

SUBJECT:

SHELLFISH SANITATION AGREEMENT

Shellfish Sanitation

Between

(FDA Agreement
Number 225-75-
2018)

THE UNITED STATES OF AMERICA

(Previously CPG
71561.01)

And

JAPAN

Excellency

Notes:

The FDA contact
for this agreement
is Frank MacKeith,
HFS-585

Tel. No.
(202) 205-4045

This agreement is
in effect
indefinitely.

I have the honor to refer to recent discussions between representatives of our two governments directed toward improving and standardizing shellfish sanitation practices and exchanging information on sanitary controls applied to the production and handling of fresh or frozen oysters, clams and mussels intended for shipment between Japan and the United States.

As a result of these discussions the following understandings were reached:

1. Uniform sanitation principles will be applied to the production and handling of all fresh or frozen oysters, clams and mussels intended for shipment between the two countries.
2. The principles in the Manual of Recommended Practice for Sanitary Control of the Shellfish Industry adopted by the United States Public Health Service, as amended from time to time, will be embodied in the relevant sanitary regulations in Japan.
3. The Ministry of Health and Welfare of Japan and the United States Public Health Service will exchange information on the state of compliance with these principles by the competent authorities in their respective countries and will maintain close contacts on matters concerning sanitary conditions of such shellfish.
4. Whenever sanitary observations of shellfish production areas or handling facilities are desired by either government, the other government will facilitate such observations.
5. Detailed arrangements for the implementation of this Agreement may be entered into from time to time by the United States Public Health Service and the Japanese Ministry of Health and Welfare.
6. This Agreement may be terminated by either Government giving thirty days written notice except that frozen oysters, clams and mussels packaged in accordance with the uniform sanitation principles under this Agreement will be accepted for a period of six

Notes:

months following the termination of the Agreement unless there are cogent public health reasons for prohibiting the importation of such products.

I have the honor to propose that if these understandings meet with the approval of the Government of the United States the present note and your Excellency's note in reply concerning therein shall constitute an agreement between our two governments, which agreement shall enter into force on the date of your Excellency's reply.

Accept, Excellency, the renewed assurances of my highest consideration.

Ambassador of
Japan is currently
Mr. Kunihiko Saito

/s/
Koichiro Asakai
Ambassador of Japan

Secretary of State
Department of State
Washington 25, D.C.

ARRANGEMENT BETWEEN THE
UNITED STATES PUBLIC HEALTH SERVICE
AND
THE JAPANESE MINISTRY OF HEALTH AND WELFARE

In accordance with the provisions of paragraph 5 of the Agreement entered into on October 24, 1962 between the Government of the United States and the Government of Japan, the United States Public Health Service and the Ministry of Health and Welfare of Japan have entered into the arrangement as set forth below insofar as concerns fresh or frozen oysters, clams and mussels intended for shipment from Japan to the United States:

1. The principles of the Manual of Recommended Practice for Sanitary Control of the Shellfish Industry approved by the United States Public Health Service and the Canadian Department of National Health and Welfare, as amended from time to time, will apply to the sanitary regulation of shellfish production and certification of shellfish exporters in Japan. It is agreed that some modifications of the technical standards contained in this Manual may be needed to assure that the sanitary quality of oysters, clams and mussels produced in Japan for export to the United States will be as high as the sanitary quality of those produced in the United States. The Ministry of Health and Welfare will be consulted in advance by the United States Public Health Service in the case of any amendment to the Manual referred to in paragraph 2 of the Agreement.

Notes:

2. The Japanese Ministry of Health and Welfare will notify the state of compliance as stipulated in paragraph 3 of the Agreement prior to May 30 of each year. These notifications will include lists of shippers holding operating permits in compliance with the principles of the Agreement.
3. If the state of compliance is acceptable to the United States Public Health Service, the names and permit numbers of the certified shippers will be included on the Public Health Service lists of certified shellfish shippers. The names and permit numbers of shippers so listed may be removed from the public lists by the Public Health Service (a) in the absence of evidence that the product has been produced and handled in accordance with these principles, (b) in a public health emergency, or (c) if there is evidence that the state of compliance with the agreed upon standards is less than that required of the States of the United States by the Public Health Service in maintaining the sanitary quality of shellfish shipped in interstate commerce.
4. It is understood that fresh or frozen oysters, clams and mussels shipped from Japan to the United States under the terms of the Agreement will be subject to the provisions of the Federal Food, Drug and Cosmetic Act.
5. The shipment of fresh or frozen oysters, clams and mussels from the United States to Japan shall be the subject of corresponding subsequent arrangements.

_____/s/_____
Luther L. Terry, Surgeon General for the United
States Public Health Service

_____/s/_____
Yoshihiko Hasegawa, Counselor, Embassy of Japan
for the Ministry of Health and Welfare of Japan

Date: October 24, 1962

