is inoculated in the 12-tube, single dilution MPN test for end product depurated shellfish samples?

How are fecal coliform counts determined using the 12-tube, single dilution MPN test for end product depurated shellfish?

Interpretation:

Two (2) mls (1 gram) of a 1:1 dilution of shellfish homogenate is inoculated into each tube of single strength lauryl tryptose presumptive broth in the 12-tube, single dilution MPN test for end product depurated shellfish samples. Inoculated tubes are incubated in an air incubator at 35°C for 24 hours. Any gas positive presumptive broth tubes are then subcultured to EC medium and incubated in a water bath at 44.5°C for 24 hours. The presence of any amount of gas or effervescence in the EC tubes constitutes a positive test. Fecal coliform counts are read from the MPN Table below and reported as MPN/100 grams.

MPN Table for End-product Depurated Shellfish Samples	
Number of Positive Tubes	**MPN/100 grams**
0	< 9.0
1	9.0
2	18
3	29
4	41
5	54
6	70
7	88
8	110
9	139
10	179
11	248
12	>248
Count range 9 to 248	

Rationale:

The use of the 12-tube, single dilution MPN test for end-product depurated shellfish was established as an acceptable method of analysis with the ISSC's adoption of the rewrite of Model Ordinance, Chapter XV, the Depuration Chapter in 1998. However, no specific guidance was provided on sample volumes to be examined or how fecal coliform counts were to be determined. Since the volume of sample inoculated in a single dilution MPN test controls the range of counts that can be determined, it is essential that an appropriate volume be inoculated to encompass the count range prescribed as the critical limits for depuration plant performance listed for all shellfish species encountered.

The inoculation of two (2) ml (yielding 1 gram) of sample from an initial 1:1 dilution of shellfish homogenate into each tube of the 12-tube, single dilution MPN produces a range of counts from 9 to 248. This range is sufficient to cover the critical limits of performance of all shellfish types listed in Chapter XV. 03. L (1) (c).

Remarks:

Comments received from the review of the draft version of Interpretation 03-XV-.03-100 indicated that the content of the Interpretation was too broad to be dealt with effectively in a single Interpretation. For this reason, this second Interpretation was developed from information presented in the first concerning the correct application of the single dilution MPN test to end product depurated shellfish.

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