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Report Name: Japanese Standards for Raw Oyster Imports

Country: Japan

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Report Highlights:

Fresh oyster imports to Japan must comply with Japan's (i) Specific Standard for Oysters for Raw Consumption and (ii) Handling of Toxic Shellfish Contaminated with Paralytic and Diarrheal Shellfish Poison. This report contains an unofficial translation of these requirements.

General Information

Fresh oyster imports to Japan must meet the requirements described in (i) the Specific Standard for Oysters for Raw Consumption and (ii) Handling of Toxic Shellfish Contaminated with Paralytic Shellfish Poison (PSP) and Diarrheal Shellfish Poison (DSP). A failure to comply with these criteria may result in a rejection of shipment. For an unofficial English translation of these requirements, please consult Appendices I and II.

Prior to approving an oyster-harvesting area for imports to Japan, the Ministry of Health, Labour and Welfare (MHLW) evaluates the proposed water area against the two standards listed above. During the evaluation process, applicants must submit the map of the area and inspection data on total coliform group count for the water area to MHLW's Food Inspection and Safety Division.

In addition, U.S. fresh oyster exports to Japan must originate from eligible entities and be accompanied by a sanitary certificate issued by the National Oceanic and Atmospheric Administration (NOAA) (JA2020-0140) or Washington State (JA2020-0109). As of November 2020, MHLW permits raw oyster imports from all water areas of Oregon, Washington, Connecticut, and New York states, as long as exporters are on the Interstate Certified Shellfish Shippers List.

The Ministry of Agriculture, Forestry and Fisheries developed guidelines on PSP and DSP risk management practices for bivalves (in Japanese only) for domestic industry and municipal governments. Although the guidelines are voluntary, they offer a reference point for MHLW's expectations for appropriate sanitary practices for oysters.

Appendix I: Specific Standard for Oysters for Raw Consumption

1 Constituent standards for oysters for raw consumption

(1) The number of bacteria must be 50,000 or less per gram of sample.

(2) The most probable number of *E. coli* must be 230 or below per 100 grams of sample.

(3) The methods for measuring the number of bacteria and the most probable number of *E. coli* in oysters for raw consumption are as follows.

1. Sample collection and reagent preparation

For shucked oysters, collect 200 grams or more of sample in a sterilized container using sterilized equipment.

For shelled oysters, disinfect the shell's surface with alcohol-soaked cotton before removing the shell using sterilized equipment, and collect 200 grams or more of sample (including oyster juice) in a sterilized container.

To prepare a stock solution, transfer the sample to a sterile homogenizer cup and crush it after adding the same amount of phosphate-buffered dilution water.

Next, to prepare the reagents, add 80 ml of phosphate-buffered dilution water to 20 ml of stock solution to produce a 10-fold dilute solution of the sample, and add 90 ml of phosphate-buffered dilution water to 10 ml of the 10-fold dilute solution to produce a 100-fold dilute solution of the sample. In addition, produce serial dilute solutions of the sample as reagents, if necessary, based on the 100-fold dilute solution production method.

Phosphate-buffered dilution water: Dissolve 34 grams of monopotassium phosphate (anhydrous) in 500 ml of purified water, with about 175 ml of roughly 1 mol/L sodium hydroxide solution added to adjust to pH 7.2, and add more purified water for a total volume of 1,000 ml as the stock solution. Add purified water to 1.25 ml of this stock solution to make 1,000 ml, with the solution sterilized under high pressure.

2. Method for measuring the number of bacteria (viable bacteria)

Among the prepared reagents, select a dilute solution from which 30 to 300 bacterial colonies can be obtained on one plate, and measure the number of bacteria in accordance with Non-alcoholic Beverage Manufacturing Standards (2) 2-b, Non-alcoholic Beverage 2 under Food Section D for Each Article of Paragraph 1 (Standards and Criteria for Food and Food Additives, Etc.).

3. Method for calculating the most probable number of *E. coli*

Inoculate 2 ml of stock solution, 1 ml of 10-fold dilute solution, and 1 ml of 100-fold dilute solution into five EC fermentation tubes to incubate in a thermostatically controlled water bath at a temperature of 44.5℃ (allowing a margin of 0.2℃) for 24 hours (allowing a margin of two hours). The stock solution or reagents confirmed to have generated gas during the period are regarded as E. coli-positive. The most probable number of *E. coli* to 100 grams of sample refers to the value 10 times the coefficient calculated

based on the following table (hereinafter "MPN table") according to the number of EC fermentation tubes inoculated with those tested E. coli-positive among the stock solution or reagents inoculated into EC fermentation tubes.

Most Probable Number (MPN) Table

Positive Tube			Coeff.	Positive Tube			Coeff.	Positive Tube			Coeff.	Positive Tube			Coeff.	Positive Tube			Coeff.	Positive Tube			Coeff.
A	B	C		A	B	C		A	B	C		A	B	C		A	B	C		A	B	C	
0	0	0		1	0	0	2	2	0	0	4.5	3	0	0	7.8	4	0	0	13	5	0	0	23
0	0	1	1.8	1	0	1	4	2	0	1	6.8	3	0	1	11	4	0	1	17	5	0	1	31
0	0	2	3.6	1	0	2	6	2	0	2	9.1	3	0	2	13	4	0	2	21	5	0	2	43
0	0	3	5.5	1	0	3	8	2	0	3	12	3	0	3	16	4	0	3	25	5	0	3	58
0	0	4	7.2	1	0	4	10	2	0	4	14	3	0	4	20	4	0	4	30	5	0	4	76
0	0	5	9	1	0	5	12	2	0	5	16	3	0	5	23	4	0	5	36	5	0	5	95
0	1	0	1.8	1	1	0	4	2	1	0	6.8	3	1	0	11	4	1	0	17	5	1	0	33
0	1	1	3.6	1	1	1	6.1	2	1	1	9.2	3	1	1	14	4	1	1	21	5	1	1	46
0	1	2	5.5	1	1	2	8.1	2	1	2	12	3	1	2	17	4	1	2	26	5	1	2	64
0	1	3	7.3	1	1	3	10	2	1	3	14	3	1	3	20	4	1	3	31	5	1	3	84
0	1	4	9.1	1	1	4	12	2	1	4	17	3	1	4	23	4	1	4	36	5	1	4	110
0	1	5	11	1	1	5	14	2	1	5	19	3	1	5	27	4	1	5	42	5	1	5	130
0	2	0	3.7	1	2	0	6.1	2	2	0	9.3	3	2	0	14	4	2	0	22	5	2	0	49
0	2	1	5.5	1	2	1	8.2	2	2	1	12	3	2	1	17	4	2	1	26	5	2	1	70
0	2	2	7.4	1	2	2	10	2	2	2	14	3	2	2	20	4	2	2	32	5	2	2	95
0	2	3	9.2	1	2	3	12	2	2	3	17	3	2	3	24	4	2	3	38	5	2	3	120
0	2	4	11	1	2	4	15	2	2	4	19	3	2	4	27	4	2	4	44	5	2	4	150
0	2	5	13	1	2	5	17	2	2	5	22	3	2	5	31	4	2	5	50	5	2	5	180
0	3	0	5.6	1	3	0	8.3	2	3	0	12	3	3	0	17	4	3	0	27	5	3	0	79
0	3	1	7.4	1	3	1	10	2	3	1	14	3	3	1	21	4	3	1	33	5	3	1	110
0	3	2	9.3	1	3	2	13	2	3	2	17	3	3	2	24	4	3	2	39	5	3	2	140
0	3	3	11	1	3	3	15	2	3	3	20	3	3	3	28	4	3	3	45	5	3	3	180
0	3	4	13	1	3	4	17	2	3	4	22	3	3	4	31	4	3	4	52	5	3	4	210
0	3	5	15	1	3	5	19	2	3	5	25	3	3	5	35	4	3	5	59	5	3	5	250
0	4	0	7.5	1	4	0	11	2	4	0	15	3	4	0	21	4	4	0	34	5	4	0	130
0	4	1	9.4	1	4	1	13	2	4	1	17	3	4	1	24	4	4	1	40	5	4	1	170
0	4	2	11	1	4	2	15	2	4	2	20	3	4	2	28	4	4	2	47	5	4	2	220
0	4	3	13	1	4	3	17	2	4	3	23	3	4	3	32	4	4	3	54	5	4	3	280
0	4	4	15	1	4	4	19	2	4	4	25	3	4	4	36	4	4	4	62	5	4	4	350
0	4	5	17	1	4	5	22	2	4	5	28	3	4	5	40	4	4	5	69	5	4	5	430
0	5	0	9.4	1	5	0	13	2	5	0	17	3	5	0	25	4	5	0	41	5	5	0	240
0	5	1	11	1	5	1	15	2	5	1	20	3	5	1	29	4	5	1	48	5	5	1	350
0	5	2	13	1	5	2	17	2	5	2	23	3	5	2	32	4	5	2	56	5	5	2	540
0	5	3	15	1	5	3	19	2	5	3	26	3	5	3	37	4	5	3	64	5	5	3	920
0	5	4	17	1	5	4	22	2	5	4	29	3	5	4	41	4	5	4	72	5	5	4	1600
0	5	5	19	1	5	5	24	2	5	5	32	3	5	5	45	4	5	5	81	5	5	5	1800

Note: A: Inoculating a stock solution
B: Inoculating a 10-fold dilute solution of the sample
C: Inoculating a 100-fold dilute solution of the sample
Coeff.: Coefficient

EC fermentation tube: Dissolve 20.0 grams of peptone, 5.0 grams of lactose, 1.5 grams of bile salt, 4.0 grams of dipotassium phosphate (anhydrous), 1.5 grams of monopotassium phosphate (anhydrous), and 5.0 grams of sodium chloride in 1,000 ml of purified water. Dispense this solution into fermentation tubes and cool it immediately after high-pressure sterilization. The final pH value must be in the range of 6.8 to 7.0.

(4) The most probable number of vibrio parahaemolyticus in shucked oysters for raw consumption must be 100 or below per gram of sample. In this case, measure the most probable number of vibrio parahaemolyticus in accordance with Constituent Standards 1 and 2 of Fresh Fish and Shellfish for Raw Consumption (for cut or shelled fresh fish and shellfish (excluding raw oysters) and for raw consumption (excluding those frozen); hereinafter the same applies in this paragraph), Fresh Fish and Shellfish for Raw Consumption 1 under Food Section D for Each Article of Paragraph 1 (Standards and Criteria for Food and Food Additives, Etc.).

2 Processing standards for oysters for raw consumption

(1) Oysters for raw materials must be collected in waters where the most probable number of the total coliform group is 70 or below per 100 ml of seawater or elsewhere, and be stored in seawater with the most probable number of the total coliform group not exceeding 70 per 100 ml or artificial saltwater with a salinity of 3 percent, with the seawater or artificial saltwater changed constantly or purified through disinfection.

Method for measuring the most probable number of the total coliform group in seawater: Inoculate 10 ml of seawater collected as a sample into five double-concentrated lactose bouillon fermentation tubes, 1 ml into five lactose bouillon fermentation tubes, and 0.1 ml into five lactose bouillon fermentation tubes to incubate at a temperature of 35℃ (allowing a margin of 1.0℃). After 24 hours (allowing a margin of two hours) or 48 hours (allowing a margin of three hours; hereinafter the same applies in this section), the seawater confirmed to have generated gas is regarded as positive for the total coliform group presumption test, and immediately proceed to the next confirmation test.

Transfer the broth in the double-concentrated lactose bouillon fermentation tubes or lactose bouillon fermentation tubes inoculated with the seawater presumed positive for the total coliform group to brilliant green lactose bile (BGLB) fermentation tubes with a 3 mm-diameter platinum loop. Incubate this liquid at 35℃ (allowing a margin of 1.0℃) for 48 hours. The seawater confirmed to have generated gas during the period is regarded as positive for the total coliform group confirmation test. The most probable number of the total coliform group to 100 ml of sample is represented by the coefficient calculated based on the MPN table according to the number of double-concentrated lactose bouillon fermentation tubes inoculated with the seawater confirmed positive for the total coliform group among the seawater collected as a sample. In this case, “a stock solution” in the MPN table is defined as 10 ml of sample seawater, “a 10-fold dilute solution of the sample” as 1 ml of sample seawater, and “a 100-fold dilute solution of the sample” as 0.1 ml of sample seawater.

(2) To temporarily store oysters for raw materials in water, seawater with the most probable number of the total coliform group not exceeding 70 per 100 ml or artificial saltwater with a salinity of 3 percent must be used, and the seawater or artificial saltwater must also be changed constantly or sterilized.

(3) Oysters for raw materials must be washed thoroughly with clean water as soon as they reach the shore.

(4) Oysters for raw consumption must be processed in a sanitary site, and chemical additives (excluding chlorous acid water, hypochlorous acid water, sodium hypochlorite, and hydrochloric acid and carbon dioxide used as acidity regulators) must not be used during the processing.

(5) Oysters must be shucked using food manufacturing water, sterilized seawater, or artificial seawater using food manufacturing water.

(6) Oyster shucking equipment must be easy to wash and sterilize, and always be washed and sterilized before use.

(7) Shucked oysters must be stored in impermeable containers made of metal, synthetic resin, or other materials that are easy to wash and sterilize. The containers must be used exclusively for oysters and always be washed and sterilized before use.

(8) Shucked oysters must be washed thoroughly with food manufacturing water, sterilized seawater, or artificial seawater using food manufacturing water.

(9) Frozen oysters for raw consumption must be frozen immediately after processing.

(10) Oyster shells removed during the processing of oysters for raw consumption must be promptly discarded, e.g., carried out to another place, to maintain hygiene at the processing site.

3 Storage standards for oysters for raw consumption

(1) Oysters for raw consumption must be refrigerated at a temperature of 10℃ or lower, while frozen oysters for raw consumption must be frozen at minus 15℃ or lower.

(2) Oysters for raw consumption must be stored in clean and sanitary lidded containers or wrapped in clean and sanitary synthetic resin, aluminum foil, or water-resistant processed paper, while frozen oysters for raw consumption must be wrapped in clean and sanitary synthetic resin, aluminum foil, or water-resistance processed paper.

Appendix II: Handling of Toxic Shellfish Contaminated with PSP and DSP

Notice 0306 No. 1 issued by Department of Food Safety
March 6, 2015

To: Prefectural governors,
Mayors of cities with public health centers, and
Mayors of special wards

Director of the Department of Food Safety, Pharmaceutical and Food Safety Bureau,
Ministry of Health, Labour and Welfare (Official seal omitted)

Handling of Toxic Shellfish Contaminated with Paralytic and Diarrheal Shellfish Poison

The handling of shellfish containing paralytic shellfish poison or diarrhetic shellfish poison is as addressed in "Handling of Shellfish Contaminated with Paralytic Shellfish Poison, etc." (Notice No.29 of July 1, 1980 issued by the Veterinary Sanitation Division of the Environmental Health Bureau; the "Former Notice").

In light of the current international move towards the introduction of the instrumental analysis method for shellfish containing diarrhetic shellfish poison, we have also decided to introduce the instrumental analysis method in Japan and, for okadaic acid ("OA"), Dinophysistoxin-1 and Dinophysistoxin-2, and ester compounds thereof, to set the sum of those figures converted to OA equivalence using the toxic equivalency factor as the regulation values for diarrhetic shellfish poison, so please be sure to observe the following operation.

This Notice will take effect as from today with respect to scallops, and as from April 1, 2015 with respect to other shellfish in consideration of the period required by inspection bodies to establish the inspection system. Please refer to a notice to be separately issued for the test method for diarrhetic shellfish poison using the instrumental analysis method.

Upon the enactment of this Notice, the Former Notice will be abolished as of April 1, 2015. We note that there has been consultation with the Ministry of Agriculture, Forestry and Fisheries of Japan with respect to the present matter.

1. Selling any shellfish containing paralytic shellfish poison or diarrhetic shellfish poison, regardless of whether unshelled, shelled, processed or in any other form, with a toxic amount per 1 g (edible portion) exceeding 4 MU (mouse unit) (in the case of paralytic shellfish poison) or with a toxic amount per 1 kg (edible portion) exceeding 0.16 mg OA equivalent (in the case of diarrhetic shellfish poison) (these figures, the "Regulation Values") will be treated as a violation of Article 6, item (ii) of the Food Sanitation Act.

   However, if, as a result of the removal of toxic portions or other treatment, it is clearly considered that the toxic amount contained in a shellfish will no longer exceed the Regulation Values and that shellfish is to be

transported to a treatment facility for that treatment, that shellfish may be treated as falling under the proviso of Article 6, item (ii) of that act.

2. Given that countermeasures taken at the place of production or shipment are most important to prevent food poisoning caused by paralytic shellfish poison and diarrhetic shellfish poison, the prefectures, cities with public health centers, or special wards ("Prefectures, etc.") of the place of production or shipment are required to endeavor to understand the progress of the toxification of shellfish, and if it is recognized there is a tendency of toxification, they must give appropriate guidance to relevant parties and strengthen the monitoring and inspection systems or otherwise take necessary measures to ensure that no violating articles will be shipped.

   In particular, if a Prefecture, etc. is to remove toxic portions or use other treatment, it must do so in accordance with the following items and sufficiently monitor the status of the compliance with the following items.

   1) Raw shellfish that may be treated is limited to where it is certain that, as a result of the treatment, the toxic amount contained in the product will no longer exceed the Regulation Values in view of the treatment method, system and other factors at the treatment facility, and a system necessary to ensure that that product will not be transported anywhere other than the treatment facility must be developed.

   2) The treatment is to be conducted only at facilities that are considered to have a system to properly carry out the treatment within the Prefecture, etc. in which the relevant shellfish was harvested, and in the cases such as where it is unavoidable to conduct secondary treatment in another Prefecture, etc., that Prefecture, etc. must be in close contact the other Prefecture, etc., and allow the other Prefecture, etc. to conduct the treatment only if such another Prefecture, etc. is deemed to have a proper transportation and treatment systems.

   3) The Prefecture, etc. shall cause the treatment business operator to prepare, prior to receiving the shellfish to be treated, the treatment procedures for proper and hygienic treatment and to:

      a. Assign a person in charge at each treatment process division who is required to comply with the treatment procedures or otherwise ensure proper treatment, and

      b. Develop a voluntary inspection system, inspect post-treatment articles by taking sufficient specimens representing each lot, and only ship those that have been confirmed to be below the Regulation Values.

3. Prefectures, etc. that are not the place of production or shipment shall make efforts to obtain information on the place of production and strengthen monitoring to ensure that they do not distribute or sell any violating products by, for example, inspecting shellfish shipped from a toxified sea area when necessary.

4. If shellfish is found to be toxic, the Prefecture, etc. that is the place of production shall make information such as the relevant sea area or the type of shellfish publicly known or otherwise endeavor to prevent any accident from happening due to harvesting, eating, etc. of that shellfish by those other than fishery operators, and shall report matters such as the status of toxification and the measures taken to the Director of the Inspection and Safety Division of the Department of Food Safety, and shall also endeavor to provide information to other relevant Prefectures, etc.

Attachments:

No Attachments.