New Food Code Definition: "In-Shell Product"

U.S. FOOD & DRUG ADMINISTRATION

In the 2022 Food Code, the FDA included a new term defining "in-shell product" **as non-living, processed shellfish with one or both shells present**. In-shell product falls under the broader definition of molluscan shellfish.

Specifically, "in-shell product" is:

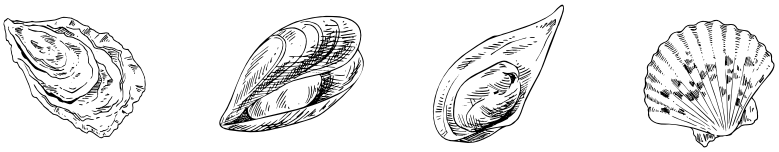
- A non-living (dead) molluscan shellfish product with one or both shells attached.
- Common examples include, but are not limited to:
  - individually quick frozen (IQF) oysters
  - whole frozen shellfish
  - banded high pressure treated oysters
  - irradiated oysters.

These products **may or may not** be treated to **limit** pathogens, such as *Vibrio sp*.

Flow Chart of FDA Food Code Terminology

Molluscan Shellfish

Any edible species of fresh or frozen oysters, clams, mussels, and scallops or edible portions thereof. (Except when the scallop product consists only of the shucked adductor muscle.)



Oysters **Clams** **Mussels** **Scallops**

Shellstock
LIVE in the shell(s)

Shucked Shellfish
Both shells removed

NEW
FOOD CODE DEFINITION

In-Shell Product
Non-living, processed in the shell(s)

"Molluscan Shellfish" includes the following: shellstock, shucked shellfish, in-shell product.

Foodborne Illness Prevention for “In-Shell Product” in Food Establishments

In-shell products are a subset of molluscan shellfish, which includes oysters, clams, mussels, and scallops (except where the final product is the shucked adductor muscle only). Pathogens, both bacteria and viruses, found where these molluscan shellfish live can cause disease in humans.

These pathogens are of particular concern to in-shell products because:

(1) Environments in which molluscan shellfish grow are commonly subject to contamination from sewage, which may contain pathogens, and to naturally occurring bacteria, which may also be pathogens.

(2) Molluscan shellfish filter and concentrate pathogens that may be present in surrounding waters.

(3) Molluscan shellfish are often consumed whole, either raw or partially cooked.

All updates to the FDA Food Code referring to “in-shell product” are as follows:

Update to Container Requirements:

- For display purposes, IN-SHELL PRODUCT may be removed from the container in which they are received, displayed on drained ice, or held in a display container, and a quantity specified by a CONSUMER may be removed from the display or display container and provided to the CONSUMER if:

  - The source of the IN-SHELL PRODUCT on display is identified as specified under § 3-202.18 and recorded as specified under § 3-203.12; and

  - It is protected from contamination. (¶ 3-203.11 C).

  Why?

  Accurate source identification of the harvesting area, harvester, and dealers must be contained on molluscan shellstock identification tags so that if a shellfish-borne disease outbreak occurs, the information is available to expedite the epidemiological investigation and regulatory action.

  Lot separation is critical to isolating shellfish implicated in illness outbreaks and tracking them to their source. Proper identification is needed for tracing the origin and determining conditions of shellfish processing and shipment. If the lots are commingled at retail, traceability is undermined and the root of the problem may remain undetected. If no causative factors are identified in the food establishment, tracing the incriminated lot helps in identifying products that need to be recalled or growing waters that may need to be closed to harvesting.

  When shucked shellfish are prepackaged in consumer self service containers, the labeling information as specified under § 3-202.18 must be recorded on a log sheet to correlate with the date of sale of the consumer sized containers.

Update to Labeling Requirements:

- If IN-SHELL PRODUCT is removed from its tagged or labeled container the source identification will be preserved by using a record keeping system as specified under sub¶ 3-203.12 (C)(1).

Why?

Accurate records that are maintained in a manner that allows them to be readily matched to each lot of molluscan shellfish provide the principal mechanism for tracing molluscan shellfish to its original source. If an outbreak occurs, regulatory authorities must move quickly to close affected growing areas or take other appropriate actions to prevent further illnesses. Records must be kept for 90 days to allow time for hepatitis A virus infections, which have an incubation period that is significantly longer than other shellfish-borne diseases, to come to light.

For more information:

- The FDA Food Code is available at: http://www.fda.gov/FoodCode
- See the NSSP Guide for the Control of Molluscan Shellfish (Model Ordinance): https://www.fda.gov/media/143238/download
- Conference for Food Protection (CFP) developed guide for:
  Retail Industry Best Practices and Regulatory Guidance Toolkit for Shellstock Investigations
  http://www.foodprotect.org/guides-documents/retail-industry-best-practices-and-regulatory-guidance-toolkit-for-shellstock-investigations/