cooled before time is used, are properly cooled; and food items (marked or identified) do not exceed the 4-hour limit at any temperature or 6-hour limit at 70°F or less. This item should be marked OUT of compliance when the PIC implies the use of TPHC but does not have an effective mechanism for indicating the point in time when the food is removed from temperature control to the 4 or 6-hour discard time, or a written procedure or an effective mechanism for using TPHC is not present at the facility.

N.A. This item may be marked N.A. when the establishment does not use time only as the public health control.

N.O. This item may be marked N.O. when the establishment uses time only as the public health control, but is not using this practice at the time of inspection.

Applicable Code Sections:
3-501.19 Time as a Public Health Control (P, Pf, C)

Consumer Advisory

25. Consumer advisory provided for raw or undercooked food
IN/OUT This item should be marked IN or OUT of compliance based on a thorough review with the PIC of the posted, written and special/daily menus, to determine if untreated shell eggs, meats, fish, or poultry are used as an ingredient or ordered as a raw, raw-marinated, partially cooked, or undercooked food. The advisory also applies to shellstock offered for sale from a retail service case. This item should be marked IN compliance if the establishment provides an advisory that meets the intent of the Food Code for both the disclosure and reminder components. This item should be marked OUT of compliance when raw or undercooked foods are served or sold and there is no consumer advisory, the food item is not disclosed, or there is no reminder statement. The consumer advisory does not exempt the requirement for freezing for parasite control, nor should it be used for foods that have only gone through the initial heating and cooling stages of a non-continuous cooking process.

N.A. This item may be marked N.A. when a food establishment does not serve a ready-to-eat food that necessitates an advisory, i.e., an animal food that is raw, undercooked, or not otherwise processed to eliminate pathogens.

N.O. Do Not Mark this item N.O.

Applicable Code Sections:
3-603.11 Consumption of Animal Foods that are Raw, Undercooked, or Not Otherwise Processed to Eliminate Pathogens (Pf)

Highly Susceptible Population

26. Pasteurized foods used; prohibited foods not offered
NOTE: Discussions with the PIC and employees regarding whether or not certain foods are served or certain practices occur in the establishment, along with observations should be used to determine compliance.

IN/OUT This item should be marked IN or OUT of compliance based on direct observations and discussions with the PIC and food employees regarding whether or not certain foods are served or certain practices occur in an establishment serving a highly susceptible population. Violations of bare hand contact by food employees serving a highly susceptible population ¶ 3-801.11(D) is marked under Item #7. This item should be marked IN compliance if only treated/pasteurized juices/ juice beverages are served; only pasteurized eggs are used in recipes if eggs are undercooked and if eggs are combined, unless there is a cook step or HACCP plan to control Salmonella enteriditis; no raw or partially cooked animal foods or raw
Providing this information on the label of fish packaged and offered for sale at retail will inform the consumer of the presence of these additives

21 CFR 73.75 promulgates requirements for the use of canthaxanthin in salmonid fish. 21 CFR 73.35 promulgates requirements for the use of astaxanthin in salmonid fish. For additional information, see the Federal Register announcement 63 FR 14814, March 27, 1998, Listing of Color Additives Exempt from Certification, Canthaxanthin.

Safe Handling Instructions

Refer to public health reason for § 3-201.11 Labeling for Meat and Poultry.

**Consumer Advisory**

3-603.11 Consumption of Raw or Undercooked Animal Foods.

Refer to the public health reason for § 3-401.11.

Purpose:

At issue is the role of government agencies, the regulated industry, and others in providing notice to consumers that animal-derived foods that are not subjected to adequate heat treatment pose a risk because they may contain biological agents that cause foodborne disease. The deliverance of a balanced message that communicates fairly to all consumers and, where epidemiologically supported, attempts to place risk in perspective based on the consumer's health status and the food being consumed is part of the challenge. Notification of risk must be achieved via a meaningful message and in a manner that is likely to affect behavior. The following information is to alert the reader to the options available to food establishments in advising consumers of the increased possibility of foodborne illness when animal-derived foods are eaten raw or undercooked.

Background:

Although no specific advisory language was recommended, beginning with the 1993 Food Code, FDA included a codified provision for a point-of-purchase consumer advisory and stated in Annex 3:

"FDA has requested comments and will consider the responses as well as other information that is available related to the risks involved and methods of risk communication to determine what action may be necessary by FDA to effectively inform consumers."
Consumer Focus Groups:

During 1996 - 1998, FDA conducted two different consumer focus group studies. Because the first set of focus groups (conducted before the 1997 Code) were not receptive to the language recommended at the 1996 Conference for Food Protection (CFP) meeting, that language was not included in the 1997 Code. Before the 1998 CFP meeting, the Agency convened a second set of focus groups with a modified approach. The latter set expressed similar thoughts as those in the earlier set and a pattern for consumer acceptance and receptiveness to menu-based advisories emerged.

It became apparent that there is a general appreciation for "disclosure" of what consumers view as "hidden ingredients," for example, whether a particular menu item contains raw egg. In addition to disclosure being viewed as helpful, consumers are accepting, if not appreciative, of a "reminder" that consuming raw or undercooked animal-derived foods carries an increased risk of foodborne illness. In the food establishment venue, consumers are less willing to accept a message that extends beyond a reminder and becomes a lesson or an educational message.

Satisfactory Compliance:

FDA submitted to the 1998 CFP meeting an Issue that asked the Conference to discuss an approach that incorporated the knowledge obtained from the consumer testing. It was the consensus of the CFP that **satisfactory compliance with the Code’s consumer advisory provision is fulfilled when both a disclosure and reminder are provided**, as described in § 3-603.11 of the Code. **Disclosure is** achieved when there is clear identification of animal-derived foods that are sold or served raw or undercooked, and of items that either contain or may contain (to allow for ingredient substitution) such raw or undercooked ingredients. A third option for the consumer “reminder” was added later. The **reminder is** a notice about the relationship between thorough cooking and food safety.

Two options were endorsed for disclosure and two for the reminder. One of the reminder options is a menu statement that advises consumers that food safety information about the disclosed items is available upon request. Essential criteria for such written information are available from FDA through the Retail Food Protection Team by writing to: FDA/CFSAN, 5100 Paint Branch Parkway, (HFS-320) College Park, Maryland 20740. All brochures must meet these essential criteria. The other option is a short notice alerting consumers to the increased risk of consuming the disclosed menu items.

In response to concerns raised by the Interstate Shellfish Sanitation Conference (ISSC) in an October 8, 1998 letter to FDA, a third option has been added to allow for a statement that links an increased risk of illness to consumption of raw or undercooked animal foods by persons with certain medical conditions.
The information contained in both the disclosure and reminder should be publicly available and readable so that consumers have benefit of the total message (disclosure and reminder) before making their order selections.

It is not possible to anticipate all conceivable situations. Therefore, there will always be need for discussion between the food establishment and the Regulatory Authority as to the most effective way to meet the objectives of satisfactory compliance.

The Implementation Guidance for the Consumer Advisory Provision of the FDA Food Code (section 3-603.11 in the FDA Model Food Code), is a resource intended to assist regulators and industry in the implementation of the Consumer Advisory provision. It is recommended that it be used in conjunction with the FDA Food Code. It is available from FDA through the Retail Food Protection Team by writing to: FDA/CFSAN, 5100 Paint Branch Parkway, (HFS-320) College Park, Maryland 20740.

**Locating the Advisory:**

Disclosure of raw or undercooked animal-derived foods or ingredients and reminders about the risk of consuming such foods belong at the point where the food is selected by the consumer. Both the disclosure and the reminder need to accompany the information from which the consumer makes a selection. That information could appear in many forms such as a menu, a placarded listing of available choices, or a table tent.

**Educational Messages:**

Educational messages are usually longer, more didactic in nature, and targeted to consumers who have been alerted to the food safety concern and take the initiative to obtain more detailed information. It is expected that, in most cases, educational messages that are provided pursuant to § 3-603.11 (i.e., in situations where the option for referring the consumer to additional information is chosen), will be embodied in brochures that will not be read at the site where the immediate food choice is being made. Nonetheless, such messages are viewed as an important facet of arming consumers with the information needed to make informed decisions and, because the information is being requested by the consumer, it would be expected to play a role in subsequent choices.
Applicability:

**Food Establishments:**

The consumer advisory is intended to apply to all food establishments where raw or undercooked animal foods or ingredients are sold or served for human consumption in a raw or undercooked form. This includes all types of food establishments whenever there is a reasonable likelihood that the food will be consumed without subsequent, thorough cooking - such as restaurants, raw bars, quick-service operations, carry-outs, and sites where groceries are obtained that have operations such as delicatessens or seafood departments.

"... Otherwise Processed to Eliminate Pathogens...":

This phrase is included in § 3-603.11 to encompass new technologies and pathogen control/reduction regimens as they are developed and validated as fulfilling a specific performance standard for pathogens of concern. Pasteurization of milk is an example of a long-standing validated process. For purposes of the Food Code, the level of pathogen reduction that is required before a raw or undercooked animal food is allowed to be offered without a consumer advisory must be equivalent to the levels provided by § 3-401.11 for the type of food being prepared.

The absorbed dose levels of radiation approved by FDA on December 3, 1997 for red meat are insufficient to reduce the level of most vegetative pathogens to a point that is equivalent to the reductions achieved in ¶¶ 3-401.11(A) and (B). Irradiated poultry provides a 3D kill which does not provide the level of protection of the 7D kill that results from the cooking regimen in the Food Code. Therefore, irradiated meat and poultry are not allowed to be offered in a ready-to-eat form without a consumer advisory. It is intended that future Food Code revisions will address time/temperature requirements that take into consideration the pathogen reduction that occurs with irradiated foods.

**Recognition of Other Processes:**

Animal-derived foods may undergo validated processes that target a specific pathogen. In such instances, along with the required consumer advisory may appear additional language that accurately describes the process and what it achieves. For example, a technology for reducing *Vibrio vulnificus* in oysters to nondetectable levels has been validated. FDA concurs that shellfish subjected to that process can be labeled with a truthful claim that appropriately describes the product. That is, a statement could be made such as, "pasteurized to reduce *Vibrio vulnificus*" or "temperature treated to reduce *Vibrio vulnificus." Such a claim must be in accordance with labeling laws and regulations, accurate, and not misleading. The claim would not, however, negate the need for a consumer advisory because the treatment only reduces the level of one pathogenic organism.
Product-specific Advisories:

Consumer advisories may be tailored to be product-specific if a food establishment either has a limited menu or offers only certain animal-derived foods in a raw or undercooked ready-to-eat form. For example, a raw bar serving molluscan shellfish on the half shell, but no other raw or undercooked animal food, could elect to confine its consumer advisory to shellfish. The raw bar could also choose reminder, option #3, which would highlight the increased risk incurred when persons with certain medical conditions ingest shellfish that has not been adequately heat treated.

Terminology:

It should be noted that the actual on-site (e.g., on-the-menu) advisory language differs from the language in the codified provision, § 3-603.11. In the insert page for § 3-603.11, the Reminder options 2 and 3 use terms for foods that are less specific than the terms used in the actual code section. That is, the words “meat” rather than “beef, lamb, and pork” and “seafood” rather than “fish” are used. Categorical terms like “meat” are simpler and may be more likely used in conversation, making them suitable for purposes of a menu notice.

Milk:

In addition, “milk” is not mentioned in the actual on-site advisory language. The sale or transportation of final packaged form of unpasteurized milk into interstate commerce is specifically prohibited by 21 CFR 1240.61. Also the consumption of raw milk is not recommended by FDA (this statement is in the form of an official FDA position statement found at [http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Milk/ucm2007973.htm](http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Milk/ucm2007973.htm). Nonetheless, approximately 25 states allow unpasteurized milk in intrastate commerce which usually involves direct dairy farm-to-consumer procurement.

In the event that a food establishment governed by § 3-603.11 of this Code operates in conjunction with a dairy farm in a State that allows the in-State sale or service of unpasteurized milk, or in the case where a State allows unpasteurized milk to be marketed via retail-level food establishments, consumers need to be advised of the risk associated with drinking unpasteurized milk. In these situations, the actual advisory language needs to be amended to include milk (refer to Consumer Advisory Reminder, paragraph 3-603.11(C), options 2 or 3).
Molluscan Shellstock:

In addition to areas of retail food stores such as delis in supermarkets, the consumer advisory is to be provided when a seafood department or seafood market offers raw molluscan shellstock for sale or service. There is a risk of death from *Vibrio* infections from consuming raw molluscan shellstock for persons who have certain medical conditions.

Disposition 3-701.11 Discarding or Reconditioning Unsafe, Adulterated, or Contaminated Food.

Pathogens may be transmitted from person to person through contaminated food. The potential spread of illness is limited when food is discarded if it may have been contaminated by employees who are infected, or are suspected of being infected, or by any person who otherwise contaminates it.

Additional Safeguards 3-801.11 Pasteurized Foods, Prohibited Re-Service, and Prohibited Food.

Refer to the public health reason for § 3-201.11.

The Code provisions that relate to highly susceptible populations are combined in this section for ease of reference and to add emphasis to special food safety precautions that are necessary to protect those who are particularly vulnerable to foodborne illness and for whom the implications of such illness can be dire.

As a safeguard for highly susceptible populations from the risk of contracting foodborne illness from juice, prepackaged juice is required to be obtained pasteurized or in a commercially sterile, shelf-stable form in a hermetically sealed container. It is important to note that the definition of a “juice” means it is served as such or used as an ingredient in beverages. Puréed fruits and vegetables, which are commonly prepared as food for service to highly susceptible populations, are not juices and do not require HACCP plans or compliance with 21 CFR Part 120. There are documented cases of foodborne illness throughout the United States that were associated with the consumption of various juice products contaminated with microorganisms such as *Cryptosporidium*, Shiga toxin-producing *Escherichia coli*, *Salmonella* spp., and *Vibrio cholera*. As new information becomes available, the Food Code will be modified or interim interpretive guidance will be issued regarding foodborne illness interventions for on-site juicing and puréeing.

The 21 CFR 120 regulation applies to products sold as juice or used as an ingredient in beverages. This includes fruit and vegetable purees that are used in juices and beverages, but is not intended to include freshly prepared fruit or vegetable purees that are prepared on-site in a facility for service to a highly susceptible population.