

The twin problem of encouraging foreign trade while protecting the health of the Nation . . . Shellfish, in the shellfish sanitation control program of the Public Health Service, are defined as "fresh or frozen oysters, clams, and mussels."

Shellfish Importation into the United States

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IMPORTATION of shellfish presents several complex sanitation problems to health and food control officials, as well as to industry. The program of shellfish sanitation control of the Public Health Service is based on the endorsement of State operations. The listing of certified dealers in a periodic compilation, designed for use in consumer areas, is the backbone of this voluntary system of control. Since 1948, Canada and the United States have operated under an agreement to use this technique for shellfish shipped across the border.

The acceptance of this concept of the certification system and an understanding of the health department surveillance involved in it brought about demands for similar attention to the growing volume of shipments of shellfish from other countries. Since many health services in the United States require that oysters, clams, and mussels be purchased from certified

dealers, shipments from foreign countries other than Canada have found a restricted market, even though they have been admitted legally to the country under the terms of the Federal Food, Drug, and Cosmetic Act (1). The Food and Drug Administration is responsible for permitting or denying entry to food imports under that act.

Representatives of foreign countries and United States importers have asked the Public Health Service how their shellfish can be accepted in a manner similar to domestic and Canadian shellfish. At the same time, State and local health departments have asked the Service what they should do about foreign shellfish which have appeared on the market. The Public Health Service, although it has guided the domestic control program for many years, has no legal jurisdiction in this issue. Since the shellfish sanitation program was developed, and still functions, through cooperation among the States, industry, and the Public Health Service, major adjustments in the program must be worked out by agreement among these interested parties.

As indicated above, responsibility for permitting or denying entry of shellfish shipments when presented at ports of entry, under the terms of the Food, Drug, and Cosmetic Act, lies with the Food and Drug Administration, a companion agency of the Public Health Service in the Department of Health, Education, and

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Welfare. Whenever the Food and Drug Administration finds, from the examination of samples, or otherwise, that such shipments of shellfish are insanitary, adulterated, or misbranded, their entry is refused. In the absence of such evidence, entry must be permitted.

The Concept of Control at Source

It is generally agreed that, in the instance of oysters, clams, and mussels, protection of the consumer is best assured by sanitary controls over conditions attending the growing, harvesting, packing, and shipping of the shellfish. This principle of "control at source" has governed the cooperative domestic shellfish program of the Public Health Service, the States, and industry. It is employed also in the agreement with Canada. Its value may be judged by the low incidence of shellfish-borne enteric disease, despite the more than 400 polluted areas on our coastlines that are legally closed to shellfish harvesting.

Objective examination of samples collected from foreign shellfish shipments on their arrival at an American port does not always give satisfactory evidence as to the conditions under which the shellfish were produced and packed. It is, therefore, difficult to decide which shipments should be admitted and which denied entry, particularly when bacteriological findings do not show presence of significantly large numbers of coliform organisms, and when other objective findings are satisfactory.

Prior to World War II, few shipments of shellfish came into the United States except from Canada and Mexico. Most of the shipments from Mexico were pismo clams (*Tivela stultorum*), although an occasional shipment of shucked oysters was offered for entry. In 1952 somewhat over a half million pounds of clam meats were imported from Mexico, principally through the San Diego and Los Angeles ports of entry. In 1953 this figure was close to three-fourths of a million pounds. It is believed that almost all of these clams are used in production of heat-processed clam chowder; since no apparent attempt has been made to distribute unprocessed clams beyond the State of entry, the question of certification of clam producers in Mexico has not arisen.

With expansion of the frozen food industry since the end of World War II, several other foreign countries have developed an interest in the United States market for bivalve shellfish, principally frozen clams. Japan, Iceland, Australia, The Netherlands, France, Spain, China, and Panama have all exported or indicated an interest in exporting frozen clams, mussels, or oysters to the United States. The total volume of shellfish shipped here has been relatively small, somewhere in the neighborhood of 1 or 2 percent of domestic production. However, foreign shellfish, except those produced in Canada, have been faced with the restrictions resulting from lack of certification. It is uncertain what the ultimate volume of shellfish imports might be if such restrictions were overcome.

The Case for International Trade

Although it is outside the usual field of public health to dwell on such facts as dollar exchange value, tariffs, and the importance to these foreign governments of trade with the United States, these factors bear directly on the regulatory problem. Specialists in such matters have analyzed the situation about as follows:

International trade in frozen shellfish, thanks to technical advances, is now possible on a worldwide basis. Producers of shellfish in distant countries are eager to help to satisfy what appears to be an expanded demand for shellfish in the United States. The interest of foreign governments stems from the importance of trade to their national economies and the importance that all free world countries attach to close ties with the United States. It is held to be in our interest to foster such ties and to enable friendly countries to gain strength through trade. Their welfare and ours are said to require that they be able to earn dollars from their exports to the United States in order to buy the products of our farms and factories.

Japan and Iceland, in particular, must sell the United States more goods than they now do to pay for American products they need and want. Iceland has virtually nothing except marine products to sell abroad, and marine products are among the few commodities which

Japan can produce without the use of imported raw materials.

In the last few years, the Governments of Iceland, Japan, The Netherlands, and Australia have made known to the Department of State and to the Public Health Service their interest in working out some arrangements which would remove unnecessary restrictions against the marketing of imported shellfish without endangering public health. As the Department of State has asserted America's interest in this problem, the Public Health Service has examined available facts with respect to the issue of expanding the present system of certification to these and other foreign countries.

The Public Health Service does not want its cooperative system of shellfish sanitation control within the United States to act as an artificial trade barrier against legitimate shellfish shipments which have been produced and packed under conditions equal to those required of American packers. On the other hand, even if the Public Health Service had the authority to do so—which it does not—there are difficulties in extending this certification system to other countries. Full knowledge of these difficulties is necessary in order to deal with the problem intelligently.

The Complexity of Foreign Control

Public Health Service endorsement of State shellfish sanitation programs presumes that representatives of the Service keep in close touch with control measures of the individual producing States by reasonably frequent consultations with State personnel, cooperative investigations, and check inspections. Without this kind of contact, the Public Health Service could not report adequately to the country as a whole on the effectiveness of the local procedures. The agreement with Canada specifically includes provisions for the exchange of information on methods of production and handling of shellfish, and for inspection visits across the border.

From a practical point of view, it has been easy for the Public Health Service to meet these provisions of the agreement with Canada. The capitals of the two countries are only a few hours apart by air, and long distance telephone conversations are relatively inexpensive.

It costs the United States Government a very small sum each year to keep in close touch with operations in the Canadian Maritime Provinces of eastern Canada and in British Columbia, by extending routine field trips to those areas while Public Health Service inspectors are working in the State of Maine or the State of Washington. Health officials in the two countries have many mutual concerns; thus, official business easily includes shellfish sanitation along with other topics, and a constant interchange of information is possible at relatively low cost. In addition, cooperative efforts with Canada have been built on a long history of parallel development in the two countries, both as to technical procedures and administrative operations.

There are no provisions in the Food, Drug, and Cosmetic Act which would make possible routine international exchange of information about techniques of sanitation control at source. There is no provision for setting up any plan of international certification or endorsement of any foreign control program. In the view of officials of the Food and Drug Administration, the only justification under the Food, Drug, and Cosmetic Act for that Administration to use its appropriated funds to send a representative to a foreign country would be to gain information considered necessary for the proper enforcement of the act in connection with foods or drugs offered for entry into the United States.

Such visits have been rare for various reasons. In the first place, a single trip to a foreign country for inspection purposes can develop information of only limited usefulness. In order to carry out the type of inspections performed in this country under authority of the Federal Food, Drug, and Cosmetic Act, it is sometimes necessary to visit one or more plants several times during the year. Because of limitations of funds and personnel, such trips to foreign countries have limited value for control purposes. Compared with the expenditure on inspections in this country, they are also uneconomic, although occasions may arise when a single trip or visit to a foreign country may supply basic information necessary to evaluate a particular situation.

Aside from the complicated administrative problems, certain other factors are important. There are limitations to the objective ex-

amination of shellfish at the time of arrival of shipments in this country. If strongly positive bacteriological results are obtained, one may assume that the shellfish were produced or handled under insanitary conditions. However, when bacteriological results are negative, interpretation becomes much more difficult.

In spite of a great deal of research, there has not been established for even our own species of shellfish any firm relationship between bacterial content of shucked shellfish in the market and the quality of growing areas and conditions of handling. This is why it is not yet possible to adopt a final bacteriological standard for market quality. Work which has been done so far in this field has dealt chiefly with fresh shucked oysters and clams and has not considered frozen products. Undoubtedly, the freezing and prolonged storage of shellfish produced abroad will have some effect on their apparent bacterial content.

In the United States and Canada, certain species of shellfish, notably clams and mussels, are sometimes subject to the accumulation of organic toxins. The origin and action of these toxins are fairly well understood, and a complex administrative control program is in operation to prevent toxic shellfish from being used commercially. Adequate test procedures are available and are being improved. However, there is some reason to believe that toxin which sometimes affects certain species of foreign shellfish may not be so well understood, and it is not certain that adequate tests have been developed.

Most of the frozen shellfish which would be shipped to the United States would be cooked before use. In fact, one importer has been investigating the feasibility of introduc-

ing clams which would be given some cooking before being frozen for shipment, this product being intended for use as chowder stock. It is unlikely that many frozen shellfish from abroad would be consumed raw. This factor is mentioned, not because there should be any significantly different standards applied to shellfish intended to be heat processed before sale but simply because the facts seem to indicate that any health hazard which might be present in connection with bacterial contamination of frozen shellfish from abroad would be considerably reduced by cooking. However, this expected heat treatment should not be employed in any way as a coverup for a filthy item. The Food and Drug Administration and the Public Health Service both hold this position.

There are in operation two parallel mechanisms of sanitary control for imported shellfish. One admits shellfish to this country, and, at the same time, the other restricts their market. Foreign governments find it difficult to understand that two different sources of legal authority in the United States, one Federal and one State, govern the importation and the marketing, respectively.

After a free exchange of views at the National Conference on Shellfish Sanitation, September 9 and 10, 1954, industry and government representatives agreed that recommendations on the significance of traffic in imported shellfish should come from the State Department. The State Department continues to study the developing trends of this commerce.

REFERENCE

- (1) Food, Drug, and Cosmetic No. 1, Revision 4; 21 U.S.C. 301 et seq.; 21 C.F.R. 1.1 et seq.

