511-6-1-.04 Food

Condition **Safe, Unadulterated, and Honestly Presented.**
Sources **Compliance with Food Law.**

Source.

A primary line of defense in ensuring that food meets the requirements of 511-6-1-.04 is to obtain food from approved sources, the implications of which are discussed below. However, it is also critical to monitor food products to ensure that, after harvesting and processing, they do not fall victim to conditions that endanger their safety, make them adulterated, or compromise their honest presentation. The regulatory community, industry, and consumers should exercise vigilance in controlling the conditions to which foods are subjected and be alert to signs of abuse. Food in hermetically sealed containers that are swelled or leaking is considered to be adulterated. Depending on the circumstances, rusted and pitted or dented cans may also present a serious potential hazard.

Food, at all stages of production, is susceptible to contamination. The source of food is important because pathogenic microorganisms may be present in the breeding stock of farm animals, in feeds, in the farm environment, in waters used for raising and freezing aquatic foods, and in soils and fertilizers in which plant crops are grown. Chemical contaminants that may be present in field soils, fertilizers, irrigation water, and fishing waters can be incorporated into food plants and animals. For these reasons, food is required to be obtained from sources that comply with the law. All food products will be obtained from sources that are under inspection of the authority having jurisdiction or otherwise approved by the Health Authority except for fresh produce. Fresh produce may be obtained from local sources.

Sources of molluscan shellfish are a particular concern because shellfish are frequently consumed raw or in an undercooked state and thus receive neither heat treatment nor any other process that would destroy or inactivate microbial pathogens. For safety, these foods must be accompanied by certification that documents that they have been harvested from waters that meet the water quality standards contained in the National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish. Certification also provides confidence that processing, packaging, and shipping have been conducted under sanitary conditions.

Food should be purchased from commercial supplies under regulatory control. Home kitchens, with their varieties of food and open entry to humans and pet animals, are frequently implicated in the microbial contamination of food. Because commercial items seldom are eaten right away, the home kitchen's limited capacity for maintaining food at proper temperatures may result in considerable microbial growth and toxin production

by microorganisms introduced through the diverse sources of contamination. Controlled processing is required for the safe preparation of food entering commerce.

Labeling - General

Sources of packaged food must be labeled in accordance with law. Proper labeling of foods allows consumers to make informed decisions about what they eat. Many consumers, as a result of an existing medical condition, may be sensitive to specific foods or food ingredients. This sensitivity may result in dangerous medical consequences should certain foods or ingredients be unknowingly consumed. In addition, consumers have a basic right to be protected from misbranding and fraud.

Except for certain species of large tuna and raw molluscan shellfish, if fish are intended for raw consumption, they must be properly frozen before they are served. If this process is done off-premises, purchase specifications ensuring that proper freezing techniques are used to destroy parasites must be provided. Labeling should accompany the product to advise as to whether the product was frozen properly. This is necessary because fish from natural bodies of water may carry parasitic worms that can infect and injure consumers who eat such raw fish dishes as sushi, ceviche, green (lightly marinated) herring, and cold-smoked salmon. The worms are often deeply imbedded inside fish muscle. Thorough freezing kills these worms if the fish are subjected to a low enough temperature for a long enough time.

Labeling for Fish

Except for raw molluscan shellfish, certain species of large tuna, certain aquacultured fish, and fish eggs that have been removed from the skein and rinsed, if fish are intended for raw or undercooked consumption, they must be properly frozen before they are served. If this process is done off-premises, purchase specifications ensuring that proper freezing techniques are used to destroy parasites must be provided. Labeling or other information should accompany the product to advise as to whether the product was frozen properly. This is necessary because fish from natural bodies of water may carry parasitic worms that can infect and injure consumers who eat such raw fish dishes as sushi, ceviche, green (lightly marinated) herring, and cold-smoked salmon. The worms are often deeply imbedded inside fish muscle. Thorough freezing kills these worms if the fish are subjected to a low enough temperature for a long enough time as per the Chapter.

Labeling for Juice

On July 8, 1998, FDA announced in the Federal Register a final rule that revised its food labeling regulations to require a warning statement on fruit and vegetable juice products that have not been processed to prevent, reduce, or eliminate pathogenic microorganisms that may be present. FDA took this action to inform consumers, particularly those at greatest risk, of the hazard posed by such juice products. FDA

expects that providing this information to consumers will allow them to make informed decisions on whether to purchase and consume such juice products, thereby reducing the incidence of foodborne illnesses and deaths caused by the consumption of these juices.

On July 18, 2001 FDA announced a final rule designed to improve the safety of fruit and vegetable juice and juice products. Under the rule, juice processors must use Hazard Analysis and Critical Control Point (HACCP) principles for juice processing. Processors making shelf-stable juices or concentrates that use a single thermal processing step are exempt from the microbial hazard requirements of the HACCP regulation. Retail establishments where packaged juice is made and only sold directly to consumers (such as juice bars) are not required to comply with this regulation.

Rather, the Chapter requires fresh fruit or vegetable juices that are packaged at retail (untreated juices or beverages containing untreated juices that are offered to consumers as prepackaged foods) to be processed under HACCP with a 5 log reduction in pathogens of concern OR bear the warning statement as specified in 21 CFR Section 101.17(g). That statement is: "WARNING: This product has not been pasteurized and, therefore, may contain harmful bacteria that can cause serious illness in children, the elderly, and persons with weakened immune systems." Refer to DPH 511-6-1-.01(77) for the definition of juice. It is important to note that the definition of "juice" includes puréed fruits and vegetables, which are commonly prepared for service to highly susceptible populations. Food establishments that serve a highly susceptible population (HSP) cannot serve prepackaged juice that bears the warning label and they must serve only pasteurized juice. For juice only, this population includes children who are age 9 or less and receive food in a school, day care setting, or similar facility that provides custodial care.

Unpackaged juice (glasses of juice prepared at a juice bar, for example) does not require the 5 log reduction nor a warning statement or other consumer advisory (juice is not an animal food and therefore not covered by the consumer advisory for animal foods that are raw, undercooked, or not otherwise processed to eliminate pathogens) when prepared and served at retail. Usually the juice is served by the glass or in small batches compared to that of a commercial juice processor. The risk of using "drops" and damaged fruits or vegetables is much less at retail because of buyer specifications that provide higher quality produce, meaning that fruits for juicing are less likely to be of a lower quality or damaged.

Additional information is available in the document, "Guidance for Industry: Exemptions from the Warning Label Requirement for Juice - Recommendations for Effectively Achieving a 5-Log Pathogen Reduction; Final Guidance", October 7, 2002 which can be found at:
http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm058962.htm or obtained from the FDA Office of Nutritional Products Labeling and Dietary Supplements.

Labeling for Meat and Poultry

Retail food establishments that process and package meat or poultry in a form that is not ready-to-eat, are obligated by Federal regulation to label the product with safe food handling instructions. USDA issued final rules on August 8, 1994 requiring all raw meat or poultry products have a safe-handling label or sticker or be accompanied by a leaflet that contains information on proper handling and cooking procedures. The intent of this requirement is to ensure that all consumers are alerted to the fact that such products may contain bacteria and that food safety hinges upon their thoroughly cooking the product, regardless of where they obtain the products. That is, the labeling would exist if they obtain their meat and poultry at an establishment that handles only prepackaged and prelabeled products or if they obtain their meat or poultry at an operation such as a supermarket with a meat processing operation or from a small neighborhood butcher.

Labeling Guidance for Irradiated Raw Meat and Meat Products

In December 1999, the U.S. Department of Agriculture, Food Safety and Inspection Service (USDA/FSIS) issued a final regulation to permit the use of ionizing radiation to reduce foodborne pathogens, including *Escherichia coli O*157:H7, and extend the shelf life of raw refrigerated and frozen meat and meat products (Irradiation of Meat Food Products 64 *Federal Register* 72150, December 23, 1999).

The final regulations are published in Title 9 of the Code of Federal Regulations (9 CFR 424.21 Use of food ingredients and sources of radiation and provide that raw refrigerated products may receive a maximum absorbed dose of no more than 4.5 kGy, and that frozen product receive no more than 7.0 kGy, in accordance with the FDA restrictions provided for in Title 21 of the Code of Federal Regulations (21 CFR 179.26(a) Ionizing radiation for the treatment of food, (a) Energy sources). The regulations further require that all irradiated meat and meat products bear labeling that reflects that the product was irradiated, or that the product contains an irradiated meat or poultry product. This labeling requirement is applicable even at retail facilities where irradiated coarse ground beef might be finely ground for retail sale, or in cases where irradiated product is combined with other non-irradiated meat or poultry product for retail sale.

In cases where the entire package of product is irradiated, the labeling must include both a statement and the international symbol, called the radura. Additionally, the product name must include the word “irradiated,” or the labeling must bear a disclosure statement such as, “treated with radiation” or “treated by irradiation.” If either statement is used, the logo must be placed in conjunction with the statement. If an irradiated meat or meat product is used to formulate a multi-ingredient product with other non-irradiated components, the irradiated meat ingredient must be identified as such in the ingredients statement, but the logo is not required. For example, the ingredients statement for a Chicken and Beef Sausage product that contains irradiated beef would be, Ingredients: chicken, irradiated beef, seasonings (salt, pepper, spice), and the logo

would not be required to be present.

All labels for products produced at federally inspected establishments bearing statements about irradiation must be submitted to USDA/FSIS for evaluation and approval prior to use.

Optional labeling statements about the purpose of the irradiation process may be included on the labeling of irradiated products provided they are not false or misleading and have been evaluated first by USDA/FSIS. If such statements indicate a specific benefit from irradiation, such as a reduction of microbial pathogens, such statements must be substantiated by processing documentation and validated through the processing and Hazard Analysis and Critical Control Point (HACCP) system. Such validation and documentation of the HACCP system would only be applicable in federally inspected establishments.

Because irradiation can substantially reduce and, in some situations, eliminate any detectable level of pathogenic bacteria, it is important that the meat products be held at the proper refrigerated temperatures to prevent growth of any pathogens present, and that the packaging is not compromised. Although co-mingling irradiated beef with non-irradiated meat or poultry is not prohibited under the current regulations, USDA/FSIS believes that such a process would decrease the benefit of irradiation by potentially exposing the irradiated product to pathogenic bacteria. While FSIS considers such comingling to be highly unlikely, if it did occur, a statement advising the consumer that the product contains both irradiated and non-irradiated components would be required.

The Radura, International Symbol:

Further information about labeling irradiated raw meat is available through Directive 7700.1, Irradiation of Meat and Poultry Products, on the USDA/FSIS website at http://www.fsis.usda.gov/wps/wcm/connect/058dd732-7fc8-4787-a283-30ed50d6f7e0/7700.1Rev1.pdf?MOD=AJPERES. Irradiation Questions & Answers can be found at http://www.fsis.usda.gov/wps/portal/fsis/topics/food-safety-education/get-answers/food-safety-fact-sheets/production-and-inspection/irradiation-and-food-safety.

Labeling for Raw Shell Eggs

In regards to shell eggs, Chapter 511-6-1-.04(2)(a)7. references the Code of Federal Regulations 21 CFR 101.17(h) **Food Labeling warning, notice, and safe handling statements**, which states, "The label of all shell eggs, whether in intrastate or interstate commerce, shall bear the following statement: 'SAFE HANDLING INSTRUCTIONS: To prevent illness from bacteria; keep eggs refrigerated, cook eggs until yolks are firm, and cook foods containing eggs thoroughly.'" This requirement does not apply to shell eggs that have been specifically processed to destroy all viable *Salmonella*.

Labeling for Whole-muscle, Intact Beef Steaks

In order for a food establishment operator to know that a steak is a whole-muscle, intact cut of beef that can therefore be undercooked and served without a consumer advisory, the incoming product must be labeled. Processors can accommodate this need at the retail level by developing proposed labels, obtaining the necessary USDA Food Safety Inspection Service review and approval, and appropriately affixing the labels to their products.

Food in a Hermetically Sealed Container.

Processing food at the proper high temperature for the appropriate time is essential to kill bacterial spores that, under certain conditions in an airtight container, begin to grow and produce toxin. Of special concern is the lethal toxin of ***Clostridium botulinum***, an organism whose spores (i.e., survival stages for non-growth conditions) are found throughout the environment. Even slight underprocessing of low acid food which is canned can be dangerous, because spoilage microbes are killed and there are no signs to warn consumers that botulinum spores have germinated into vegetative cells and produced their toxin. If these foods are not processed to be commercially sterile, they must be received frozen or under proper refrigeration.

Fluid Milk and Milk Products.

Milk, which is a staple for infants and very young children with incomplete immunity to infectious diseases, is susceptible to contamination with a variety of microbial pathogens such as Shiga toxin-producing ***Escherichia coli***, ***Salmonella*** spp., and ***Listeria monocytogenes***, and provides a rich medium for their growth. This is also true of milk products. Pasteurization is required to eliminate pathogen contamination in milk and products derived from milk. Dairy products are normally perishable and must be received under proper refrigeration conditions.

Fish.

After December 18, 1997, all processors of fish are required by 21 CFR 123 to have conducted a hazard analysis of their operation, identify each hazard that is reasonably

likely to occur, and implement a HACCP plan to control each identified hazard. Retailers should assure that their seafood suppliers have complied with this requirement. Hazards known to be associated with specific fish species are discussed in the FDA Fish and Fishery Products Hazards and Controls Guide, available from the FDA Office of Seafood. Species-related hazards include pathogens, parasites, natural toxins, histamine, chemicals, and drugs.

The seafood implicated in histamine poisoning are the scombroid toxin-forming species, defined in 21 CFR 123.3(m) as meaning bluefish, mahi-mahi, tuna, and other species, whether or not in the family **Scombridae**, in which significant levels of histamine may be produced in the fish flesh by decarboxylation of free histidine as a result of exposure of the fish after capture to temperatures that allow the growth of mesophilic bacteria.

Ciguatera toxin is carried to humans by contaminated fin fish from the extreme southeastern U.S., Hawaii, and subtropical and tropical areas worldwide. In the south Florida, Bahamian, and Caribbean regions, barracuda, amberjack, horse-eye jack, black jack, other large species of jack, king mackerel, large groupers, and snappers are particularly likely to contain ciguatoxin. Many other species of large predatory fishes may be suspect. In Hawaii and throughout the central Pacific, barracuda, amberjack, and snapper are frequently ciguatoxic, and many other species both large and small are suspect. Mackerel and barracuda are frequently ciguatoxic from mid to northeastern Australian waters.

RECREATIONALLY CAUGHT FISH

Recreationally caught fish received for sale or service may be approved by the regulatory authority. The EPA recognizes that fish are a healthy part of our diet and recognizes fishing as an all-American recreational pastime, however, they add the cautionary note that some individuals, such as pregnant women and small children, may need to limit their intake of certain noncommercial fish. Recreationally caught fish may contain possible contaminants that may pose health risks. Fish advisories can be found in EPA Listing of Fish Advisories the EPA website at: http://www.epa.gov/waterscience/fish/.

States issue fish consumption advisories if elevated concentrations of chemicals such as mercury or dioxin are found in local fish. For most people, the risk from mercury by eating fish is not a health concern. Yet, some fish and shellfish contain higher levels of mercury that may harm an unborn baby or young child's developing nervous system. Therefore, the FDA and the EPA recently advised women who may become pregnant, pregnant women, nursing mothers, and young children to avoid some types of fish and eat fish and shellfish that are lower in mercury. (http://www.epa.gov/waterscience/fishadvice/advice.html).

State-issued advisories apply primarily to non-commercial fish obtained through sport, recreation, and subsistence activities. Each advisory is different; it may recommend

unrestricted, limited, or totally restricted consumption; may be targeted to everyone or limited to women, children, or other people at risk; and may apply to certain species or sizes of fish or a specific waterbody.

Regulatory authorities are encouraged to monitor and review the National Listing of Fish Advisories (See EPA Fact Sheet at http://www.epa.gov/waterscience/fish/advisories/factsheet.pdf as well as the local listings, as part of the decision-making process regarding the approval of recreationally caught fish being used in food establishments.

There are six approved sources of fish:

1. Fish from a "Licensed Commercial Fisherman" as regulated through Georgia Department of Natural Resources;
2. Live fish from an "Aquaculturist (domestic fish farmer)" registered with and regulated by the Georgia Department of Natural Resources Law Enforcement Section;
3. Live fish from a "Wholesale Fish Dealer" as permitted through the Georgia Department of Natural Resources; and
4. Processed fish obtained from "Processing Plants and Distributors" as permitted through the Georgia Department of Agriculture.
5. Fish, other than molluscan shellfish, that are intended for consumption in their raw form must be purchased from a supplier that meets applicable Law and that freezes the fish to destroy pathogens as per the Chapter.
6. Fish, other than molluscan shellfish, that is properly frozen on the premises of the food service establishment as per the Chapter.

Upon request by the Health Authority, the permit holder must furnish evidence that fish in their possession complies with all applicable law (Federal and State). This evidence may be in the form of sale receipts, copies of permits and or registration with the agency having regulatory authority over the product.

Molluscan Shellfish.

Pathogens found in waters from which molluscan shellfish are harvested can cause disease in consumers. Molluscan shellfish include: 1) oysters; 2) clams; 3) mussels; and, 4) scallops, except where the final product is the shucked adductor muscle only. The pathogens of concern include both bacteria and viruses.

Pathogens from the harvest area are of particular concern in molluscan shellfish 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; and, 3) molluscan shellfish are often consumed whole, either raw or partially cooked.

To minimize the risk of molluscan shellfish containing pathogens of sewage origin, State and foreign government agencies, called Shellfish Control Authorities, classify waters in which molluscan shellfish are found, based, in part, on an assessment of water quality. As a result of these classifications, molluscan shellfish harvesting is allowed from some waters, not from others, and only at certain times or under certain restrictions from others. Shellfish Control Authorities then exercise control over the molluscan shellfish harvesters to ensure that harvesting takes place only when and where it has been allowed.

Significant elements of Shellfish Control Authorities' efforts to control the harvesting of molluscan shellfish include: 1) a requirement that containers of in-shell molluscan shellfish (shellstock) bear a tag that identifies the type and quantity of shellfish, harvester, harvest location, and date of harvest; and, 2) a requirement that molluscan shellfish harvesters be licensed; 3) a requirement that processors that shuck molluscan shellfish or ship, reship, or repack the shucked product be certified; and, 4) a requirement that containers of shucked molluscan shellfish bear a label with the name, address, and certification number of the shucker-packer or repacker.

Pathogens, such as ***Vibrio vulnificus***, ***Vibrio parahaemolyticus***, ***Vibrio cholerae***, and ***Listeria monocytogenes*** that may be present in low numbers at the time that molluscan shellfish are harvested, may increase to more hazardous levels if they are exposed to time/temperature abuse. To minimize the risk of pathogen growth, Shellfish Control Authorities place limits on the time between harvest and refrigeration. The length of time is dependant upon either the month of the year or the average monthly maximum air temperature (AMMAT) at the time of harvest, which is determined by the Shellfish Control Authority.

Paralytic shellfish poisoning (PSP) results from shellfish feeding upon toxic microorganisms such as dinoflagellates. In the U.S., PSP is generally associated with the consumption of molluscan shellfish from the northeast and northwest coastal regions of the U.S. PSP in other parts of the world has been associated with molluscan shellfish from environments ranging from tropical to temperate waters. In addition, in the U.S., PSP toxin has recently been reported from the viscera of mackerel, lobster, dungeness crabs, tanner crabs, and red rock crabs.

Neurotoxic shellfish poisoning (NSP) in the U.S. is generally associated with the consumption of molluscan shellfish harvested along the coast of the Gulf of Mexico, and, sporadically, along the southern Atlantic coast. There has been a significant occurrence of toxins similar to NSP in New Zealand, and some suggestions of occurrence elsewhere.

For diarrhetic shellfish poisoning there has been no documented occurrence to date in the U.S. However, instances have been documented in Japan, southeast Asia, Scandinavia, western Europe, Chile, New Zealand, and eastern Canada.

Amnesic shellfish poisoning (ASP) is generally associated with the consumption of molluscan shellfish from the northeast and northwest coasts of North America. It has not yet been a problem in the Gulf of Mexico, although the algae that produce the toxin have been found there. ASP toxin has recently been identified as a problem in the viscera of dungeness crab, tanner crab, red rock crab, and anchovies along the west coast of the United States.

Marine toxins are not ordinarily a problem in scallops if only the adductor muscle is consumed. However, products such as roe-on scallops and whole scallops do present a potential hazard for natural toxins.

To reduce the risk of illness associated with raw shellfish consumption, the Food and Drug Administration (FDA) administers the National Shellfish Sanitation Program (NSSP). The NSSP is a tripartite, cooperative action plan involving Federal and State public health officials and the shellfish industry. Those groups work together to improve shellfish safety. States regularly monitor waters to ensure that they are safe before harvesting is permitted. FDA routinely audits the States' classification of shellfish harvesting areas to verify that none pose a threat to public health. Patrolling of closed shellfishing waters minimizes the threat of illegal harvesting or "bootlegging" from closed waters. Bootlegging is a criminal activity and a major factor in shellfish-borne illnesses. Purchases from certified dealers that adhere to NSSP controls is essential to keep risks to a minimum.

Key points on Shellfish

- Live molluscan shellfish must be received at a temperature of 45ºF or below.
- Shellfish must be maintained in original container in which received.
- Shellfish identification tags must be attached to the container that shellfish are received in.
- Shells of clams, mussels and oysters will be closed if alive. If the shells are partially open, it may mean that the shellfish are dead. When tapped on, the shells should close if the shellfish are still alive. If the shells do not close, the shellfish should not be accepted.
- Shellfish must be obtained from a “Certified Shellfish Shipper”. The Interstate Certified Shellfish Shippers List (ICSSL) is published monthly for the information and use by food control officials, seafood industry and other interested persons. The publication is distributed under authorities of the Public Health Service Act and the Food, Drug and Cosmetic Act by the U.S. Food and Drug Administration (FDA) in conjunction with the Office of Compliance, Shellfish Safety Team, 5100 Paint Branch Parkway, College Park, MD 20740.
- The Interstate Certified Shellfish Shippers List is available online at: http://www.cfsan.fda.gov/~ear/shellfis.html

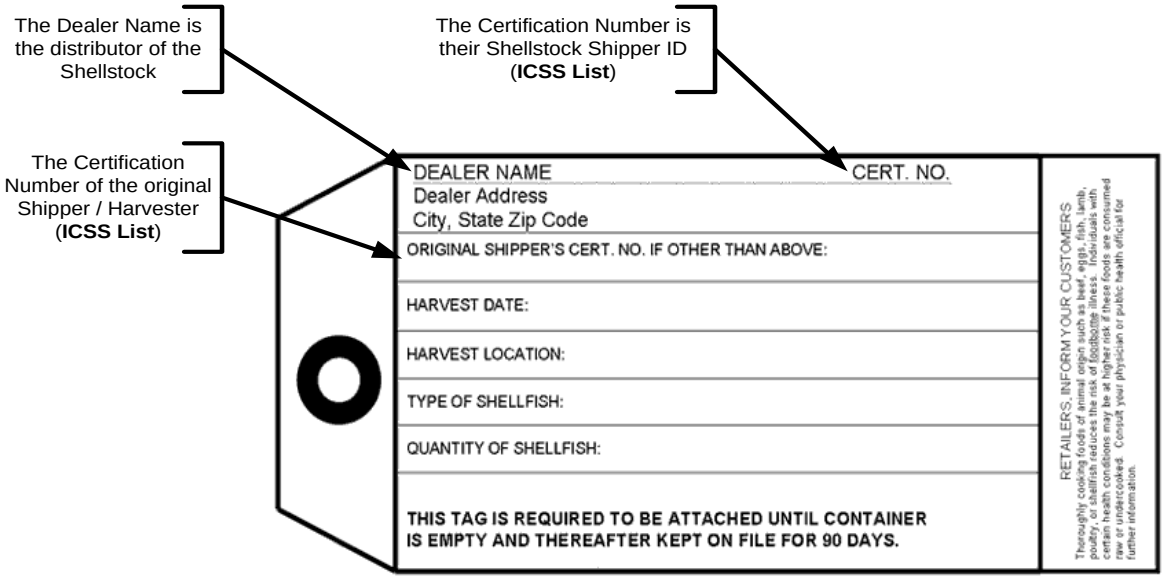
Shucked Shellfish, Packaging and Identification.

- “Shucked Shellfish” means one or both shells removed.
- Nonreturnable packages must bear the name, address, and certification number of shucker-packer or repacker.
- Maintained in original container in which received. Exceptions to original container are made for storage on ice, but source records must be maintained so they can be matched to individual displays.
- Use one tagged or labeled container at a time, or if using more than one container, the establishment management will need a record keeping system to ensure source identification of shellstock - no commingling of product. Records must be maintained to match exactly the product of concern. WHY? – Product trace back. In case of food-borne illness investigation, the consumer may be able to provide the date of purchase and it will be possible to identify the source of the product. If illness is a threat, it is necessary to determine the harvest location so that evaluation of the water can be made. If necessary, the waters may be closed to further harvesting.

Shellstock Identification.

- The requires all raw molluscan shellfish entering a food establishment to have a Shellstock Tag attached to the container. Shellstock shall only be obtained from Certified Harvesters or Dealers – consult the Interstate Certified Shellfish Shippers (ICSS) List for a list of approved sources.
- The National Shellfish Sanitation Program (NSSP) recognizes two types of Shellstock Tags: Harvester Tags and Dealer Tags. Many of the requirements are the same for both tag types.

Key features of a Shellstock Tag.



- When both the dealer and harvester tags appear on the container, the dealer tag is not required to list the date of harvesting, and the harvest location.

White or Gold Banded Oysters.

These type oysters have undergone a high pressure or pasteurization process to destroy potential pathogens. In addition to the other required information, their shellstock tag that is usually blue in color will also display a Lot Number. They will have a yellow heat shrink band or white rubber band around the oyster to keep the oyster shell closed. They may be consumed raw like a regular oyster. However, this pasteurization process does not negate the need for a consumer advisory because the treatment only reduces the level of one pathogenic organism.

"For Cooking Only" Labeled Oysters.

FDA is advising retail and food service establishments to be aware that raw oysters shipped in containers bearing a "For Cooking Only" label may have a greater likelihood of containing harmful levels of the Vibrio parahaemolyticus (Vp) bacterium, which may cause illness, than do raw oysters not labeled in this manner. Special considerations are as follows:

- Retail and food service establishments must not purchase containers or packages of raw oysters that bear the "For Cooking Only" label unless the operator intends to fully cook the product to an internal time/temperature of at least 145°F for 15 seconds before offering it for sale or service to the consumer.

- "For Cooking Only" labeled oysters must be handled in such a way to prevent cross-contamination between raw animal foods and ready-to-eat foods and surfaces that may contact ready-to-eat foods. Strict adherence to proper separation of raw and ready-to-eat foods and effective cleaning and sanitizing of surfaces between uses are among the most important to prevent cross-contamination.

Neon-Green Tag Oysters.

These type oysters have been harvested in a manner that will not allow them to be consumed raw. They should only be found at a Certified Dealer facility licensed to further process them (see ICSS List). If these are found offered or held for sale, a withhold from sale order should be issued and they should be discarded immediately. Also, the Atlanta Office of the Georgia Department of Agriculture or Seafood Safety Officer should be contacted immediately. Further, the local Health Authority should obtain shipping documents and or invoices from the food service establishment for investigation purposes.

Wild Mushrooms.

A Wild-harvested Mushroom means a fresh mushroom that has been picked in the wild and has not been processed (e.g., dried). A Wild-harvested Mushroom does not include mushrooms that have been packaged in an approved food processing plant or cultivated mushrooms.

The sale and service of wild harvested mushrooms occurs nationwide at retail food establishments and poses the risk of death if toxic species are inadvertently offered in place of species that are safe to eat. Over 5000 species of fleshy mushrooms grow naturally in North America. The vast majority have never been tested for toxicity. It is known that about 15 species are deadly and another 60 are toxic to humans whether they are consumed raw or cooked. An additional 36 species are suspected of being poisonous, whether raw or cooked. At least 40 other species are poisonous if eaten raw, but are safe after proper cooking. Some wild mushrooms that are extremely poisonous may be difficult to distinguish from edible species. The previous Chapter required an approved mushroom identification expert; however, the text regarding an approved mushroom identification expert had little meaning and was difficult to enforce. The new language prohibits the sale of wild mushrooms unless a food establishment gets approval from the Health Authority. The conditions for granting approval to a food establishment are 1) the mushroom species picked in the wild must be obtained from sources where each mushroom is individually inspected and found to be safe by an approved mushroom identifier that has passed an approved mushroom identification course and procedures are in place for record-keeping and traceability as listed in that section (below) or 2) the food establishment that sells, uses or serves mushrooms picked in the wild conspicuously identifies the mushrooms by a label, placard, or menu notation that states the following consumer notification:

- The common and usual name of the mushroom; and
- The statement "Wild-harvested mushrooms: not an inspected product and is harvested from a non-inspected site."

An approved mushroom identifier is an individual that has successfully completed a required course on identification of selected species of harvested mushrooms, the appropriate harvest, storage and preparation of those species; and who has demonstrated competence by passing an exam acceptable to the Georgia Department of Public Health's Environmental Health Section.

Record-Keeping and Traceability

To facilitate traceback and foodborne illness investigation, the food establishment must keep records (e.g. tag or label) provided by the approved wild mushroom identifier attached to the container in which the wild harvested mushrooms are received and stored until the container is empty. These records must remain on file in the food establishment for at least 90 days from the date of sale or service of the wild harvested mushrooms. The records provided by the approved wild mushroom identifier must

include the following information:

- Approved identifier name;
- Address & phone number;
- Latin binomial name and locally used common name of the mushroom;
- Harvest date;
- Harvest location (e.g., town, county, township, etc.);
- Harvest weight; and
- Name of forager, if not harvested by an approved identifier.

Commingling of wild harvested mushroom lots is not recommended as it serves to confound traceback or foodborne illness investigations and could hinder efforts to remove implicated product from the food chain. As stated previously, the records must be retained for at least 90 days from the date the container is emptied. This retention period accounts for potentially long asymptomatic latent periods (that can be up to 14 days from consumption), diagnosis and investigation timeframes that can be up to 3 weeks.

The Conference for Food Protection (CFP) has developed guidance material titled "Draft Model Guidance for Wild Harvested Mushrooms" posted on their website at www.foodprotect.org so state and local regulatory authorities can use the information to develop and implement their own wild harvested mushroom program.

The following CFP criteria is used by the State Office of Environmental Health to evaluate Wild Harvested Mushroom Identifier Course Learning Objectives:

1. Illness Information (Symptoms, Cause and Prognosis).
   a. Identify foodborne illnesses associated with the consumption of wild harvested mushrooms.
   b. Describe the symptoms and the consequences of consuming poisonous mushroom species specific to the region in which the mushrooms will be harvested.
2. Identification.
   a. Describe the anatomy of a mushroom as it relates to identification.
   b. Demonstrate the use of keys in the identification of edible mushrooms and their poisonous look-a-likes.
   c. Demonstrate accurate identification of edible species of mushrooms from physical specimens.
3. Harvesting.
   a. Describe specific information in regards to the habitat and seasonality in which mushrooms can be harvested, including areas that are considered inappropriate for harvest (treated areas, contaminated sites, etc.)
   b. Describe proper collection and harvesting techniques.
4. Best Handling Practices.
   a. Recognize and describe the conditions and practices that could

contribute to post harvest contamination.
b. Describe storage and transportation methods that would prevent the contamination of mushrooms.
c. Describe the relationship between personal hygiene and the potential for contamination that could contribute to foodborne illness.

5. Regulatory Requirements.
a. Cite the regulatory requirements in the local jurisdiction for wild mushroom harvesting location and distribution.

Game Animals.

The primary concern regarding game animals relates to animals obtained in the wild. Wild game animals may be available as a source of food only if a regulatory inspection program is in place to ensure that wild animal products are safe. This is important because wild animals may be carriers of viruses, rickettsiae, bacteria, or parasites that cause illness (zoonoses) in humans. Some of these diseases can be severe in the human host. In addition to the risk posed to consumers of game that is not subject to an inspection program, there is risk to those who harvest and prepare wild game because they may contract infectious diseases such as rabies or tularemia.

Specifications for Receiving

Temperature.

Temperature is one of the prime factors that controls the growth of bacteria in food. Many, though not all, types of pathogens and spoilage bacteria are prevented from multiplying to microbiologically significant levels in properly refrigerated foods that are not out of date. USDA published a final rule (63 FR 45663, August 27, 1998 Shell Eggs; Refrigeration and Labeling Requirements) to require that shell eggs packed for consumer use be stored and transported at an ambient temperature not to exceed 45ºF.

High temperatures for a long enough time, such as those associated with thorough cooking, kill or inactivate many types of microorganisms. However, cooking does not always destroy the toxins produced in foods by certain bacteria (such as the enterotoxins of ***Staphylococcus aureus***). Cooking or hot holding that follows temperature abuse may not make the food safe. Keeping cooked foods hot as required in the Chapter prevents significant regrowth of heat-injured microorganisms and prevents recontamination with bacteria that are newly introduced.

Additives.

It is imperative for safety that food supplies come from sources that are in compliance with laws regarding chemical additives and contaminants.

Food additives are substances which, by their intended use, become components of food, either directly or indirectly. They must be strictly regulated. In excessive amounts or as a result of unapproved application, additives may be harmful to the consumer. Unintentional contaminants or residues also find their way into the food supply. The tolerances or safe limits designated for these chemicals are determined by risk assessment evaluations based on toxicity studies and consumption estimates.

Food and Color additives must be used in compliance with a federal food, or color additive regulation, an effective food-contact notification, or a threshold of regulation exemption. Such regulations, notifications, and exemptions are generally composed of three parts: the *identity* of the substance, *specifications* including purity or physical properties, and *limitations* on the conditions of use. In order for a food, or color additive use to be in compliance, the use must comply with all three criteria.

Federal Food Additive regulations are found in Title 21 CFR, Parts 172-180. Color additive regulations are found in Title 21 CFR Parts 73-Subpart A, 74-Subpart A, 81 and 82. Effective food-contact notifications are listed at http://www.accessdata.fda.gov/scripts/fcn/fcnNavigation.cfm?rpt=fcsListing&displayAll=false&page=17, and threshold of regulation exemptions are listed at http://www.fda.gov/Food/IngredientsPackagingLabeling/PackagingFCS/ThresholdRegulationExemptions/ucm093685.htm.

Other substances that are added to food include those prior sanctioned for use in food by either the FDA or USDA, or those generally recognized as safe for their intended use in food. Some of these are listed in Title 21 CFR Parts 181-186, Title 9 CFR Section 424.21(b) and at http://www.fda.gov/Food/IngredientsPackagingLabeling/GRAS/NoticeInventory/default.htm. Tolerances and exemptions from tolerance for pesticide chemical residues in or on food are found in Title 40 CFR Part 180. Substances that are prohibited form use in human food are listed in Title 21 CFR Part 189.

Eggs.

Damaged shells permit the entry of surface bacteria to the inside of eggs. Eggs are an especially good growth medium for many types of bacteria. Damaged eggs must not be used as food.

The Definition of "Restricted Egg" contains several terms that are explained in this paragraph. An egg may be restricted because it is a/an:

(i) "Check" meaning an egg that has a broken shell or crack in the shell but has its shell membranes intact and contents not leaking.

(ii) "Dirty egg or Dirties" meaning an egg that has a shell that is unbroken and has adhering dirt, foreign material, or prominent stains.

(iii) "Incubator reject" meaning an egg that has been subjected to incubation and has been removed from incubation during the hatching operations as infertile or otherwise unhatchable.

(iv) "Inedible" meaning eggs of the following descriptions: Black rots, yellow rots, white rots, mixed rots, sour eggs, eggs with green whites, eggs with stuck yolks, moldy eggs, musty eggs, eggs showing blood rings, and eggs containing embryo chicks (at or beyond the blood ring stage).

(v) "Leaker" meaning an egg that has a crack or break in the shell and shell membranes to the extent that the egg contents are exposed or are exuding or free to exude through the shell.

(vi) "Loss" meaning an egg that is unfit for human food because it is smashed or broken so that its contents are leaking; or overheated, frozen, or contaminated; or an incubator reject; or because it contains a bloody white, large meat spots, a large quantity of blood, or other foreign material.

On December 5, 2000 Federal regulations were amended to require that shell egg cartons bear safe handling instructions and be placed under refrigeration at 45°F or lower upon delivery at retail establishments (65 FR 76091, December 5, 2000, Food Labeling, Safe Handling Statements, Labeling of Shell Eggs; Refrigeration of Shell Eggs Held for Retail Distribution). The amended provisions include:

- 21 CFR Part 16 Regulatory Hearing before the Food and Drug Administration, § 16.5 Inappplicability and limited applicability, (4) A hearing on an order for re-labeling, diversion or destruction of shell eggs…
- 21 CFR Part 101 Food Labeling § 101.17 Food labeling warning, notice, and safe handling statements, (h) *Shell eggs*.
- 21 CFR Part 115 Shell Eggs, § 115.50 Refrigeration of shell eggs held for retail distribution.

The labeling rule became effective September 4, 2001, and the refrigeration rule became effective June 4, 2001. These rules are one part of a larger farm-to-table approach for ensuring the safety of our nation's egg supply. The public health goal is a 50 percent reduction in all salmonellosis and a 50 percent reduction in ***Salmonellae* Enteritidis** illnesses by 2010.

Eggs and Milk Products, Pasteurized.

Liquid egg, fluid milk, and milk products are especially good growth media for many types of bacteria and must be pasteurized. Pasteurization is a heat process that will kill or inactivate bacteria and other harmful microorganisms likely to be in these time/temperature control for safety foods. Freezing and drying of unpasteurized products will stop microbial growth and may reduce their bacterial populations; however, some organisms will survive because neither process invariably kills bacteria. Under certain conditions, freezing and drying may preserve microbes. An alternative to pasteurization may be applicable to certain cheese varieties cured or aged for a specified amount of time prior to marketing for consumption.

Package Integrity.

Damaged or incorrectly applied packaging may allow the entry of bacteria or other contaminants into the contained food. If the integrity of the packaging has been compromised, contaminants such as ***Clostridium botulinum*** may find their way into the food. In anaerobic conditions (lack of oxygen), botulism toxin may be formed.

Packaging defects may not be readily apparent. This is particularly the case with low acid canned foods. Close inspection of cans for imperfections or damage may reveal punctures or seam defects. In many cases, suspect packaging may have to be inspected by trained persons using magnifying equipment. Irreversible and even reversible swelling of cans (hard swells and flippers) may indicate can damage or imperfections (lack of an airtight, i.e., hermetic seal). Swollen cans may also indicate that not enough heat was applied during processing (underprocessing). Suspect cans must be returned and not offered for sale.

Ice.

Freezing does not invariably kill microorganisms; on the contrary, it may preserve them. Therefore, ice that comes into contact with food to cool it or that is used directly for consumption must be as safe as drinking water that is periodically tested and approved for consumption.

Shucked Shellfish, Packaging and Identification.

Plastic containers commonly used throughout the shellfish industry for shucked product bear specific information regarding the source of the shellfish as required by the NSSP Guide for the Control of Molluscan Shellfish. These containers must be nonreturnable so that there is no potential for their subsequent reuse by shellfish packers which could result in shucked product that is inaccurately identified by the label.

Shellstock Identification.

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.

Shellstock, Condition.

Dirty, damaged, or dead shellstock can contaminate and degrade live and healthy shellstock and lead to foodborne illness. Harvesters have the primary responsibility for culling shellstock, but this responsibility continues throughout the distribution chain.

Original Containers and Records **Molluscan Shellfish, Original Container.**

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 must be recorded on a log sheet to correlate with the date of sale of the consumer sized containers.

Shellstock, Maintaining Identification.

Accurate records that are maintained in a manner that allows them to be readily matched to each lot of shellstock provide the principal mechanism for tracing shellstock 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.

The 90 day requirement is based on the following considerations:

Shelf-life of the product.....14 days
Incubation period .....56 days
Medical diagnosis and confirmation ..... 5 days
Reporting ..... 5 days

Epidemiological investigation .....10 days

Total.....90 days

In reality and as stated in the provision, the 90-day "clock" starts at the time the container of shellstock is emptied. Starting from the date of harvest is not correct because the shellstock may be sold/consumed in less than the 14 days of shelf life cited in the chart above. Therefore, the 90 days may expire and the tag discarded before an illness is reported and investigated.

Shellstock could be frozen in the food establishment during the 14-day estimated shelf life period, which would effectively stop the clock on the shelf life. The shellstock could be thawed and consumed past the 14-day shelf life. In this case, the 90 days would expire before consumption if the clock started 90 days from the harvest date.

Freezing shellstock in the food establishment is not usually done because, although oysters-in-the-shell can be frozen with fair results, they do not have the same texture and appearance of a fresh oyster when thawed. Commercially frozen oysters are frozen rapidly to retain product quality.

Preventing Contamination by Employees **Preventing Contamination from Hands.**

In November 1999, the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) concluded that bare hand contact with ready-to-eat foods can contribute to the transmission of foodborne illness and agreed that the transmission could be interrupted. The NACMCF recommended exclusion/restriction of ill food workers as the first preventative strategy and recognized that this intervention has limitations, such as trying to identify and manage asymptomatic food workers.

The three interdependent critical factors in reducing foodborne illness transmitted through the fecal-oral route, identified by the NACMCF, include exclusion/restriction of ill food workers; proper handwashing; and no bare hand contact with ready-to-eat foods. Each of these factors is inadequate when utilized independently and may not be effective. However, when all three factors are combined and utilized properly, the transmission of fecal-oral pathogens can be controlled. Depending on the microbial contamination level on the hands, handwashing with plain soap and water, as specified in the Food Code, may not be an adequate intervention to prevent the transmission of pathogenic microbes to ready-to-eat foods via hand contact with ready-to-eat foods. Handwashing as specified in the Food Code will reduce microbial contamination of the hands by 2-3 logs.

Food employees and conditional employees infected with fecal-oral pathogens can shed viral and protozoan pathogens in the feces at levels up to 10^8 viral particles or oocysts per gram of feces. Having a high potential contamination level on the hands

combined with a very low infectious dose necessary to cause infection are the reasons that FDA believes that handwashing alone is not an effective single barrier in the transmission of these fecal-oral pathogens. The infective dose for ***Giardia*** and ***Cryptosporidium*** is believed to be as low as 1-10 oocysts, and as few as 10 virus particles can infect an individual with Norovirus or hepatitis A.

The CDC now estimates that Norovirus is the leading cause of foodborne illness in the United States. Contaminated hands are a significant factor in the transmission of enteric viruses, including Norovirus and hepatitis A virus. Further, contamination of food by an infected food worker is the most common mode of transmission of hepatitis A in foodborne disease outbreaks. Research has shown the viral transfer rate from contaminated hands to ready-to-eat food to be about 10% and that proper handwashing will significantly reduce the chance of transmitting pathogenic viruses. However, with heavy initial contamination of the hands, especially in the subungal space of the fingers, a basic 2-3 log reduction handwash procedure may not be adequate to prevent the transmission of viral foodborne illness.

Even though bare hands should never contact exposed, ready-to-eat food, thorough handwashing is important in keeping gloves or other utensils from becoming vehicles for transferring microbes to the food.

If a ready-to-eat food is being added as an ingredient to a food item that is subsequently subjected to a pathogen kill step (such as adding cheese or other ready-to-eat toppings to a pizza dough or adding vegetables to a raw meat dish before cooking) then strict prohibition of bare hand contact is not necessary. Cooking foods to the temperatures required in the Chapter will reduce the likelihood of survival of pathogens that might be transferred from an employee's hands to the surface of the ready-to-eat foods. The exception specifically targets bare hand contact with ready-to-eat food at the time it is added as an ingredient to food that will be cooked in the food establishment to the minimum temperatures specified in the Chapter. The exception does not apply when adding ready-to-eat foods as ingredients to foods that will only be lightly heated, melted, or browned rather than cooked to the minimum temperatures specified in this section. Nor does this exception apply when adding ready-to-eat foods as ingredients to foods that are intended for preparation by the consumer offsite. When proper heat treatment is used in combination with the exclusion/restriction of ill food workers and proper handwashing, the proper heat treatment provides an additional means of interrupting disease transmission.

Preventing Food and Ingredient Contamination **Packaged and Unpackaged Food – Protection Separation, Packaging, and Segregation.**

It is important to separate foods in a ready-to-eat form from raw animal foods during storage, preparation, holding and display to prevent them from becoming contaminated

by pathogens that may be present in or on the raw animal foods. An exception is permitting the storage and display of frozen, commercially packaged raw animal food adjacent to or above frozen, commercially packaged ready-to-eat food. The freezer equipment should be designed and maintained to keep foods in the frozen state. Corrective action should be taken if the storage or display unit loses power or otherwise fails. Raw or ready-to-eat foods or commercially processed bulk-pack food that is packaged on-site presents a greater risk of cross-contamination. Additional product handling, drippage during the freezing process, partial thawing or incomplete seals on the package increase the risk of cross-contamination from these products packaged in-house.

With regard to the storage of different types of raw animal foods, it is the intent of the Chapter to require separation based on anticipated microbial load and raw animal food type (species). Separating different types of raw animal foods from one another during storage, preparation, holding and display will prevent cross-contamination from one to the other. The required separation is based on a succession of cooking temperatures which are based on thermal destruction data and anticipated microbial load. For example, to prevent cross-contamination, fish and pork, which are required to be cooked to an internal temperature of 145°F for 15 seconds, shall be stored above or away from raw poultry, which is required to be cooked to an internal temperature of 165°F for 15 seconds due to its considerably higher anticipated microbial load. In addition, raw animal foods having the same cooking temperature, such as pork and fish, shall be separated from one another during storage and preparation by maintaining adequate spacing or by placing the food in separate containers because of the potential for allergen cross-contamination or economic adulteration via inadvertent species substitution.

Food that is inadequately packaged or contained in damaged packaging could become contaminated by microbes, dust, or chemicals introduced by products or equipment stored in close proximity or by persons delivering, stocking, or opening packages or overwraps. Packaging must be appropriate for preventing the entry of microbes and other contaminants such as chemicals. These contaminants may be present on the outside of containers and may contaminate food if the packaging is inadequate or damaged, or when the packaging is opened. The removal of food product overwraps may also damage the package integrity of foods under the overwraps if proper care is not taken.

Food Storage Containers, Identified with Common Name of Food.

Certain foods may be difficult to identify after they are removed from their original packaging. Consumers may be allergic to certain foods or ingredients. The mistaken use of an ingredient, when the consumer has specifically requested that it not be used, may result in severe medical consequences.

The mistaken use of food from unlabeled containers could result in chemical poisoning. For example, foodborne illness and death have resulted from the use of unlabeled salt,

instead of sugar, in infant formula and special dietary foods. Liquid foods, such as oils, and granular foods that may resemble cleaning compounds are also of particular concern.

Pasteurized Eggs, Substitute for Raw Shell Eggs for Certain Recipes.

Raw or undercooked eggs that are used in certain dressings or sauces are particularly hazardous because the virulent organism ***Salmonella*** **Enteritidis** may be present in raw shell eggs. Pasteurized eggs provide an egg product that is free of pathogens and is a ready-to-eat food. The pasteurized product should be substituted in a recipe that requires raw or undercooked eggs.

Protection from Unapproved Additives.

Use of unapproved additives, or the use of approved additives in amounts exceeding those allowed by food additive regulations could result in foodborne illness, including allergic reactions. For example, many adverse reactions have occurred because of the indiscriminate use of sulfites to retard "browning" of fruits and vegetables or to cause ground meat to look "redder" or fresher.

The concern for misuse of additives also applies to food establishments operating under a variance and to Annex 6 Food Processing Criteria (in FDA Food Code Annex) which addresses the use of sodium nitrite or other curing agents in smoking and curing operations. However, if this process is done incorrectly, it could cause illness or death because of excessive nitrite or because the food is insufficiently preserved.

Washing Fruits and Vegetables.

Pathogenic microorganisms, such as *Salmonella* spp., and chemicals such as pesticides, may be present on the exterior surfaces of raw fruits and vegetables. It has been assumed that washing removes the majority of organisms and/or chemicals present; however, more recent studies have demonstrated washing to fall short of their complete removal. Biofilm development by *Salmonella* allows bacterial cells to survive under adverse environmental conditions and also reduces the ability to remove pathogens by washing, even with antimicrobial agents. All fresh produce, except commercially washed, pre-cut, and bagged produce, must be thoroughly washed under running, potable water or with chemicals, or both, before eating, cutting or cooking. Even if you plan to peel or otherwise alter the form of the produce, it is still important to remove soil and debris first.

Infiltration of microorganisms can occur through stem scars, cracks, cuts or bruises in certain fruits and vegetables during washing. Once internalized, bacterial pathogens cannot be removed by further washing or the use of sanitizing solutions. To reduce the likelihood of infiltration, wash water temperature should be maintained at 10°F warmer than the pulp temperature of any produce being washed. Because certain fruits and

vegetables are susceptible to infiltration of microorganisms during soaking or submersion, it is recommended that soaking or submerging produce during cleaning be avoided. It is important to follow practices that minimize pathogens in the water or on the surface of produce. It is important that proper handwashing procedures are followed before and after handling fresh produce.

Scrubbing with a clean brush is only recommended for produce with a tough rind or peel, such as carrots, cucumbers or citrus fruits that will not be bruised easily or penetrated by brush bristles. Scrubbing firm produce with a clean produce brush and drying with a clean cloth towel or fresh disposable towel can further reduce bacteria that may be present. Washing fresh fruits and vegetables with soap, detergent or other surfactants should be avoided as they facilitate infiltration and may not be approved for use on food. Toxic or undesirable residues could be present in or on the food if chemicals used for washing purposes are unapproved or applied in excessive concentrations. Unless otherwise stipulated in 21 CFR 173.315, chemicals used to wash or peel fruits and vegetables should not exceed the minimum amount required to accomplish the intended effect, need to be accurately tested for proper concentration, and must adhere to any indications as dictated on the product label.

A separate sink with hot and cold running water must be provided when vegetables are to be prepared in the establishment that is not purchased pre-cut and pre-washed. This sink is for vegetable washing only. The only exception to this rule is found in DPH 511-6-1-.04(4)(g)3. which allows ready-to-eat foods such as potatoes, soups, chili, sauces, etc. to be thawed, rehydrated, or cooled after cooking in the sink if the sink is cleaned and sanitized before ready to eat food is placed in the sink and again before washing whole, raw fruits and vegetables. This exception does not apply to ready to eat food that is served as raw or undercooked animal foods. Other sinks such as ware washing sinks, hand washing sinks, mop sinks, and sinks used for the preparation of other food cannot be used for this purpose. The purpose of a designated sink for fruits and vegetables is to eliminate any cross-contamination potential from hazards (biological, chemical, or physical) that may be present should other sinks, such as warewashing sinks, mop sinks, or hand sinks, be used for the preparation of raw fruits and vegetables. While only cold water is used for washing vegetables, the hot water is needed to properly clean and sanitize the sink and therefore, hot water must be plumbed to the sink's fixtures.

Many pre-cut, bagged produce items are pre-washed. If so, these products will be identified as such on the package label, and can be used as ready-to-eat without further washing. The label should also state if further washing is recommended or necessary. Precut or prewashed produce in open bags should <u>not</u> be washed before use. After being cut, certain produce such as melons, leafy greens and tomatoes are considered time/temperature control for safety food (TCS) requiring time/temperature control for safety and should be refrigerated at 41°F or lower to prevent any pathogens that may be present from multiplying. For more retail food guidance on the storage and handling of tomatoes, leafy greens, and other produce, you may consult the FDA Program

Information Manual, Retail Food Protection Storage and Handling of Tomatoes, dated October 5, 2007, available at http://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/IndustryandRegulatoryAssistanceandTrainingResources/ucm113843.htm, the document, Time as a Public Health Control for Cut Tomatoes, dated June 8, 2010 available at http://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/IndustryandRegulatoryAssistanceandTrainingResources/ucm215053.htm and the FDA Program Information Manual, Recommendations for the Temperature Control of Cut Leafy Greens during Storage and Display in Retail Food Establishments dated July 7, 2010 available at http://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/IndustryandRegulatoryAssistanceandTrainingResources/ucm218750.htm

On October 26, 1998 a voluntary guidance document for the produce industry which addresses microbial hazards and good agricultural and management practices commonly used by fresh fruit and vegetable producers was issued jointly by FDA, USDA, and CDC. This voluntary guidance contains useful information related to washing fruits and vegetables as well as the application of antimicrobial agents and was updated on August 19, 2003. This "Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables", October 26, 1998, is available from FDA's Food Safety Initiative staff and also on the Internet at http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ProducePlantProducts/ucm064574.htm.

Additionally, in February 2008, the FDA Center for Food Safety and Applied Nutrition (CFSAN) issued "Guidance for Industry, Guide to Minimize Microbial Food Safety Hazards of Fresh-cut Fruits and Vegetables," which covers fresh-cut fruits and vegetables that have been minimally processed (e.g. no kill step) and altered in form, by peeling, slicing, chopping, shredding, coring, or trimming with or without washing or other treatment, prior to being packaged for use by the consumer or a retail establishment. This guide is available at: http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ProducePlantProducts/ucm064458.htm.

On January 11, 2006 FDA/CFSAN published additional safe handling advice on the purchase, storage, and preparation of fresh produce, as well as Q & A's for consumers on their website at: http://www.fda.gov/Food/ResourcesForYou/Consumers/ucm114299.htm. This document is available in PDF (3.5 MB) format (also available in Spanish) and provides additional information on the cleaning of fresh produce.

Preventing Contamination from Ice Used as a Coolant

Ice Used as Exterior Coolant, Prohibited as Ingredient.

Ice that has been in contact with unsanitized surfaces or raw animal foods may contain pathogens and other contaminants. For example, ice used to store or display fish or packaged foods could become contaminated with microbes present on the fish or packaging. If this ice is then used as a food ingredient, it could contaminate the final product.

Storage or Display of Food in Contact with Ice and Water.

Packages that are not watertight may allow entry of water that has been exposed to unsanitary exterior surfaces of packaging, causing the food to be contaminated. This may also result in the addition of water to the food that is unclaimed in the food's formulation and label.

Unpackaged foods such as fresh fish are often stored or displayed on ice. A potential for increasing the microbial load of a food exists because, as the ice melts, pathogens from one food may be carried by water to other foods. The potential for contamination is reduced by continuous draining of melting ice.

Preventing Contamination From Equipment, Utensils, and Linens

Food Contact with Equipment and Utensils.

Pathogens can be transferred to food from utensils that have been stored on surfaces which have not been cleaned and sanitized. They may also be passed on by consumers or employees directly, or indirectly from used tableware or food containers.

Some pathogenic microorganisms survive outside the body for considerable periods of time. Food that comes into contact directly or indirectly with surfaces that are not clean and sanitized is liable to such contamination. The handles of utensils, even if manipulated with gloved hands, are particularly susceptible to contamination.

The Chapter defines gloves as a "utensil" and therefore gloves must meet the applicable requirements related to utensil construction, cleaning, and storage.

In-Use Utensils, Between-Use Storage.

Once a food employee begins to use a utensil such as a ladle, spatula, or knife, that has been previously cleaned and sanitized, it is then considered an in-use utensil. In-use utensils, used on a continuous or intermittent basis during preparation or dispensing, must be cleaned and sanitized on a schedule that precludes the growth of pathogens that may have been introduced onto utensil surfaces. In-use utensils may be safely stored in hot water maintained at 135^{o}F or above during intermittent use because microbial growth is controlled at such temperatures.

A food utensil should be designed and used to prevent bare hand contact with ready-to-eat food or to minimize contact with food that is not in a ready-to-eat form. On-site evaluations can be made to determine if a utensil is improperly designed for the task or whether a food employee is misusing an appropriately designed utensil.

Linens and Napkins, Use Limitation.

Because of their absorbency, linens and napkins used as liners that contact food must be replaced whenever the container is refilled. Failure to replace such liners could cause the linens or napkins to become fomites.

Wiping Cloths, Use Limitation.

Soiled wiping cloths, especially when moist, can become breeding grounds for pathogens that could be transferred to food. Any wiping cloths that are not dry (except those used once and then laundered) must be stored in a sanitizer solution of adequate concentration between uses. Wiping cloths soiled with organic material can overcome the effectiveness of, and neutralize, the sanitizer. The sanitizing solution must be changed as needed to minimize the accumulation of organic material and sustain proper concentration. Proper sanitizer concentration should be ensured by checking the solution periodically with an appropriate chemical test kit.

Wiping down a surface with a reusable wet cloth that has been properly stored in a sanitizer solution is an acceptable practice for wiping up certain types of food spills and wiping down equipment surfaces. However, this practice does not constitute cleaning and sanitizing of food contact surfaces where and when such is required to satisfy the methods and frequency requirements in the Chapter. The same is true of the practice of wiping down a surface using dry disposable towels and a spray bottle containing pre-mixed sanitizing solution. This practice is not prohibited; however, it alone does not constitute proper cleaning and sanitizing of food contact surfaces where and when such is required to satisfy the methods and frequency requirements in the Chapter. Further, for the purpose of wiping up food spills from surfaces in situations where full cleaning and sanitizing is not required (such as when a soft drink overflows onto the side of a cup or onto a countertop) the use of dry cloths and disposable towels is also acceptable as long as the cloth or towel is used for no other purpose. Again, this does not constitute a proper cleaning and sanitizing procedure for a food contact surface, when such is called for in the Chapter.

In order to effectively clean and sanitize food contact surfaces, where and when required to satisfy the requirements in the Chapter, the surface must be first cleaned properly to remove organic material. In most cases this requires use of detergents or other cleaners. After the surface is clean to sight and touch, a sanitizing solution of adequate temperature with the correct chemical concentration should then be applied to the surface. The sanitizing solution must stay on the surface for a specific contact time as specified in this Chapter and in accordance with the manufacturer's EPA-registered label.

Gloves, Use Limitation.

Gloves used in touching ready-to-eat food are defined as a "utensil" and must meet the applicable requirements related to utensil construction, good repair, cleaning, and storage.

Multiuse gloves, especially when used repeatedly and soiled, can become breeding grounds for pathogens that could be transferred to food. Soiled gloves can directly contaminate food if stored with ready-to-eat food or may indirectly contaminate food if stored with articles that will be used in contact with food. Multiuse gloves must be washed, rinsed, and sanitized between activities that contaminate the gloves. Hands must be washed before donning gloves. Gloves must be discarded when soil or other contaminants enter the inside of the glove.

Slash-resistant gloves are not easily cleaned and sanitized. Their use with ready-to-eat foods could contaminate the food.

Using Clean Tableware for Second Portions and Refills.

The purpose of using clean tableware for second portions and refills is to prevent cross-contamination of food on display or in dispensers from utensils and articles previously used by consumers. Clean and sanitized utensils or articles must be used to revisit food self-service displays and or food dispensing devices. The exception is that drinking cups and containers allowed for re-use by self-service consumers if the refilling process is done in such a way as to be a contamination-free process. An example of this type of re-use would be a soda fountain dispenser designed in such a way that ice and beverage cannot be contaminated by the rim of the cup or its contents.

Refilling Returnables.

Food establishments may provide multi-use to-go containers to consumers with the intention that the containers are to be returned to the food establishment for refilling or reuse. These containers are likely to be soiled when the consumer returns the container to the food establishment. As a result, pathogens may be transferred to food by consumers or employees directly, or indirectly, from used take-home food

containers. The existing provisions in the Chapter, specifically the cleaning and sanitization provisions, if carried out properly upon return of a used container, are sufficient to ensure that the container is safe to refill or reuse if performed in conjunction with a visual inspection by a food employee to verify that the container is in good condition, and the establishment only uses Health Authority approved containers that are designed to withstand proper cleaning and sanitizing procedures. Reusing single-service and single-use articles is prohibited by the Chapter.

The refilling of consumer-owned, personal take-out beverage containers, such as thermally insulated bottles, nonspill coffee cups, and promotional beverage glasses, by a consumer or food employee introduces the possibility of contamination of the filling equipment or product by improperly cleaned containers or the improper operation of the equipment. To prevent this contamination and possible health hazards to the consumer, the refilling of consumer-owned, personal take-out beverage containers is limited to beverages that are not potentially hazardous (time/temperature control for safety) foods. Equipment must be designed to prevent the contamination of the equipment and means must be provided to clean the containers at the facility.

Preventing Contamination from the Premises

Food Storage.
Food Storage, Prohibited Areas.

Pathogens can contaminate and/or grow in food that is not stored properly. Drips of condensate and drafts of unfiltered air can be sources of microbial contamination for stored food. Shoes carry contamination onto the floors of food preparation and storage areas. Even trace amounts of refuse or wastes in rooms used as toilets or for dressing, storing garbage or implements, or housing machinery can become sources of food contamination. Moist conditions in storage areas promote microbial growth.

Vended Time/Temperature Control for Safety Food, Original Container.

The possibility of product contamination increases whenever food is exposed. Changing the container(s) for machine vended time/temperature control for safety food allows microbes that may be present an opportunity to contaminate the food. Pathogens could be present on the hands of the individual packaging the food, the equipment used, or the exterior of the original packaging. In addition, time/temperature control for safety foods are vended in a hermetically sealed state to ensure product safety. Once the original seal is broken, the food is vulnerable to contamination.

Food Preparation.

Food preparation activities may expose food to an environment that may lead to the food's contamination. Just as food must be protected during storage, it must also be protected during preparation. Sources of environmental contamination may include splash from cleaning operations, drips form overhead air conditioning vents, or air from an uncontrolled atmosphere such as may be encountered when preparing food in a building that is not constructed according to Chapter requirements.

Preventing Contamination by Consumers

Food Display.

During display, food can be contaminated even when there is no direct hand contact. Many microbes can be conveyed considerable distances on air currents through fine sprays or aerosols. These may originate from people breathing or sneezing, water sprays directed at drains, or condensate from air conditioners. Even wind gusts across sewage deposits and fertilized fields have been known to contaminate food in adjacent establishments where food was unprotected.

Protective devices for counters, serving lines, salad bars and other similar food displays in public eating establishments shall be designed and constructed to intercept contaminants which may be expelled from the customer's mouth or nose. Protective devices must be designed to prevent contamination from the majority of the people using the self-service display.

A provision was added to Rule -.04(4)(w)5 that requires a advance written procedures for tracking the total accumulative time that unwrapped food is displayed on the consumer self-service buffet, if an establishment wishes to use the option of storing the food up to a maximum of 24 hours. The procedures must be maintained in the establishment and be made available to the Health Authority upon request. The procedures must specify how displayed foods will be identified, how each food item will be monitored in regards to tracking its display time, and the corrective action that will be taken if the 24 hour time has been exceeded.

Condiments, Protection.

Unpackaged condiments are exposed to contamination by consumers who could be suffering from a disease transmissible through food. Once the condiments are contaminated, subsequent consumers using the condiments may be exposed to pathogens. Condiments in individual packages are protected from consumer contamination.

On- or off-site facilities for refilling condiment dispensers must be adequately equipped to ensure that the filling operation does not introduce contaminants.

Consumer Self-Service Operations.

Raw foods of animal origin usually contain pathogens. In addition, these foods, if offered for consumer self-service, could cross contaminate other foods stored in the same display. Because raw foods of animal origin are assumed to be contaminated and do provide an ideal medium for the growth of pathogenic organisms, they should not be available for consumer self-service. Self-service operations of ready-to-eat foods also provide an opportunity for contamination by consumers. The risk of contamination can be reduced by supplying clean utensils and dispensers and by employee monitoring of these operations to ensure that the utensils and dispensers are properly used.

Rule -.04 subsection (4) (w) 4& 5. of the Chapter applies only to unwrapped food when time and temperature is used for protection from contamination of TCS or non-TCS food items which have been placed out for consumer self-service. The food items will have to be maintained at temperatures of 41°F or below or 135°F or above. Food service establishments may choose between two methods of limiting time for ready-to-eat foods to be displayed for consumer self-service. Establishments may elect to discard to waste all unwrapped ready-to-eat foods at the end of its business day, or to allow up to a maximum accumulative time of twenty-four (24) hours to display food for self-service. If the twenty-four (24) maximum accumulative time limit is chosen, the establishment will be required to place the date and time on the container of food when placed out for self-service. Any addition of new food to the displayed food is to be discouraged. However, any new food that has been added to existing displayed food will assume the date and time marked on the original displayed food. Further, establishments will be allowed to remove displayed food at the end of the day, properly process it for storage and reserved it the next day. Once the twenty-four (24) maximum time has expired as per the date and time marked on the container of food, the food must be discarded to waste.

“Time as a “Public Health Control” cannot be used to avoid food product temperature control violations. The food service establishment must choose which method of foodborne pathogen growth control (Time as a “Public Health Control or Time in Conjunction with Temperature Control) will be used for safe holding, storage, or display of time/temperature control for safety foods. If “Time as a “Public Health Control” is used to control foodborne pathogen growth during display for service, a written plan must be maintained within the food service establishment. Finally, maximum time limits for foods displayed using “Time as a “Public Health Control” will supersede the maximum self-service display time limits found within Rule -.04 subsection (4) (w) 5. of the Chapter 511-6-1.

Returned Food and Re-Service or Sale.

Food can serve as a means of person-to-person transmission of disease agents such as hepatitis A virus. Any unpackaged foods, even bakery goods in a bread basket that are not time/temperature control for safety foods and that have been served to a consumer, but not eaten, can become vehicles for transmitting pathogenic microorganisms from the initial consumer to the next if the food is served again.

Preventing Contamination from Other Sources **Miscellaneous Sources of Contamination.**

This provision within the Chapter is to capture all sources of contamination that can not be anticipated by which food can become contaminated after receipt.

Outdoor Cooking and Service of Food.

Rule -.04 subsection (4)(y) allows foods to be cooked and served outside of a fixed food service establishment for a specific occasion similar to that which is allowed at temporary food service establishments. An example of this type of service would be cooking and serving of food during an outdoor wedding on the premises of the food service establishment. “Foods requiring only cooking” means that all preparation except for cooking and seasoning, such as basting with barbeque sauce, has been done in the permitted food service establishment. Open displays of food are not allowed. The food must be served immediately upon being cooked. The local Health Authority must evaluate the risk potential of the proposed menu and service prior to giving its approval for outdoor cooking and service of food.

Permanent Cooking Equipment located Outside of the Fixed Food Service Establishment.

There are several items to consider. First, Chapter 511-6-1 does not specifically prevent the use of outdoor cooking equipment, such as country style barbeque pits or barrel/grill (coverable) cookers. It also does not specifically limit as to where these cooking facilities can be located on the food establishment premises. The only limitation placed on outdoor cooking is found in Rule -.04 subsection (4) (y) that limits outdoor cooking AND serving of foods to special events and to specific special event (ex. a wedding party) on the food service establishment’s premises. The food is limited to being cooked and served immediately – all being done outside the establishment and with implied food handling and time limitations. This situation would be conducted similar to a temporary food service operation that allows outside limited preparation, such as seasoning, and service with the difference of being conducted on the premises of a regularly fixed permitted food service establishment. However, the permanent cooking facilities located outside of the main building of the establishment would differ from that of temporary food service operation; because, all food preparation and service would be conducted inside the building of the food service establishment and it would not be limited to special events. The outside cooking equipment (country style barbeque pits/barrel grills/smokers) would be considered as a separate cooking area only and they would not include the preparation and immediate service of food outside. They are usually located outside the food establishment in out buildings and they are used to cook volumes of whole pieces of meat, such as hams, slabs of ribs, or chicken. They cannot be used for immediate service such as that of a short order grill. This cooking process step produces a lot of grease-laden smoke and heat, creating difficulties in maintaining good sanitation. It is for this large production of grease-laden smoke and heat, leading to the burden of maintaining good sanitation of facilities, that these types of cooking equipment are, at times, located outside of the main building of a fixed food establishment. However, recent modern design of smoking, grilling, and pit-cooked barbequing equipment is available for inside commercial cooking that is designed to address the exhaust and sanitation issues of traditional barbequing/grilling.

Secondly, barbeque pits or barrel grills/smokers are considered as cooking equipment and as such, they are part of the cooking operational step of the flow of food through the establishment. Therefore, the cooking equipment and its associated cooking facilities would be considered as a separate cooking area of the establishment and not part of a food preparation operational step. This stated rationale would be true; because, operational steps in the flow of food through the establishment would be: receiving, cooling, packing, storing, reheating, serving, preparing, holding, cooking and assembling. The operational step, "Preparing", would be: mixing, adding (i.e. reconstitution of milk powder to form liquid milk by adding water), grading, slicing, chopping or blending. The Rule -.04 does require that foods be protected at all times; however, it specifically focuses on times of preparation. Rule -.04 subsection (4)(t) states, "During preparation, unpackaged food shall be protected from environmental sources of contamination." This is why no food preparation except for that such as basting barbeque sauce can occur outside of the protective environment of the fixed food service establishment building.

Thirdly, the protection of food and equipment must be considered. Being a separate outdoor cooking area, no food preparation can take place at the outdoor cooking area unless the same requirements for food preparation and protection can be can be met as per the Chapter, specifically Rules -.04, -.05, -.06, and -.07. For food preparation to take place at an outdoor cooking area, it would have to be enclosed within non-absorbent, washable, durable light colored walls and ceilings and with non-absorbent, cleanable, durable floors. Conveniently located, properly installed and properly equipped hand washing station(s) would have to be provided within the cooking/food preparation area, as well. Further and depending on the method of operation, other equipment such as food preparation sink(s), vegetable sink(s), refrigeration, ventilation systems, and or hot-holding equipment may be required to be located in this outside cooking and food preparation facility.

If food preparation is not taking place at these outside separate cooking areas, then outside cooking equipment, such as barrel grills/smokers, must be capable of being closed except when adding, turning, or removing meats. The meat should be prepped inside the food service facility and taken to the barrel grill/smoker in sanitized covered containers where the entire quantity of meat is immediately placed inside the cooker that have been made ready for cooking. It must be noted here that the Chapter requires separation of different types of raw animal foods during holding as per Rule -.04 subsection(4)(c) 1. (ii)(I). When cooked meats are removed from the cooking equipment, separate cleaned and sanitized utensils must be used to immediately place them in cleaned and sanitized pans that are then covered and taken back to inside the food service establishment for any preparation, such as slicing, cutting, chopping, grinding or mixing. At no time shall any food item(s) be left outside the cooking equipment unattended.

The area around the outside separate cooking area must be easily cleanable. It can be constructed of sealed smooth concrete pad or sealed asphalt. It should be located in

an area that will not be subjected to blowing sand or dust. If the outside cooking facility is to be used in inclement weather, overhead protection (such as a shelter or fire resistant tent, etc.) must be provided. Another issue that must be considered is control of vermin at these facilities.

All outside cooking equipment and associated facilities cannot exist by themselves. They must be on the premises of a permitted fixed food service establishment. They also must meet all equipment material and construction requirements of the Chapter, as well as, any other applicable Federal, State or local codes.

Cooking **Raw Animal Foods.**
Microwave Cooking.
Plant Food Cooking for Hot Holding.

Cooking, to be effective in eliminating pathogens, must be adjusted to a number of factors. These include the anticipated level of pathogenic bacteria in the raw product, the initial temperature of the food, and the food's bulk which affects the time to achieve the needed internal product temperature. Other factors to be considered include post-cooking heat rise and the time the food must be held at a specified internal temperature.

Greater numbers and varieties of pathogens generally are found on poultry than on other raw animal foods. Therefore, a higher temperature, in combination with the appropriate time is needed to cook these products.

To kill microorganisms, food must be held at a sufficient temperature for the specified time. Cooking is a scheduled process in which each of a series of continuous time/temperature combinations can be equally effective. For example, in cooking a beef roast, the microbial lethality achieved at 112 minutes after it has reached 130°F is the same lethality attained as if it were cooked for 4 minutes after it has reached 145°F. Cooked beef and roast beef, including sectioned and formed roasts, chunked and formed roasts, lamb roasts and cooked corned beef can be prepared using one of the time and temperature combinations within the Chapter to meet a 6.5-$\log_{10}$ reduction of Salmonella. The stated temperature is the minimum that must be achieved and maintained in all parts of each piece of meat for a least the stated time. The source of the time and temperature parameters is from the USDA/FSIS Appendix A. Compliance Guidelines For Meeting Lethality Performance Standards For Certain Meat And Poultry Products found at http://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/compliance-guides-index/compliance-guides-index.

Cooking requirements are based in part on the biology of pathogens. The thermal destruction of a microorganism is determined by its ability to survive heat. Different species of microorganisms have different susceptibilities to heat. Also, the growing stage of a species (such as the vegetative cell of bacteria, the trophozoite of protozoa,

or the larval form of worms) is less resistant than the same organism's survival form (the bacterial spore, protozoan cyst, or worm egg).

Food characteristics also affect the lethality of cooking temperatures. Heat penetrates into different foods at different rates. High fat content in food reduces the effective lethality of heat. High humidity within the cooking vessel and the moisture content of food aid thermal destruction.

Heating a large roast too quickly with a high oven temperature may char or dry the outside, creating a layer of insulation that shields the inside from efficient heat penetration. To kill all pathogens in food, cooking must bring *all* parts of the food up to the required temperatures for the correct length of time.

The temperature and time combination criteria specified in Rule -.04 of the Chapter are based on the destruction of *Salmonellae*. This organism, if present in raw shell eggs, is generally found in relatively low numbers. Other foods, uncomminuted fish and meats including commercially raised game animal meat, specified as acceptable for cooking at this temperature and time parameter are expected to have a low level of internal contamination. The parameters are expected to provide destruction of the surface contaminants on these foods. Rule -.04 of the Chapter includes temperature and time parameters that provide "D" values (decimal log reduction values) that may surpass 7D. For example, at 145^{o}F, a time span of 15 seconds will provide a 3D reduction of ***Salmonella* Enteritidis** in eggs.

The requirements specified under Rule -.04(5)(a)4 acknowledge the rights of an informed consumer to order and consume foods as preferred by that consumer based on the consumer's health status and understanding of the risks associated with eating raw or partially-cooked animal foods.

In consumer self-service operations, such as buffets, salad bars, sushi bars, or display cases, the consumer advisory as specified under Rule -.04(7)(e) must be posted or available at the self-service unit where the raw or partially cooked food is held for service and readily accessible to consumers prior to making their food selections. In a catered situation, such as a wedding reception, guests are responsible for making their own requests or selections.

Slow-cooked roasts - Heating Deviations and Slow Come Up Time

(Source: USDA/FSIS Appendix A Compliance Guidelines For Meeting Lethality Performance Standards For Certain Meat And Poultry Products found at http://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/compliance-guides-index/compliance-guides-index.

Heating deviations, which most often involve slow come-up time or an inordinate dwell time within the optimum temperature range for microorganism growth can foster the multiplication of many pathogens. This multiplication sometimes can be so prodigious

that even recooking may be ineffective in rendering the product safe. Also, certain toxigenic bacteria can release toxins into the product. Some of these toxins, such as those of ***Staphylococcus aureus***, are extremely heat stable and are not inactivated by normal recooking temperatures.

Further, the sampling of product following a heating deviation may not yield sufficient information to determine the safety of the product in question. Heating deviations can favor the multiplication of many types of bacteria. It would be difficult and expensive to sample for all of them. Depending on the circumstances, establishments may want to use computer modeling to estimate the relative multiplication of bacteria. For example, in a past incident involving an extreme heating deviation, product was put in an oven in which the temperature was inadvertently set to 95°F for about 12 hours. Computer modeling was easily applied in this case because much of the dwell time was at one temperature. The USDA/FSIS determined that within a 6-hour time frame (with other growth conditions assumed to be favorable), the relative multiplication of many pathogens of concern could have exceeded 5-logs. Clearly the product could not be salvaged by reprocessing and was therefore destroyed. Under changing conditions of temperature, however, computer modeling becomes more difficult. One approach is to average lag/log times over small increments such as 5° and add these times to get an approximation of possible total relative growth over a larger increment of time. Establishments must keep in mind that the population of bacteria before processing is generally unknown and that assumptions in the high range often are used as input parameters in the modeling.

Salmonellae are used as test microorganisms to set minimum cooking time/temperatures found within Rule -.04 subsection (5)(a)2.(i) of the Chapter; because, desiccation, or drying, at the surface of foods actually provides the salmonellae with a mechanism to better survive the cooking process. Rule -.04 subsection (5)(a)2.(i) applies to all roasts including formed and comminuted roasts. The following oven cooking parameter chart found within the subsection (5)(a)2.(i) of the Chapter is based on roast weight and moisture content of the oven or cooking bag:

Oven Type	**Oven Temperature Based on Roast Weight**	
	Less than 4.5 kg (10 lbs)	**4.5 kg (10 lbs) or More**
Still Dry	**177°C (350°F) or more**	**121°C (250°F) or more**
Convection	**163° (325°F) or more**	**121°C (250°F) or more**
High Humidity[1]	**121°C (250°F) or less**	**121°C (250°F) or less**
[1] Relative humidity greater than 90% for at least 1 hour as measured in the cooking chamber or exit of the oven; or in a moisture-impermeable bag that provides 100% humidity.		

Within the above chart, two roast sizes indicated. Higher oven temperature for the smaller roast is necessary because of desiccation of salmonella on the surface of smaller roasts. The higher temperature is necessary to offset the shorter "come up" time while the smaller roast is in the oven. High humidity provides for better destruction of Salmonellae (or pathogens) at high humidity due to elimination of the potential desiccation of organisms. A lesser temperature for high humidity condition is possible due to lack of opportunity of drying of the surface of the roast. The oven cooking parameter chart which follows subsection (5)(a)2.(i) of the Chapter is based on a specific internal temperature for a specified time or roast come-up (continued rise in temperature after cooking time is reached) - holding time once the roast reaches final cook temperature is:

Temperature °C (°F)	Time[1] in Minutes	Temperature °C (°F)	Time[1] in Seconds
54.4 (130)	112	63.9 (147)	134
55.0 (131)	89	65.0 (149)	85
56.1 (133)	56	66.1 (151)	54
57.2 (135)	36	67.2 (153)	34
57.8 (136)	28	68.3 (155)	22
58.9 (138)	18	69.4 (157)	14
60.0 (140)	12	70.0 (158)	0
61.1 (142)	8		
62.2 (144)	5		
62.8 (145)	4		
[1]Holding time may include post oven heat rise.			

For example, a roast cooked at 130oF and held for 121 minutes or one cooked at 145°F for 4 minutes will provide a 7-log reduction of Salmonellae. Post oven heat rise may also be considered in establishing a time and temperature relationship. For example, a roast may be removed from the oven when it reaches a temperature of 140°F. Post oven heat rise allows the internal temperature of the roast to rise to 145°F. If it is then held at 145°F for 4 minutes before serving, the requirement of this provision is then met.

Seared Steak

The provision for allowing seared steaks was reviewed by the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) and USDA. Rule .04(5)(a)3. includes their recommendations.

USDA comments included, "For the purposes of this discussion, steak is a whole beef muscle. It does not include whole beef muscle that has been pinned, injected, or chopped and formed. It may be cut cross grain, such as sirloin, chuck, or porterhouse; or it may be cut with the grain, such as flank, skirt, or Chateaubriand. Other species, such as poultry, pork, and lamb are not included."

NACMCF comments included, “Due to the low probability of pathogenic organisms being present in or migrating from the external surface to the interior of beef muscle, cuts of intact muscle (steaks) should be safe if the external surfaces are exposed to temperatures sufficient to effect a cooked color change. In addition, the cut (exposed) surfaces must receive additional heat to effect a complete sear across the cut surfaces. Grill or char marks may be applied to the complete surface searing. The meat should be seared on both top and bottom surfaces utilizing a heating environment (e.g., grill or broiling oven) that imparts a temperature at the surface of the intact steak of at least 145^{o}F to achieve a cooked color change on all external surfaces. The searing of all surfaces should be continuous until the desired degree of doneness and appearance are attained. This is considered a ready-to-eat food.”

As reflected in the definition of “whole-muscle, intact beef steak,” marination is a food safety concern when the fascia (exterior surface) of the steak is broken by scoring or other means which allows the marinade to penetrate, and potentially contaminate, the interior of the steak. In such cases, the Chapter allowance for undercooking without a consumer advisory is negated.

Pork

In pork, ***Trichinella spiralis***, ***Toxoplasma gondii***, and ***Taenia solium***, parasites causing foodborne illness, are inactivated at temperatures below 145^{o}F. Therefore, pork roasts can be cooked like beef roasts (e.g., 145^{o}F for 3 minutes) and pork chops cooked like steaks to achieve an internal temperature of 145^{o}F for 15 seconds.

Based on the Goodfellow and Brown study, a 5D reduction of organisms is achieved at 155^{o}F for 15 seconds for the following foods: ratites and injected meats and comminuted: fish, meat, game animals commercially raised for food, and game animals that come under a USDA voluntary inspection program. Ratites such as ostrich, emu, and rhea are included in this list of raw animals foods because when cooked to a temperature greater than 155^{o}F, ratites exhibit a (metallic) "off" taste.

When USDA established the time and temperature parameters for 9 CFR 318.23 Heat-Processing and Stabilization Requirements for Uncurred Meat Patties (known as the "patty rule"), the Agency based the 5D for Salmonella on extrapolations applied to the research done by Goodfellow and Brown to account for the lack of a "come up, come down" time in the thin, small mass beef patties. Consequently, there is no linear relationship between the patty rule and roast beef time and temperature parameters. The patty rule also provided for an 8D reduction in the number of Shiga toxin-producing ***Escherichia coli***. The time and temperature requirements in the Chapterfor comminuted meats are comparable to the USDA requirements.

Temperature for Comminuted Meat at Less Than 1 Second

In the "Report of the Task Force on Technical Issues Arising from the National Advisory Committee on Microbiological Criteria for Foods" (NACMCF) Review of the Meat Patty Proposal" (undated), it is stated on page 7, in Option (A), that:

> "Based on the 1998 research data ... and an assumption that instantaneous is defined as eight seconds, manufacturers would be required to process fully-cooked meat patties at a temperature of 157^{o}F. Given the lack of any significant margin of safety in this process, there should be no deviation below the 158^{o}F requirement."

In November, 1997, the NACMCF Meat and Poultry Subcommittee revisited the time and temperatures for cooking hamburger and advised FDA that cooking hamburger to 158^{o}F for less than one second is an adequate cook based on the following:

> 1. The cooking recommendations contained in the Food Code and in USDA guidance provide a large margin of safety for killing vegetative enteric pathogens;
>
> 2. The concept of integrated lethality (the kill imparted during the entire heating and cooling process) adds to the margin of safety; and
>
> 3. The time component of the time and temperature requirement will be exceeded before the temperature can be determined.

The parameters for cooking poultry, wild game animal meats, stuffed food products, etc., of 74^{o}C (165^{o}F) or above for 15 seconds yield greater than a 7D reduction.

Children's Menu

Based on the 2005 FDA Food Code, the previous Chapter 290-5-14 allowed operators to serve raw or partially cooked animal food items on their customer's request, as long as the establishment does not serve a "Highly Susceptible Population" and the customer is informed of the risks associated with consuming undercooked items.

The definition of "Highly Susceptible Population" however, only includes young children who are of pre-school age and who obtain food under custodial care (as from a child daycare center). This definition does not address pre-school and older children eating in retail food establishments (such as restaurants), where it is common practice to offer menu items intended for children (e.g. "Kids Menu").

The Chapter seeks to increase current protection of children beyond custodial care facilities and establish needed safeguards in all retail food establishments. The importance of this issue can be demonstrated for numerous combinations of raw animal

foods and associated pathogens. The greatest impact on children however, is undercooked ground beef, where the specific organism of concern is *Escherichia coli* O157:H7.

Children are at relatively high risk for infection with *E.coli* O157:H7. It is possibly the leading cause of acute kidney failure and Hemolytic Uremic Syndrome (HUS) in children [10]. Infection with *E. coli* O157:H7 can result with mild to severe symptoms such as: non-bloody or bloody diarrhea to HUS, which is a condition that includes destruction of red blood cells, problems with blood clotting and kidney failure. About 2% to 20% of patients that are infected with *E. coli* O157:H7 develop HUS [6]. The risk of illness from *E. coli* O157:H7 in ground beef has been shown to be about 2.5 times higher for preschool children and infants than for the rest of the population [6]. The CDC has reported the following *E. coli* 0157:H7 infection rates per 100,000 by age range: 8.2 for young children 1-9 years old and 3.0 for older children 10-20 years of age.

Precluding undercooked foods from being offered on a children's menu may result in increased protection to children from foodborne illness, particularly *E. coli* O157:H7, which can result in severe consequences in children.

Microwave Cooking.

The rapid increase in food temperature resulting from microwave heating does not provide the same cumulative time and temperature relationship necessary for the destruction of microorganisms as do conventional cooking methods. In order to achieve comparable lethality, the food must attain a temperature of 165^{o}F in all parts of the food. Since cold spots may exist in food cooking in a microwave oven, it is critical to measure the food temperature at multiple sites when the food is removed from the oven and then allow the food to stand covered for two minutes post microwave heating to allow thermal equalization and exposure. Although some microwave ovens are designed and engineered to deliver energy more evenly to the food than others, the important factor is to measure and ensure that the final temperature reaches 165^{o}F throughout the food.

"The factors that influence microwave thermal processes include many of the same factors that are important in conventional processes (mass of objects, shape of objects, specific heat and thermal conductivity, etc.). However, other factors are unique in affecting microwave heating, due to the nature of the electric field involved in causing molecular friction. These factors are exemplified by moisture and salt contents of foods, which play a far more important role in microwave than conventional heating." (Reference: Heddelson and Doores, see Annex 2 of the FDA Food Code)

Plant Food Cooking for Hot Holding.

Fruits and vegetables that are fresh, frozen, or canned and that are heated for hot

holding need only to be cooked to the temperature required for hot holding. These foods do not require the same level of microorganism destruction as do raw animal foods since these fruits and vegetables are ready-to-eat at any temperature. Cooking to the hot holding temperature of 135°F prevents the growth of pathogenic bacteria that may be present in or on these foods. In fact, the level of bacteria will be reduced over time at the specified hot holding temperature.

Non-Continuous Cooking of Raw Animal Foods.

Close attention must be paid to control of biological hazards when a food establishment cooks raw animal foods using a process in which the food is partially cooked then cooled with the expectation of fully cooking the food at a later date or time. Rule -.04(5)(d) requires that establishments wishing to use a non-continuous process for the cooking of raw animal foods establish and follow a written plan that ensures each stage of the process is completed within time and temperature parameters that adequately prevent pathogen survival and growth. Rule -.04(5)(d) also requires that establishments take special precautions to ensure that raw animal foods that have only been initially heated to temperatures that are not lethal to the pathogens of concern are clearly identified so that they will not be inadvertently sold or served to the consumer in a partially cooked state.

To ensure the food does not dwell for extended periods within temperature ranges that favor pathogen growth, Rule -.04(5)(d) establishes limits on the time permitted to initially heat the food (initial “come-up” time) and the time permitted to cool the product to temperatures that are safe for refrigerated storage. Together, these limits should prevent food from remaining at temperatures at which pathogen growth to harmful levels may occur.

The criteria in Rule -.04(5)(d) were developed with consideration of the United States Department of Agriculture/Food Safety and Inspection Service (USDA/FSIS) *Performance Standards for Partially Cooked and Char-Marked Meat Patties and Partially Cooked Poultry Breakfast Strips* found in 9 CFR 318.23 and 9 CFR 381.150. (http://edocket.access.gpo.gov/cfr_2008/janqtr/pdf/9cfr318.23.pdf, http://www.access.gpo.gov/nara/cfr/waisidx_08/9cfr381_08.html)

The maximum one hour time limit for the initial heating stage was established based on estimates from predictive microbial modeling. It is intended to limit the cumulative growth of *Clostridium perfringens* that may occur during the come-up time and the subsequent cooling of the product in accordance with the requirements in Rule -.04(6)(d)1. Unless properly controlled, processes in which animal foods are heated to sub-lethal temperatures and times and then cooled may create an environment for the growth of ***Clostridium perfringens, Clostridium botulinum*** and other spore forming, toxigenic bacteria.

The product temperature achieved during the initial heating process may not be

sufficient to destroy vegetative cells of ***Clostridium botulinum*****,** ***Clostridium perfringens*****,** and ***Bacillus cereus,*** if present***.*** The concern is the generation of a large number of vegetative cells of ***Clostridium perfringens*** and/or ***Clostridium botulinum*** before the final cooking stage. For ***Clostridium botulinum***, if enough vegetative cells are produced, toxigenesis can occur in the product before the product is fully cooked. The toxin is not destroyed at the minimum required cooking temperatures. For ***Clostridium perfringens***, if a large number of vegetative cells are consumed, illness can result. In either case a high number of vegetative cells may challenge the lethality step of the ultimate cooking process to the extent that it will be unable to completely eliminate all of these vegetative cells. The cumulative growth of these bacterial pathogens must be taken into account during both the initial heating and cooling steps. The hazard may be compounded with an extended initial "come-up" time and/or a prolonged cooling stage. Hence the degree of hazard may be dependent upon the ultimate effect of the initial heating and cooling, as well as the final cooking step.

A full and adequate cook during the final cooking step is of critical importance to ensure destruction of any pathogens that may have survived and proliferated during any initial heating and cooling stages of the non-continuous cooking process. Rule -.04(5)(d) requires that animal foods cooked by a non-continuous cooking process achieve a minimum final cook temperature that heats all parts of the food to a temperature and for a time specified under Rule -.04(5)(a)1-3. This requirement also precludes serving animal foods that have undergone non-continuous cooking in an undercooked or raw state. In other words, animal foods cooked using a non-continuous process are not covered in the exceptions provided for in Rule -.04(5)(a)(4) that allow for serving undercooked animal foods upon consumer request and with an adequate consumer advisory.

Rule -.04(5)(d) requires that an establishment using non-continuous cooking processes also establish procedures for identifying foods that have only been partially cooked and cooled. This is necessary to ensure these foods are not mistaken by food workers for foods that have been fully cooked and therefore ready-to-eat without a full cook. Partially cooked foods may appear to be fully cooked.

Requiring that food establishments obtain prior approval by the regulatory authority before employing non-continuous cooking processes will help to ensure that the establishment has the proper procedures in place, as well as the necessary facilities and capacity to monitor the appropriate cooling, cooking, separation and product identification of the foods. in accordance with the requirements.

Freezing **Parasite Destruction.**

Lightly cooked, raw, raw-marinated, and cold-smoked fish may be desired by consumers for taste or perceived nutritional reasons. In order to ensure destruction of parasites, fish may be frozen before service as an alternative public health control to that which is provided by adequate cooking. Candling or other visual inspection techniques are not adequate to avoid the risk of parasites from fish which have not been frozen.

The recommended control strategies refer to the ambient air temperature during freezing and to the length of time that the fish is held at the appropriate freezer temperature, or the length of time that the fish is held after it is solid frozen, whichever it appropriate.

Fish that are exempted from parasite destruction include molluscan shellfish, scallops consisting of the shucked adductor muscle, certain large tuna species, Aquacultured fish like salmon raised in net ponds and given feed that contain no live parasites, and fish eggs removed from the skein and rinsed. The parasite hazard is not considered to be reasonably likely to occur if the finished product is fish eggs that have been removed from the skein (the tissue that contains the egg mass) and rinsed. In response to information provided to the FDA Office of Seafood, the Fish and Fisheries Products Hazards and Controls Guidance lists certain species of tuna as not being susceptible to parasites of concern and therefore exempted from the freezing requirements that apply to other fish species that are consumed raw. The Fish and Fisheries Products Hazards and Controls Guidance states that species that normally have parasites as a result of consuming infected prey, apparently do not have the same parasite hazard when raised on pelleted food in an aquaculture operation. On the other hand, aquacultured fish that are fed processing waste and by-catch fish may have a parasite hazard, even when wild caught fish of that species do not normally have a parasite hazard. Feed must not contain any live parasites. For example, the use of fresh fish meat in feed could transmit such parasites. Only heat treated feed or feed otherwise produced in a manner that would kill parasite intermediate stages infective to the aquacultured fish, such as most pelleted feeds, should be used. Based on FDA's current assessment, parasites are not considered a significant hazard in molluscan shellfish or in scallop products consisting only of the shucked abductor muscle. Therefore these products are not required to be subject to the parasite destruction procedures prior to sale or service in a raw or partially cooked form.

Records, Creation and Retention.

Records must be maintained to verify that the critical limits required for food safety are being met. Records provide a check for both the operator and the regulator in determining that monitoring and corrective actions have taken place.

While the Country of Origin Labeling requirements, http://www.ams.usda.gov/COOL/ effective Sept. 30, 2004, mandate identification of wild and farm-raised fish and shellfish, the requirements do not address contents of pelleted feed used in the aquaculture operation. Documentation must be available in the food establishment from the source-through-purchase specifications or labeling that pelleted feed used did not contain fresh fish or plankton. Follow the guidance provided in the Fish and Fisheries Products Hazards and Controls Guidance, Table #3-1 – Potential Vertebrate Species Related Hazards and Table #3-2 – Potential Invertebrate Species Related Hazards.

If raw, raw-marinated, partially cooked, or marinated-partially cook fish are served or sold in the ready-to-eat form, the person in charge must furnish records for proper parasite destruction as follows:

1. When fish are commercially frozen, the supplier must provide a certificate or letter of guaranty, *renewed annually*, that identifies the specific company, fish species that were frozen, and states that the fish have been frozen for a time/temperature specified in the Chapter. These records must be retained for at least ninety (90) days beyond the day of service or sale of the fish products. It would also be acceptable for this information to be included on invoices.

2. If the fish product is frozen on-site of the food service establishment, the food service establishment must have enough freezing equipment present to freeze fish product to the time/temperature requirements in the Chapter. The time/temperature of the freezing process must be electronically recorded and records of it must be held within the establishment for Health Authority review for at least ninety (90) calendar days beyond the time of service or sale of the fish.

3. If fish products are from a source where the fish are raised and fed as specified in subsection (5)(e) 2(iv) of Rule -.04, then a written agreement or statement from the supplier or Aquaculturist stipulating with the requirements of subsection (5)(d) 2(iv)(III) must be retained by the person in charge. These records must be retained within the establishment for at least ninety (90) calendar days beyond the time of service or sale of the fish.

Reheating **Reheating for Hot Holding.**

When food is held, cooled, and reheated in a food establishment, there is an increased risk from contamination caused by personnel, equipment, procedures, or other factors.

If food is held at improper temperatures for enough time, pathogens have the opportunity to multiply to dangerous numbers. Proper reheating provides a major degree of assurance that pathogens will be eliminated. It is especially effective in reducing the numbers of ***Clostridium perfringens*** that may grow in meat, poultry, or gravy if these products were improperly cooled. Vegetative cells of ***C. perfringens*** can cause foodborne illness when they grow to high numbers. Highly resistant ***C. perfringens*** spores will survive cooking and hot holding. If food is abused by being held at improper holding temperatures or improperly cooled, spores can germinate to become rapidly multiplying vegetative cells.

Although proper reheating will kill most organisms of concern, some toxins such as that produced by ***Staphylococcus aureus***, cannot be inactivated through reheating of the food. It is imperative that food contamination be minimized to avoid this risk.

The potential for growth of pathogenic bacteria is greater in reheated cooked foods than in raw foods. This is because spoilage bacteria, which inhibit the growth of pathogens by competition on raw product, are killed during cooking. Subsequent recontamination will allow pathogens to grow without competition if temperature abuse occurs.

Shelf-stable, commercially prepared ready-to eat foods in hermetically sealed containers will have received a controlled retort process that destroys all bacterial pathogens, both vegetative cells and spores, to provide a commercially sterile product. Refrigerated, commercially processed, ready-to-eat, TCS food will have received controlled thermal processing that destroys vegetative bacterial cells and a controlled cooling process that prevents the germination of any spores present. Packaging prevents recontamination and refrigeration prevents spore germination. Because there is limited risk of contamination in these types of products, reheating such foods to the minimum hot holding temperature of 135°F is considered adequate when reheating for hot holding. This should be the case for product that remains in the container or package after it is opened, provided the proper steps are taken to protect the remaining portions from contamination and they are maintained at the appropriate cold holding temperatures as specified in the Chapter.

Foods that have been cooked and cooled within the establishment must be reheated to 165°F for 15 seconds prior to hot holding for service. Foods reheated within a microwave oven must be reheated to this same temperature and allowed stand two (2) minutes after reheating. These ovens are known for their uneven heating of foods, the extra time for these foods to stand, be rotated, stirred and covered after being reheated in the microwave is to ensure that a kill step has been evenly distributed throughout the food.

Treating Juice.

To understand when requirements for "Treating Juice" takes effect, the definition of "Juice" in Rule -.01 of the Chapter must be understood as to how it relates to ingredients. It is interpreted as meaning that a juice is considered made from fruits and

or vegetables. A flower of a plant is not considered a vegetable or a fruit. Likewise, seaweed receives the same consideration as a flower - it is neither a fruit nor a vegetable.

In regards to a "Juice", the food service establishment has two options:

1. Provide a HACCP plan conforming to the content as stated within Rule -.02 where the juice is treated to attain a 5-log reduction, which is equal to a 99.999% reduction (or pasteurization), of the most resistant microorganism of public health significance (Clostridium botulinum); or

2. Label the bottled juice with "WARNING: This product has not been pasteurized and, therefore, may contain harmful bacteria that can cause serious illness in children, the elderly, and persons with weakened immune systems." It must also state, "Keep refrigerated".

A 5-log pathogen reduction requirement is the minimum level of pathogen "kill" that pathogen control measures must consistently achieve. Processing experts evaluate treatments intended to destroy or inactivate pathogens in food in terms of "logs" of kill, where the term "log" is a shorthand expression of the mathematical term logarithm. A logarithm is "the exponent of the power to which a base number must be raised to equal a given number." If the base number is ten, it must be raised to the second power to equal 100, so the exponent is 2, i.e., 10 X 10 = 100. Again, if the base number is ten, it must be raised to the third power to equal 1000, so the exponent is 3, i.e., 10 X 10 X 10 = 1000.

Submitted HACCP plans for treating juice must use treatments capable of consistently achieving at least a 5-log reduction (using ten as the base number) in the level of the pertinent microorganism in the juice. The important thing to understand is that each log of kill is capable of causing a tenfold reduction in the number of organisms of the pathogen that the treatment is designed to kill. In other words, the process would be one that is capable of reducing the level of the pertinent microorganism in the food by 10 fold, e.g., from 100 organisms (of the pathogen) per gram of food to 10 organisms (of the pathogen) per gram of food. A 2-log process further reduces the level of the target pathogen by another factor of 10, i.e., from 10 organisms (of the pathogen) per gram to 1 organism (of the pathogen) per gram of food. Thus, the 5-log performance standard means that the food service establishment operator must treat his juice using a process capable of reducing levels of the pertinent pathogen in the juice by at least 100,000-fold (10 X 10 X 10 X 10 X 10 = 100,000).

This is illustrated in the following table:

Initial number of pertinent microorganism bacteria per gram of food	Log reduction	Decrease in pertinent microorganism bacteria levels	Percent of change	Final number of bacteria per gram of food
100,000 (10^5)	5	10x10x10x10x10=100,000 fold	99.999 %	1 (10^0)

Each in-house bottled juice or beverage intended for self-service must contain the following information on its label 1) name of beverage; 2) ingredients; 3) quantity; 4) nutritional information; and 5) the name and address of the restaurant

It must be remembered that some establishments may attempt to make certain health claims. They may have signage that advertises the beverages as providing certain benefits to health such as energy boosting, immune system enhancement, virility inducing, etc. If claims are made that the drink can be used in the diagnosis, cure, mitigation, treatment or prevention of disease in man or animals, it may fall under the definition of drug or health claims under the Nutrition Labeling and Education Act (NLEA), and the FDA should be contacted for verification. All restaurant-bottled beverages, especially juices, are to be refrigerated and maintained at 41°F or lower until sold to the consumer.

Temperature and Time Control **Frozen Food.**
Time/Temperature Control for Safety Food, Slacking.
Thawing.

Foods are considered frozen at a temperature of 32°F or lower and hard to touch. Freezing shellstock cannot be allowed because freezing kills it and defeats the purpose of obtaining it live. Once dead shellstock begins to decay, it becomes unfit for consumption. Freezing prevents microbial growth in foods, but usually does not destroy all microorganisms. Improper thawing provides an opportunity for surviving bacteria to grow to harmful numbers and/or produce toxins. If the food is then refrozen, significant numbers of bacteria and/or all preformed toxins are preserved.

ROP Fish

Retailers should be aware that when a manufacturer packages fish and fishery products a hazard analysis is required under 21 CFR Parts 123 and 1240, Procedures for the Safe and Sanitary Processing and Importing of Fish and Fishery Products (the Seafood HACCP Rule) to provide for control for nonproteolytic *C. botulinum.* Factors that make formation of *C. botulinum* toxin reasonably likely to occur during finished product storage and distribution are those that may result from the use of a reduced

oxygen packaging (ROP) environment in a food that does not contain barriers to growth of *C. botulinum.*

The processing control for *C. botulinum* can be either freezing, refrigeration alone or refrigeration in combination with chemical inhibitors, (e.g. salt, water activity control). The Fish and Fishery Products Hazards and Control Guidance, Fourth Edition, Chapter 13, addresses freezing as a control strategy for frozen product. This control is intended to prevent exposure of the product to conditions conducive to the production of toxin by nonproteolytic strains of *C. botulinum* in the closed ROP package.

If freezing was chosen by the manufacturer as the barrier to control for nonproteolytic strains of *C. botulinum*, then each individual package of the ROP fish should be labeled to be kept frozen and thawed according to the manufacturer's label instructions. Typically ROP fish will come into retail food establishments in a frozen state with a label that indicates to "thaw immediately before use" or indicates that the product needs to be "kept frozen, and thawed under refrigeration immediately before use."

If a "Keep Frozen" label is not present on each individual ROP package unit, it may or may not be acceptable to store under refrigeration, depending in part on whether there are barriers such as pH or water activity to growth of *C botulinum* in addition to refrigeration.

As an added safeguard to prevent the possibility of *C. botulinum* toxin formation, the Chapter requires that any frozen ROP fish that does not have barriers to growth of *C. botulinum* in addition to refrigeration be completely removed from the ROP environment or package prior to thawing. This is to discourage the practice of thawing frozen ROP fish and holding it at 41ºF or less for a prolonged time period and/or selling it as a refrigerated product.

Cooling.

Safe cooling requires removing heat from food quickly enough to prevent microbial growth. Excessive time for cooling of time/temperature control for safety foods has been consistently identified as one of the leading contributing factors to foodborne illness. During slow cooling, time/temperature control for safety foods are subject to the growth of a variety of pathogenic microorganisms. A longer time near ideal bacterial incubation temperatures, 70°F - 125°F is to be avoided. If the food is not cooled in accordance with the Chapter requirements, pathogens may grow to sufficient numbers to cause foodborne illness.

The Chapter provisions for cooling provide for cooling from 135ºF to 41°F in 6 hours, with cooling from 135ºF to 70°F in 2 hours. The 6-hour cooling parameter, with an initial 2-hour rapid cool, allows for greater flexibility in meeting the Chapter. The initial 2-hour cool is a critical element of this cooling process. An example of proper cooling might involve cooling from 135ºF to 70ºF in 1 hour, in which case 5 hours remain for

cooling from 70ºF to 41ºF. Conversely, if cooling from 135ºF to 41°F is achieved in 6 hours, but the initial cooling to 70ºF took 3 hours, the food safety hazards may not be adequately controlled.

If the cooking step prior to cooling is adequate and no recontamination occurs, all but the spore-forming organisms such as ***Clostridium perfringens*** or ***Bacillus cereus*** should be killed or inactivated. However, under substandard sanitary conditions, other pathogens such as ***Salmonella*** or ***Listeria monocytogenes*** may be reintroduced. Thus, cooling requirements are based on growth characteristics of organisms that may survive or be a post-cook contaminate and grow rapidly under temperature abuse conditions..

Shell eggs.

FDA has approved the use of ionizing radiation for shell eggs. This approval means that FDA has not found the ionizing radiation process to be unsafe for shell eggs. However, shell eggs that have been subjected to the approved ionizing radiation process are not considered to have been pasteurized. Shell egg pasteurization requires the egg to have been subjected to a 5-log kill process for ***Salmonella* Enteritidis**, while the approved ionizing radiation process may deliver only 2 or 3 logs reduction. Therefore, eggs treated by ionizing radiation process alone must be held under refrigeration, as it cannot be guaranteed that ***Salmonella* Enteritidis** will be eliminated in all treated eggs.

Further, irradiated eggs must be labeled in accordance with 21 CFR 179.26 *Ionizing radiation for the treatment of food*.

Hard-boiled eggs with shell intact may be cooled in ambient air and are not considered to be a time/temperature control for safety food after cooling. Hard-boiled eggs may be cooled in drinking water but are considered to be a time/temperature control for safety food after cooling because pathogens, which may be present in the water, may pass through the egg shell during cooling.

***Salmonella* Enteritidis** has been shown to have an extended lag phase in shell eggs due to inhibitory characteristics of the albumen. Research indicates that the organisms are physically located near the exterior of the yolk membrane, in contact with the bacteriostatic components. Growth does not appear until the yolk membrane is weakened by age or physically breached and the yolk nutrients, such as iron, become available to the organisms.

Federal regulations effective August 27, 1999, require shell eggs to be transported and distributed under refrigeration at an ambient temperature not to exceed 45°F. Packed shell eggs must be labeled indicating that refrigeration is required. Imported shell eggs packed for consumer use are required to include a certification that the eggs, at all

times after packing, have been stored and transported at an ambient temperature of no greater than 45°F.

On December 5, 2000 federal regulations were amended to require that shell egg cartons bear safe handling instructions and be placed under refrigeration at 45°F or lower upon delivery at retail establishments (65 FR 76091, December 5, 2000, Food Labeling, Safe Handling Statements, Labeling of Shell Eggs; Refrigeration of Shell Eggs Held for Retail Distribution). The amended provisions include:

- 21 CFR Part 16 Regulatory Hearing before the Food and Drug Administration, § 16.5 Inappplicability and limited applicability, (4) A hearing on an order for re-labeling, diversion or destruction of shell eggs…
- 21 CFR Part 101 Food Labeling § 101.17 Food labeling warning, notice, and safe handling statements, (h) *Shell eggs*.
- 21 CFR Part 115 Shell Eggs, § 115.50 Refrigeration of shell eggs held for retail distribution.

Shell eggs must be placed immediately after receipt in refrigerated equipment that is capable of maintaining an ambient air temperature of 45°F. With the newly established Federal requirement for eggs to be in an ambient storage and transportation temperature of 45°F, and with refrigeration of eggs at retail as described above, the overall time that eggs are stored at temperatures that allow the growth of ***Salmonella*** spp. should be shortened. Additionally, this requirement negates the need to "cool" shell eggs upon receipt, although food establishment operators should maximize the circulation of cooled air in refrigeration units by separating flats, cases, and multiple cartons of eggs.

CFSAN/FSIS Joint Position Paper on Cooling

The processing of most ready-to-eat products includes a heat treatment or cooking step to eliminate pathogenic and spoilage microorganisms. However, this heat treatment does not eliminate spores of ***Clostridium botulinum*** and ***Clostridium perfringens*** and other spore-forming bacteria. Furthermore, these organisms can thrive in the warm product since other competing organisms have been eliminated. Non-refrigerated, anaerobic conditions are conducive to their growth and multiplication.

To prevent the growth and multiplication of spore-forming organisms, product should be cooled rapidly after cooking. When there is inadequate cooling, spores can germinate and the resulting vegetative cells can multiply to hazardous levels. The presence of sufficient numbers of ***C. botulinum*** or other spore-forming organisms may lead to production of harmful toxins. Therefore, ensuring no growth of these organisms will provide the greatest amount of safety.

The USDA/FSIS Performance Standards for the Production of Certain Meat and Poultry Products require a stabilization step (cooling) after the lethality step. The stabilization requirements allow for no growth of ***C. botulinum*** and no more than 1 log growth of ***C. perfringens***. The performance standard of no more than 1 log growth of ***C. perfringens*** was based on the following reasons:

1. The Centers for Disease Control and Prevention (CDC) suggested viable counts of 10^5 or greater of ***C. perfringens*** per gram as one of the criteria for incriminating ***C. perfringens*** as a causative agent of foodborne illness in finished product. However, foods responsible for ***C. perfringens*** outbreaks were found usually to contain 10^6 vegetative ***C. perfringens*** cells per gram.
   In FSIS microbiological raw product surveys, samples were found to contain more than 1000 ***C. perfringens*** per gram. There is some probability that greater than 10^4 ***C. perfringens*** per gram can occur in the raw product on rare occasions. It is a conservative assumption that the great majority of ***C. perfringens*** in the raw product are spores.

2. Heating activates spores that, during cooling, become vegetative cells that can multiply to hazardous levels. If there are more than 10^4 ***C. perfringens*** (spores) per gram on raw product, it is possible that there may be more than 10^4 vegetative ***C. perfringens*** per gram in the product if it is improperly cooled after cooking.

3. Based on the CDC recommended upper limit of 10^5 which should not be exceeded, it was determined that a limit of no more than 1 $\log_{10}$ growth of ***C. perfringens*** would be appropriate to ensure that there would be no more than 10^5 ***C. perfringens*** per gram on the finished product after cooling.

4. The performance standard was discussed with experts on clostridia research. The experts agreed that limiting the relative growth of ***C. perfringens*** to no more than 1 $\log_{10}$ would be reasonable and somewhat conservative with respect to product safety. (64 FR 732, January 6, 1999, Performance Standards for the Production of Certain Meat and Meat Products).

In response to the CFP recommendation, the FSIS Administrator and CFSAN agreed that the data referenced in the CFP recommendation do not support a change in the FSIS guidance or the Food Code Rule -.04(6)(d) and considered it inadvisable to ask the NACMCF to undertake the task requested for several reasons:

1. The study did not address growth of ***C. botulinum***.

2. The results are from a carefully controlled laboratory study in which cooling of the product was steady and continuous, conditions difficult to maintain in most commercial processing or retail environments even with data loggers and other control mechanisms in place.

3. The study was done only on ground beef and may not be applicable to other meat and poultry or to other time/temperature control for safety foods.

As an alternative response, CFSAN and FSIS advised CFP that they would provide this written position paper to clarify their joint position on the cooling issues.

Cooling Methods.

Large food items, such as roasts, turkeys, and large containers of rice or refried beans, take longer to cool because of the mass and volume from which heat must be removed. By reducing the volume of the food in an individual container, the rate of cooling is dramatically increased and opportunity for pathogen growth is minimized. If the hot food container is tightly covered, the rate of heat transfer is reduced, i.e., the time required for cooling and the time the food is exposed to optimal temperatures for bacterial multiplication or toxin production are increased.

Alternatives to conventional methods include avoiding the need to cool larger masses by preparing smaller batches closer to periods of service or chilling while stirring hot food in containers within an ice water bath. Commercial refrigeration equipment is designed to hold cold food temperatures, not cool large masses of food. Rapid chilling equipment is designed to cool the food to acceptable temperatures quickly by using very low temperatures and high rates of air circulation.

Time/Temperature Control for Safety Food, Hot and Cold Holding.

Bacterial growth and/or toxin production can occur if time/temperature control for safety food remains in the temperature "Danger Zone" of 41°F to 135°F too long. Up to a point, the rate of growth increases with an increase in temperature within this zone. Beyond the upper limit of the optimal temperature range for a particular organism, the rate of growth decreases. Operations requiring heating or cooling of food should be performed as rapidly as possible to avoid the possibility of bacterial growth.

The only times that time/temperature control for safety foods are allowed to be held at temperatures above 41°F or below 135°F – the temperature danger zone – is during times of preparation, cooking, cooling, or when time is used as the public health control of foodborne pathogens. This is provided in the Chapter because of the recognition that necessary time must be allowed for foods to be processed. Even during these points of processing foods, time must be managed to conduct these processes with the least amount of time possible or not to exceed time as established by the Chapter.

Cold Holding

Maintaining TCS foods under the cold temperature control requirements prescribed in this code will limit the growth of pathogens that may be present in or on the food and may help prevent foodborne illness. All microorganisms have a defined temperature

range in which they grow, with a minimum, maximum, and optimum. An understanding of the interplay between time, temperature, and other intrinsic and extrinsic factors is crucial to selecting the proper storage conditions for a food product. Temperature has dramatic impact on both the generation time of an organism and its lag period.

When considering growth rate of microbial pathogens, time and temperature are integral and must be considered together. Increases in storage and/or display temperature will decrease the shelf life of refrigerated foods since the higher the temperature, the more permissive conditions are for growth.

Hot Holding

In a January 2001 report, the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) recommended that the minimum hot holding temperature specified in the Food Code:

- Be greater than the upper limit of the range of temperatures at which ***Clostridium perfringens*** and ***Bacillus cereus*** may grow; and
- Provide a margin of safety that accounts for variations in food matrices, variations in temperature throughout a food product, and the capability of hot holding equipment to consistently maintain product at a desired target temperature.

C. perfringens has been reported to grow at temperatures up to 126°F. Growth at this upper limit requires anaerobic conditions and follows a lag phase of at least several hours. The literature shows that lag phase duration and generation times are shorter at incubation temperatures below 120°F than at 125°F. Studies also suggest that temperatures that preclude the growth of ***C. perfringens*** also preclude the growth of ***B. cereus***.

CDC estimates that approximately 250,000 foodborne illness cases can be attributed to ***C. perfringens*** and ***B. cereus*** each year in the United States. These spore-forming pathogens have been implicated in foodborne illness outbreaks associated with foods held at improper temperatures. This suggests that preventing the growth of these organisms in food by maintaining adequate hot holding temperatures is an important public health intervention.

Taking into consideration the recommendations of NACMCF and the 2002 Conference for Food Protection meeting, FDA believes that maintaining food at a temperature of 135°F or greater during hot holding is sufficient to prevent the growth of pathogens and is therefore an effective measure in the prevention of foodborne illness.

Ready-to-Eat, Time/Temperature Control for Safety Food, Date Marking.
Ready-to-Eat, Time/Temperature Control for Safety Food, Disposition.

Refrigeration prevents food from becoming a hazard by significantly slowing the growth of most microbes. The growth of some bacteria, such as ***Listeria monocytogenes***, is significantly slowed but not stopped by refrigeration. Over a period of time, this and similar organisms may increase their risk to public health in ready-to-eat foods.

Based on a predictive growth curve modeling program for ***Listeria monocytogenes***, ready-to-eat, time/temperature control for safety food may be kept at 41°F a total of 7 days. Food which is prepared and held, or prepared, frozen, and thawed must be controlled by date marking to ensure its safety based on the total amount of time it was held at refrigeration temperature, and the opportunity for ***Listeria monocytogenes*** to multiply, before freezing and after thawing. Time/temperature control for safety refrigerated foods must be consumed, sold or discarded by the expiration date.

Date marking is the mechanism by which the Chapter requires active managerial control of the temperature and time combinations for cold holding. Industry must implement a system of identifying the date or day by which the food must be consumed, sold, or discarded. Date marking requirements apply to containers of processed food that have been opened and to food prepared by a food establishment, in both cases if held for more than 24 hours, and while the food is under the control of the food establishment. This provision applies to both bulk and display containers.

A date marking system may be used which places information on the food, such as on an overwrap or on the food container, which identifies the first day of preparation, or alternatively, may identify the last day that the food may be sold or consumed on the premises. A date marking system may use calendar dates, days of the week, color-coded marks, or other effective means, provided the system is disclosed to the Regulatory Authority upon request, during inspections.

FDA/USDA/CDC *Listeria monocytogenes* Risk Assessment

In September, 2003, FDA, in cooperation with USDA/FSIS and CDC, released the Quantitative Assessment of the Relative Risk to Public Health from Foodborne *Listeria monocytogenes* Among Selected Categories of Ready-to-Eat Foods at http://www.fda.gov/downloads/Food/ScienceResearch/ResearchAreas/RiskAssessmentSafetyAssessment/UCM197329.pdf. This initiative included the development of 23 separate risk assessments and analysis of the relative risks of serious illness and death associated with consumption of 23 categories of ready-to-eat foods. These categories included: seafood, produce, meats, dairy products, and deli salads.

In examining these closely, FDA showed that 5 factors are important in measuring the public health impact to consumers from foodborne listeriosis. These factors are: (1) amounts and frequency of consumption of a ready-to-eat food; (2) frequency and levels of ***L. monocytogenes*** in a ready-to-eat food; (3) potential of the food to support growth of the bacterium during refrigeration; (4) refrigerated storage temperature; and (5) duration of refrigerated storage before consumption.

Based on these 5 factors, the 23 categories of ready-to-eat foods were ranked according to their relative risk of contamination and growth of ***Listeria monocytogenes***. The risk categories used were: very high risk; high risk; moderate risk; low risk; and very low risk.

Impact of the Listeria monocytogenes Risk Assessment on Date Marking

Based on the results of the risk assessment and the recommendations from the 2004 Conference for Food Protection meeting, it was necessary to re-evaluate date marking in an effort to focus the provision on very high and high risk foods, while at the same time, exempting foods that present a very low, or low risk of contamination and growth of ***Listeria monocytogenes***. Based on this evaluation, date marking provisions of the Food Code do not apply to the following foods:

Deli Salads Prepared and Packaged in a Food Processing Plant

Examples of deli salads include ham salad, chicken salad, egg salad, seafood salad, pasta salad, potato salad, and macaroni salad, manufactured according to 21 CFR 110. According to data from the risk assessment, deli salads prepared and packaged by a food processing plant contain sufficient acidity, along with the addition of preservatives (e.g., sorbate, benzoates), to prevent the growth of ***Listeria monocytogenes***. There are estimates that 85% of all deli salads are prepared and packaged in a food processing plant and do not support growth. Based on discussions with deli salad manufacturers and trade associations, it is a nearly universal practice for food processing plants preparing and packaging deli salads to add one or more preservatives that inhibit the growth of ***Listeria monocytogenes***. Based on their wide use within this segment of the industry and their effectiveness at inhibiting the growth of ***Listeria monocytogenes***, all deli salads prepared and packaged in a food processing plant are exempt from date marking. However, all deli salads prepared in a food establishment require date marking.

Hard and Semi-Soft Cheeses

In December, 1999, FDA issued an exemption from date marking for certain types of hard and semi-soft cheeses (http://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/IndustryandRegulatoryAssistanceandTrainingResources/ucm113942.htm), based on the presence of

several factors that may control the growth of ***Listeria monocytogenes***. These factors may include organic acids, preservatives, competing microorganisms, pH, water activity, or salt concentration. The results of the risk assessment support this interpretation and therefore, hard and semi-soft cheeses each manufactured according to 21 CFR 133 are exempt from date marking.

Hard Cheeses Exempt from Date Marking	List of Semi-Soft Cheeses Exempt from Date Marking
Asadero	Asiago soft
Abertam	Battelmatt
Appenzeller	Bellelay (blue veined)
Asiago medium or old	Blue
Bra	Brick
Cheddar	Camosum
Christalinna	Chantelle
Colby	Edam
Cotija Anejo	Fontina
Cotija	Gorgonzola (blue veined)
Coon	Gouda
Derby	Havarti
Emmentaler	Konigskase
English Dairy	Limburger
Gex (blue veined)	Milano
Gloucester	Manchego
Gjetost	Monterey
Gruyere	Muenster
Herve	Oka
Lapland	Port du Salut
Lorraine	Provolone
Oaxaca	Queso de Bola
Parmesan	Queso de la Tierra
Pecorino	Robbiole
Queso Anejo	Roquefort (blue veined)
Queso Chihuahua	Samsoe
Queso de Prensa	Tilsiter
Romanello	Trappist
Romano	
Reggiano	
Sapsago	
Sassenage (blue veined)	
Stilton (blue veined)	
Swiss	
Tignard (blue veined)	
Vize	
Wensleydale (blue veined)	

Cultured Dairy Products

Cultured dairy products include yogurt, sour cream, and buttermilk, each manufactured according to 21 CFR 131. Many of these products often are low pH foods manufactured with lactic acid fermentation. Data from the risk assessment show that ***Listeria monocytogenes*** does not grow in these foods and therefore, these products are exempt from date marking.

Preserved Fish Products

Preserved fish products include pickled herring and dried, or salted cod, and other acidified fish products, manufactured according to 21 CFR 114. Data from the risk assessment show that the high salt and/or acidity of these products does not allow for the growth of ***Listeria monocytogenes*** and therefore, these products are exempt from date marking. This exemption does not apply to hot or cold smoked fish products, nor does it apply to fish products that are dried, marinated, or otherwise preserved on-site, in a food establishment, such as ceviche.

Shellstock

Although ***Listeria monocytogenes*** has been isolated from shellstock there have been no reported Listeriosis cases linked to the consumption of this product at retail. The competitive microflora present in and on shellstock inhibits the growth of ***Listeria monocytogenes*** to harmful levels when the product is held under refrigeration at retail. Therefore shelllstock are exempt from date marking.

USDA-regulated products

Date marking provisions of the Food Code do not apply to shelf stable ready-to-eat meat and poultry products. Shelf stable ready-to-eat meat and poultry products are not required by USDA to be labeled “Keep Refrigerated.” For these products, the nitrite and salt in the cure and the lower pH resulting from fermentation give additional protection against microbial growth. Some fermented sausages and salt-cured products are shelf stable, do not require refrigeration, and do not bear the label “Keep Refrigerated.” To be shelf stable, a product manufactured under USDA inspection must have a process that results in a product that meets one of the recognized objective criteria for shelf stability, such as water activity, moisture-protein ratio (MPR), or combination of MPR and pH (acidity). Therefore they are exempt from the Food Code date marking requirements.

Shelf stable fermented sausages such as pepperoni and dry salami do not have to be refrigerated or date marked. Shelf stable salt-cured products such as prosciutto, country cured ham, or Parma ham do not require refrigeration or Food Code date marking. Other salt-cured products include basturma, breasaola, coppa, and capocolla.

Some ready-to-eat fermented sausages and salt-cured products must be refrigerated and therefore bear the USDA-required label “Keep Refrigerated.” Examples of these products are cooked bologna, cooked salami, and sliced country ham which are ready-to-eat fermented products that need refrigeration. Bologna is a cooked, perishable sausage and there are other salamis, e.g., cotto that are perishable.

The intact casing on shelf-stable sausages may be overwrapped to protect the cut face of the sausage. With shelf stable (non-time/temperature control for safety food) sausages, the intact casing provides a barrier to contamination (although not an absolute one), the exposed face is likely to be sliced again within 4 or 7 days, and contamination is minimized because only the face is exposed. The coagulated protein that occurs on the surface of some nonshelf stable cooked sausages is not a casing.

Slices of cured and fermented sausages that require refrigeration and are kept for 24 hours or longer do need to be date marked.

If open dating information is applied to lunchmeats at a federally inspected meat or poultry establishment, the information must comply with the requirements in 9 CFR 317.8 and 381.129. However, such dating is not required by USDA/FSIS and if applied, would not supercede or replace date marking requirements established by the Food Code or by State/local authorities that apply after the food is opened in a retail establishment.

Manufacturer’s use-by dates

It is not the intent of this provision to give a product an extended shelf life beyond that intended by the manufacturer. Manufacturers assign a date to products for various reasons, and spoilage may or may not occur before pathogen growth renders the product unsafe. Most, but not all, sell-by or use-by dates are voluntarily placed on food packages. If a non-TCS food exceeds, the expiration date there is a potential for mold growth which is considered adulterated.

Although most use-by and sell-by dates (non-TCS foods) are not enforceable by regulators, the manufacturer's use-by date is its recommendation for using the product while its quality is at its best. Since expired food is most times a quality issue, the provision for expired foods was modified to address foods that by law, or model ordinance, cannot be sold after their expiration dates (eggs, milk, infant formula, shucked oysters). In focusing on risk, the expiration, use by, or sell by dates that the Health Authoriy will be concerned about, in addition to the aforementioned, are those that apply to time/temperature for safety foods (TCS) that have a “keep refrigerated” label. This requires an assessment by the EHS because there are certain foods in which refrigeration requirements may vary based on their ingredients. For example, a chocolate cake may not require refrigeration, but a cake with cream cheese icing would, so the cream cheese icing cake should be labeled as “keep refrigerated,” and therefore could not be sold after the expiration date. This does not apply to foods that have “keep

refrigerated after opening," or similar statements, on the label since these products are typically held as shelf-stable products, not requiring refrigeration at the point of sale. As far as frozen foods, must verify whether the handling statement on the package says keep refrigerated, or keep frozen. If the handling statement is included on the package, then it cannot be sold or held for sale past the stated date. This would include refrigerated products that are placed in a freezer immediately before the expiration date.

Using Time as a Public Health Control.

The 2000 Conference for Food Protection (CFP) meeting recommended that FDA ask the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) to review the Food Code provision that addresses using time alone as a public health control, section 3-501.19. In response to the CFP recommendation, FDA in consultation with USDA/FSIS, determined that there is sufficient scientific information available to support the current provision in the Food Code without requesting consideration by the NACMCF. As an alternative response, FDA informed the CFP that it would provide the following position paper on using time alone as a public health control.

Position Paper

Rule -.04(6)(i) allows time/temperature control for safety food that is ready-to-eat (RTE) to be stored without temperature control for up to 4 hours, after which it must be discarded or consumed or for up to 6 hours for refrigerated food, if the food is 41°F when initially removed from temperature control, and as long as the food temperature does not exceed 70°F. The following information is provided to explain the reasoning in allowing time alone to be used as a public health control for food safety.

Background Information

Food kept without temperature control allows product to warm or cool as it equilibrates with the environment. Each temperature scenario incurs different risks in regard to the type of foodborne pathogens able to grow and the rate of growth likely to occur. For both cooling and warming conditions, growth depends on the amount of time the food spends in an optimum growth temperature range during its equilibration with its surroundings. Several factors influence the rate of temperature change in a food, such as the type of food, thickness of the food, and temperature differential between the food and its surroundings. When evaluating the safety of a 4-hour limit for food with no temperature control, products and environmental parameters must be selected to create a worst-case scenario for pathogens growth and possible toxin production.

Holding Cold Food Without Temperature Control

When a food is removed from refrigerated storage and begins to warm to room temperature, ***Listeria monocytogenes*** is a primary organism of concern. Even while food is held at refrigeration temperatures, the growth potential of ***L. monocytogenes***

warrants concern for time/temperature control for safety foods RTE foods. Although the FDA and USDA have a zero tolerance for ***L. monocytogenes*** in RTE food, conditions are permitted in the Food Code that would allow ***L. monocytogenes*** cells 1 log of growth (3.3 generations). ***Salmonella*** is also a concern especially with products containing eggs. However ***L. monocytogenes*** grows more rapidly than ***Salmonella*** at refrigeration and room temperatures. By ensuring minimal ***Listeria*** growth in food, the threat from ***Salmonella*** would be negligible. Warming conditions will allow food to remain exposed to temperatures that allow ***B. cereus*** to produce emetic toxin. However the 4-hour time constraint in the Food Code is sufficient to prevent any toxin formation.

For food refrigerated at 41ºF then transferred to an ambient temperature of 75°F for 4 hours, the growth rate of ***L. monocytogenes*** remains slow enough to ensure that the critical limit of 1 log growth is not reached. Published generation times at 75°F for ***L. monocytogenes*** in food were not found, however published values at 68ºF and 70°F in egg and milk products confirmed slow ***L. monocytogenes*** growth at room temperatures.

Using the USDA Pathogen Modeling Program (PMP) and assuming the optimum conditions of pH 6.8, 0.5% NaCl, 0.0% nitrite, ***L. monocytogenes*** would require more than 4 hours to grow 1 log at 75°F. The PMP is based on broth studies and not on food products. Therefore, the growth rates reported at various temperatures by the PMP are faster than growth rates in most food products. Another factor exaggerating the growth rate in this warming scenario as predicted by the PMP is the assumption that the food product spent all 4 hours at 75°F. Obviously food equilibrates with the surrounding environment at a gradual rate and would not equilibrate instantly.

Unfortunately there are no models that take changing temperatures into consideration when predicting growth. Likewise there are very few published papers dealing with the growth of organisms in food during warming. The conservative nature of the 4-hour limit for keeping foods without temperature control allows for a needed margin of safety if the temperature of the environment is higher than 75°F.

It is important to note that time/temperature control for safety foods held without cold holding temperature control for a period of 4 hours do not have any temperature control or monitoring. These foods can reach any temperature when held at ambient air temperatures as long as they are discarded or consumed within the four hours.

Holding Hot Food without Temperature Control

The second scenario for food without temperature control exists when food is cooked according to Food Code recommendations, then kept at room temperature for 4 hours before discarding. Foodborne pathogens of concern for an uncontrolled temperature scenario are sporeformers including ***Clostridium perfringens*** and ***Bacillus cereus***. Food cooked according to Food Code guidelines should be free of vegetative cells.

However, the heat requirements are not sufficient to kill spores of ***C. perfringens*** or ***B. cereus*** and may actually serve as a heat shock that activates the spores. ***B. cereus*** is found commonly in outbreaks attributed to inadequate hot holding of starchy foods like rice, and has been isolated in a multitude of food products. ***C. perfringens*** is found commonly in outbreaks attributed to inadequate hot holding of beef and poultry. Despite the prevalence of both spores in nature, ***C. perfringens*** cases are estimated to be more numerous than ***B. cereus*** cases by a factor of 10.

B. cereus can produce emetic toxin in food, and the optimum temperature for the production of toxin is between 77°F and 86°F. However, the time needed to produce the toxin is longer than the time the food will be exposed to any temperature range with a 4-hour holding limit. Both ***C. perfringens*** and ***B. cereus*** produce enterotoxin inside the intestine of the infected host if substantial numbers of vegetative cells are present in the food (10^{5-7} CFU/g). Although the reported levels of both spores in raw foods vary in the literature, generally the level expected in food can be assumed to be low (around 10-1000 CFU/g). This implies that conditions allowing 1 log growth of either spore could be tolerated in food.

During the time without temperature control, the temperature of the food could decrease slowly enough to expose spores of both organisms to optimal growth conditions for a significant length of time. Like warming, several variables exist that determine the rate of heat transfer. Because of the wide variety of foods prepared it would be impossible to generalize how fast a typical product loses temperature after cooking. As with warming, it is prudent to imagine a worst-case scenario where heat loss is slowed. A beef roast slow cooked to 130°F for the appropriate time according to the Food Code was used as consideration for possible spore growth. Cooking roast beef to 130°F can create an anaerobic environment in both the meat and gravy. The low internal temperature creates a small temperature differential with the environment (assumed at 75°F), allowing for a slower decrease in the food's temperature.

After evaluating published studies as well as data collected at the FDA, the surface of a roast beef or rolled meat product would lose heat quickly enough to discourage significant growth of either ***C. perfringens*** or ***B. cereus***. If all spores were distributed on the surface of the product by either pre- or post-cooking contamination, storing this product for 4 hours at room conditions would be considered safe. Likewise, products that are stirred or products that lose heat faster than a roast would also be considered safe.

---------- End of position paper ---------

At the 2004 meeting of the CFP, a committee submitted and the Conference accepted a document that examined scientific research related to the growth of ***Listeria monocytogenes****,* and the influence of time and temperature on its growth.

The 2004 CFP report stated that the USDA-PMP program can be used as a tool to estimate time periods for a 1-log increase in growth for ***Listeria monocytogenes*** in

ideal (laboratory media) growth conditions. Using this modeling approach, at 41°F, 45°F, and 50°F, the time for a 1-log increase was, 87.8, 53.9, and 34.7 hours, respectively. At room temperature (70°F) a 1-log increase was noted at 5.2 hours and at ideal growth temperatures (95°F), the reported time for a 1-log increase was 3.0 hours. In general, the data from the USDA-PMP program provides very conservative growth data and, in most cases, growth would be expected to be less rapid in a food system. This table does provide comparative information relative to growth rates at different holding temperatures in the event that time was used as a factor in managing food safely.

The report further recommended that food could safely be held for up to 6 hours without external temperature control as long as the food temperature did not exceed 70°F. Based on that report and data from the Quantitative Assessment of the Relative Risk to Public Health from Foodborne *Listeria monocytogenes* Among Selected Categories of Ready-to-Eat Foods September 2003, the Food Code allows time/temperature control for safety food to be stored up to 6 hours without external temperature control provided that the food temperature does not exceed 70°F and the food is discarded or consumed at the end of the 6 hours.

The Safety of the Time as a Public Health Control Provision from Cooking Temperatures (135°F or above) to Ambient

FDA conducted in-house laboratory experiments to test the safety of the existing TPHC provisions of 4 hours without temperature control starting with an initial temperature of 135°F or above. *Clostridium perfringens* was chosen to represent a worst case scenario pathogen for foods allowed to cool from cooking temperatures to ambient without temperature control, because its spores can survive normal cooking procedures, it can grow at relatively high temperatures (>120°F) and it has a short lag period. *C. perfringens* spores were inoculated into foods that were cooked and then cooled to yield a cooling curve that would promote outgrowth as quickly as possible. The growth data suggest that the existing 4-hour TPHC provision will be safe for 6 hours after cooking, with the additional 2-hour margin of safety built-in for consumer handling.

Consumer Handling Practices

An Audits International study was funded in 1999 by FDA to determine the food handling practices of consumers purchasing food at retail and returning home to refrigerate their items. Forty-six (46) states are represented, and the data comprises several food groups purchased from different grocery-store types. The food groups represented were: pre-packaged lunch meat, deli-counter products, seafood, fresh meat, pre-packaged deli product, liquid dairy, semi-solid dairy product, ice cream, frozen entrées, frozen novelties and whipped topping.

The study evaluated information regarding time and food temperature at retail food stores, time to reach home refrigeration, temperature after transport home, location and

type of retail establishment where purchase was made and type of product purchased.

For product temperature at retail and after transportation, 5 product categories were used: pre packaged lunch meat, pre packaged deli product, deli counter products, seafood and fresh meat. These categories were considered most applicable to the TPHC recommendations. The temperature ranges for these products at retail and after transport to the home are summarized in Figures 1 and 2 respectively. The data suggest that with current retail refrigeration practices, 25% of items are held above 45°F (Figure 1). The data also show that by the time the product arrives at the home, 98% of products were at 65°F or less (Figure 2).

The time of transport for all food categories from the retail establishment to home refrigeration was also recorded. The data summarized in Figure 3 shows that over 97% of the foods purchased were ready to be placed in refrigeration within 2 hours of purchase. For this histogram, all food categories except for frozen entrées were included. Because all foods end up bagged and transported together, the time each product was transported to the home was considered a valid data point and therefore used. Based on the data, a benchmark was established that TCS foods purchased in a food establishment would be either consumed, or placed under temperature control, within 2 hours.

Figure 1. Temperatures of refrigerated products at retail (Audits International).

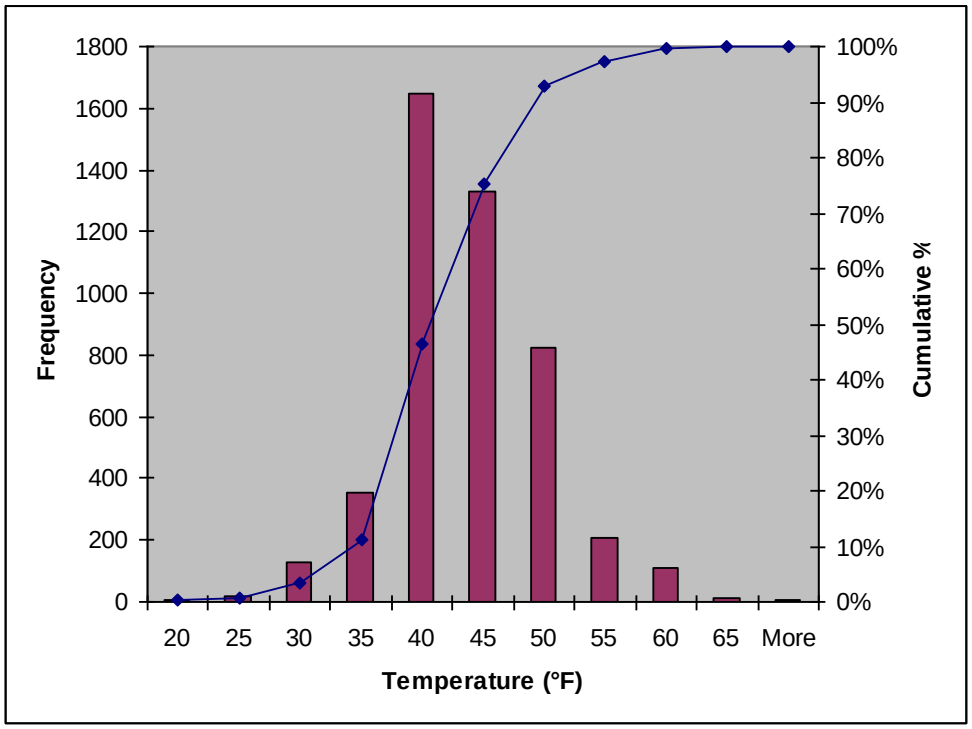


Figure 2. Product temperatures after transport to the home (Audits International).

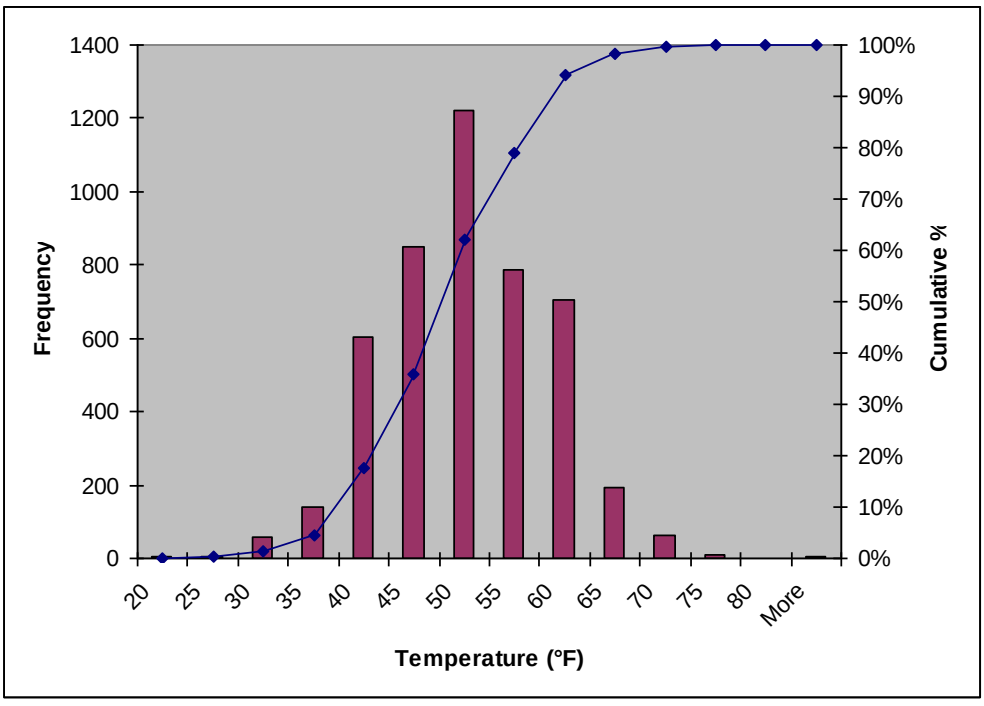
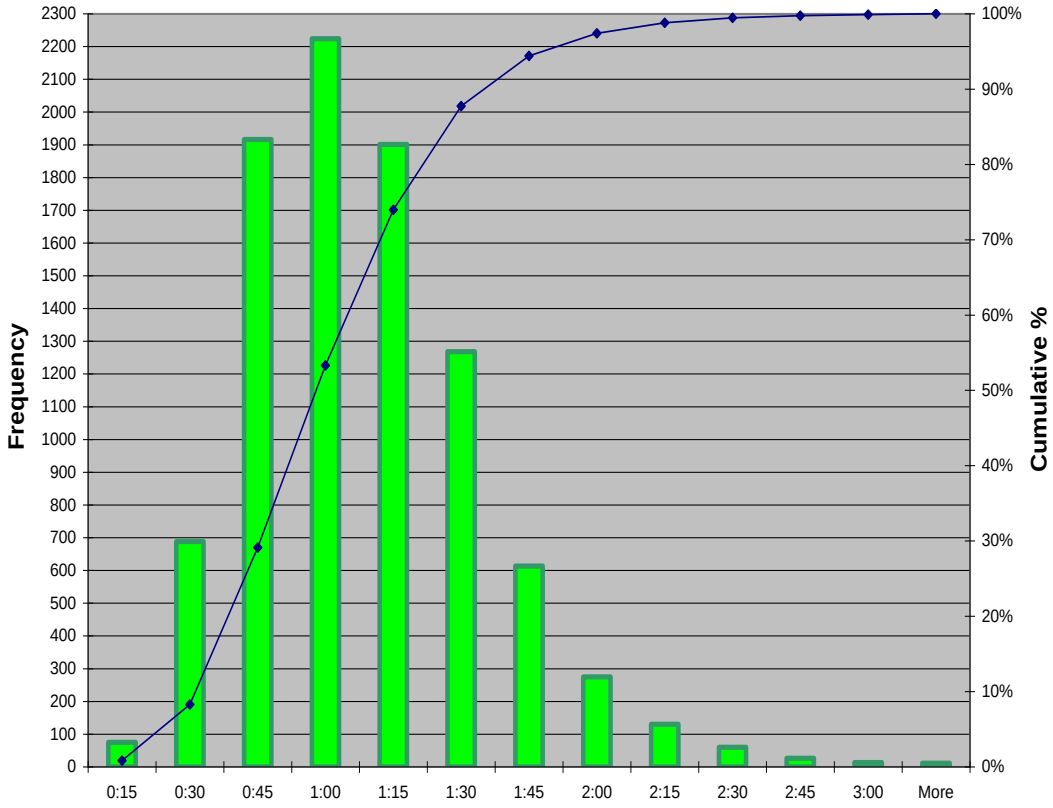


Figure 3. Times reported for transport of grocery items from the retail outlet to the home (Audits International).



The Safety of the Time as a Public Health Control Provision from Refrigeration Temperatures (41°F or less) to Ambient

As noted above, the current TPHC provision has two time provisions. Food can be kept with no temperature stipulations for 4 hours in a food establishment, at which time the food must be cooked and served, served if RTE, or discarded within the four hours. However, if food does not exceed 70°F, it may be held for 6 hours and cooked and served, served if RTE or discarded within the six hours. For foods warming from refrigeration to ambient temperatures, the data from the Audits International study outlined above, along with simulations from the USDA Pathogen Modeling Program (PMP), were used to determine the safety of the existing TPHC recommendations.

Assuming pathogen growth in foods going from refrigeration (41°F or less) to ambient temperature, the following parameters were used for the PMP simulation:

- 65°F was used as the temperature for the entire simulation;

- 2 hours were added to all times (4h or 6h) allowed in the current TPHC recommendation, to factor in transportation time (per the Audits International study outlined above);
- The data were generated from PMP broth models (pH 6.8), with the minimal NaCl and no sodium nitrite.

Table 1 summarizes the predicted growth of *Bacillus cereus* (vegetative), *Escherichia coli*, *Listeria monocytogenes*, Salmonella spp., *Shigella flexneri*, and *Staphylococcus aureus*, using the PMP and based on the assumptions discussed above. The data predicted that less than 1-log growth would be seen for each organism, during the 8 hour time period. Thus, the data show that the current 4 and 6 hour TPHC provisions from 41°F or less to ambient, allow minimal growth of a number of pathogens of concern.

Table 1. The USDA Pathogen Modeling Program estimation of growth (Log CFU/g) of several pathogens for 6 hours or 8 hours, at 65°F.

Pathogens	6 Hours	8 hours
B. cereus (vegetative cells)	0.62	0.87
E. coli	0.35	0.52
L. monocytogenes	0.47	0.71
Salmonella Spp.	0.25	0.41
S. flexneri	0.26*	0.34*
S. aureus	0.38*	0.51*

* Model predictions were in 5 hour increments, the 6 and 8 hour data was extrapolated between 5 hour and 10 hour predictions.

References

U.S. Department of Agriculture. 1997. *Pathogen Modeling Program.* USDA Agricultural Research Service, Wyndmoor, PA.

Food and Drug Administration. 2006. Growth of *Clostridium perfringens* inoculated into beef roasts and meatloaf (unpublished data).

---------- End of Summary of Consumer Handling Practices study **----------**

Raw eggs

Recipes in which more than one egg is combined carry an increased risk of illness and possible serious consequences for certain people. It is due to this increased risk, and documented occurrences of foodborne illness and death among highly susceptible

populations from temperature-abused raw shell eggs contaminated with ***Salmonella* Enteritidis**, that the use of time as a public health control in institutional settings is not allowed.

Specialized Processing Methods **Variance Requirement.**

Specific food processes that require a variance have historically resulted in more foodborne illness than standard processes. They present a significant health risk if not conducted under strict operational procedures. These types of operations may require the person in charge and food employees to use specialized equipment and demonstrate specific competencies. The variance requirement is designed to ensure that the proposed method of operation is carried out safely. Please refer to pages 26-29 for information on the variance process and contents of a HACCP plan.

Reduced Oxygen Packaging Without a Variance, Criteria.

Reduced oxygen packaging (ROP) encompasses a large variety of packaging methods where the internal environment of the package contains less than the normal ambient oxygen level (typically 21% at sea level), including vacuum packaging (VP), modified atmosphere packaging (MAP), controlled atmosphere packaging (CAP), cook chill processing (CC), and sous vide (SV). Using ROP methods in food establishments has the advantage of providing extended shelf life to many foods because it inhibits spoilage organisms that are typically aerobic. ROP may also offer benefits related to time and labor savings, portion control and quality retention. However, ROP can also increase the potential for the growth of certain pathogens in the absence of the growth of competing spoilage organisms. For example, if certain controls are not in place, the formation of ***C. botulinum*** toxin may occur before spoilage renders the product unacceptable to the consumer.

The type of food, the production and packaging methods used, and the packaging material can impact the level of oxygen present within a package and within the food matrix. Combinations of some or all of these variables may result in an oxygen level within a package, or within a food matrix, that is less than 21%. While ROP may involve different foods and different packaging materials, each process is characterized by the deliberate removal of oxygen from or the reduction in the oxygen level in the package or the food matrix at the time of packaging.

Certain foodborne pathogens that are anaerobes or facultative anaerobes are able to multiply under either aerobic or anaerobic conditions. Therefore special controls are necessary to control their growth. Refrigerated storage temperatures of 41°F may be adequate to prevent growth and/or toxin production of some pathogenic microorganisms but non-proteolytic ***C. botulinum*** and ***L. monocytogenes*** are able to

multiply well below 41°F. For this reason, ***C. botulinum*** and ***L. monocytogenes*** are the pathogens of concern for ROP. Controlling their growth will control the growth of other foodborne pathogens as well.

Reduced Oxygen Packaging with Two Barriers

When followed as written, the ROP methods in this section all provide controls for the growth and/or toxin production of ***C. botulinum*** and ***L. monocytogenes*** without a variance. Paragraph 3-502.12 (B) identifies an ROP method with secondary barriers that will control ***C. botulinum*** and ***L. monocytogenes*** when used in conjunction with a food storage temperature of 5°C (41°F) or less. These barriers are:

- a_w of 0.91 or less;
- pH of 4.6 or less;
- cured, USDA inspected meat or poultry products using substances specified in 9 CFR 424.21; or
- high levels of competing microorganisms such as those found on raw meat or raw poultry or raw vegetables.

The barriers described above are effective controls for **C. *botulinum*** and **L. *monocytogenes*** in reduced oxygen packaged foods because**:**

- ***C. botulinum*** will not produce toxin below an a_w of 0.91, and the minimum a_w for growth of ***L. monocytogenes*** is 0.92.
- ***C. botulinum*** will not produce toxin when the pH is 4.6 or below and ***L. monocytogenes*** will generally not grow at this pH under refrigeration temperatures.
- Nitrite, used in meat and poultry curing, inhibits the outgrowth of ***C. botulinum*** spores.
- Most foodborne pathogens do not compete well with other microorganisms. Therefore foods that have a high level of spoilage organisms or lactic acid bacteria that grow under ROP conditions can safely be packaged using ROP and held for up to 30 days at 41°F.

Other intrinsic or extrinsic factors can also control the growth and/or toxin production of ***C. botulinum*** and ***L. monocytogenes***.

Foods that are not time/temperature control for safety food (TCS) should not support the growth of ***C. botulinum*** and ***L. monocytogenes.*** Therefore the reduced oxygen packaging HACCP requirements for ROP apply only to TCS foods.

Reduced Oxygen Packaging with One Barrier (Cook-Chill and Sous Vide)

Some foods may not have secondary barriers to prevent the growth of ***C. botulinum*** and ***L. monocytogenes,*** such as a_w, pH, nitrite in cured meat products, high levels of competing microorganisms or intrinsic factors in certain cheeses. When these foods are packaged using a reduced oxygen packaging process, time/temperature becomes the critical controlling factor for growth of ***C. botulinum*** and ***L. monocytogenes***. Non-proteolytic ***C. botulinum*** spores are able to germinate and produce toxin at temperatures down to 38ºF. Therefore, holding ROP foods at 38ºF or less should prevent the formation of ***C. botulinum*** toxin. ***L. monocytogenes*** is able to grow, although very slowly, at temperatures down to - 1ºC (30ºF). The lag phase and generation time of both pathogens becomes shorter as the storage temperature increases. In cook-chill processing (where food is cooked then sealed in a barrier bag while still hot) and sous vide processing (where food is sealed in a barrier bag and then cooked), both depend on time/temperature alone as the only barrier to pathogenic growth. Therefore, monitoring critical limits including those established for cooking to destroy vegetative cells, cooling to prevent outgrowth of spores/toxin production, and maintaining cold storage temperatures to inhibit growth and/or toxin production of any surviving pathogens is essential. Three separate options are provided in Rule -.04(6)(k)4.(ii)(V).

These time-temperature combinations will provide equivalent food safety protection without need for a variance. (***L. monocytogenes*** will be eliminated by the cooking procedures specified in Rule -.04(5)(a)1-3 and recontamination will be prevented by filling the product into the bag while it is still hot (cook-chill) or by cooking in the sealed bag (sous vide). ***C. botulinum*** will not grow under the specified time-temperature combinations.)

Since there may not be other controlling factors for ***C. botulinum*** and ***L. monocytogenes*** in a cook-chill or sous vide packaged product, continuous monitoring of temperature control and visual examination to verify refrigeration temperatures is important. New technology makes it possible to continuously and electronically monitor temperatures of refrigeration equipment used to hold cook-chill and sous vide products at 1°C (34°F) or 5°C (41°F) or less. Thermocouple data loggers can connect directly with commonly available thermocouple probes. Recording charts are also commonly used. Temperature monitors and alarm systems will activate an alarm or dialer if temperatures rise above preset limits. Nickel-sized data loggers are available to record temperatures that can be displayed using computer software. Since surveys have shown that temperature control in home kitchens is not always adequate, food packaged using cook-chill or sous vide processing methods cannot be distributed outside the control of the food establishment doing the packaging.

Reduced Oxygen Packaging with Cheese

Cheeses, as identified in Rule -.04(6)(k)5.(i) that meet the Standards of Identity for hard, pasteurized process, and semisoft cheeses in 21 CFR 133.150, 21 CFR 133.169, or 21 CFR 133.187, respectively, contain various intrinsic factors, often acting synergistically, that together act as a secondary barrier to pathogen growth along with refrigerated storage at 41°F or less. This combination of factors could include some or all of the following:

- a lower pH;
- salt (NaCl) added during processing;
- low moisture content;
- added preservatives; and
- live competing cultures.

The extended shelf life for vacuum packaged hard and semisoft cheeses is based on the intrinsic factors in these cheeses plus the refrigeration temperature of 41°F or less to maintain safety. Examples of cheeses that may be packaged under ROP include Asiago medium, Asiago old, Cheddar, Colby, Emmentaler, Gruyere, Parmesan, Reggiano, Romano, Sapsago, Swiss, pasteurized process cheese, Asiago fresh and soft, Blue, Brick, Edam, Gorgonzola, Gouda, Limburger, Monterey, Monterey Jack, Muenster, Provolone, and Roquefort. Soft cheeses such as Brie, Camembert, Cottage, and Ricotta may not be packaged under reduced oxygen because of their ability to support the growth of ***L. monocytogenes*** under modified atmosphere conditions.

Reduced Oxygen Packaging with Fish

Unfrozen raw fish and other seafood are specifically excluded from ROP at retail because of these products' natural association with non-proteolytic ***C. botulinum*** (primarily type E) which grows at 37-38^{o}F. ROP of fish and seafood that are frozen before, during and after the ROP packaging process does not present this hazard.

HACCP Plans with Reduced Oxygen Packaging

A Hazard Analysis and Critical Control Point (HACCP) plan is essential when using ROP processing procedures. ***C. botulinum*** and ***L. monocytogenes*** are potential hazards which must be controlled in most TCS foods. Critical control points, critical limits, monitoring, record keeping, corrective actions, and verification procedures will vary based on the type of food and type of ROP technology used. Developing a HACCP plan and providing a copy to the regulatory authority prior to implementation provides notice to the regulatory authority that the food establishment intends to conduct ROP operations and makes it possible to verify that the appropriate ROP procedures are being followed and that the requirements are being met.

When a food establishment intends to conduct ROP and hold the product for more than 48 hours without using one of the secondary barriers (the criteria specified in Rule -.04(6)(k)4.(ii) combined with holding the product at 41°F or less, or hard or semisoft

cheeses manufactured using Standards of Identity for those cheeses), it is important that an application for a variance provide evidence that the ROP methodology intended for use is safe.

The Relationship Between Time and Reduced Oxygen Packaging

Time is also a factor that must be considered in ROP at retail. The use of date labels on VP, MAP, and CAP products and assuring those dates do not exceed the manufacturer's "sell by" or "use by" date is intended to limit the shelf life to a safe time period (based on a time in which growth will not occur or involves the presence of two barriers to growth). When these ROP products are frozen, there is no longer a restricted shelf life. The shelf life limits for cook-chill and sous-vide foods are based on killing all vegetative cells in the cooking process, preventing recontamination, and then refrigerating at 34°F or less for 30 days or 5°C 41°F or less for 7 days after packaging, with stringent temperature monitoring and recording requirements. These criteria allow both institutional-sized cook-chill operations that may feed thousands daily, often including transportation to their satellite locations, and individual restaurants without ice banks and tumble or blast chillers to safely use cook-chill and sous-vide processes.

Rule -.04(6)(l) exempts refrigerated, ROP foods that are always removed from the package within 48 hours of packaging from the requirements of a HACCP plan because growth and toxin formation by anaerobic pathogens in that limited time frame is not considered a significant hazard in such foods.

Accurate Representation

Standards of Identity.
Honestly Presented.
Labeling Food Labels.
Other Forms of Information.

The identity of a food in terms of origin and composition is important for instances when a food may be implicated in a foodborne illness outbreak and for nutritional information requirements. Ingredient information is needed by consumers who have allergies to certain food or ingredients. The appearance of a food should not be altered or disguised because it is a cue to the consumer of the food's identity and condition.

Food Labels and other forms of Information

Food labels serve as a primary means by which consumers can make informed decisions about their food selections. Many items in a food establishment are provided by the food employee to the consumer upon consumer request. When a consumer orders a specific food or specific amount of food from a food employee, that employee may put the food in a wrapper or carry-out container at the time the order is placed. This food is not considered "packaged", per the Food Code definition; it was merely wrapped or placed in a carry-out container to facilitate service and delivery of the food

to the consumer in a protected manner. When food is under the direct control of the operator and provided to the consumer upon consumer request, the consumer has an opportunity to ask about ingredients, nutrients, allergens and weight.

Alternatively, some food items are enclosed in a container or wrapping for use in the display of that item for consumer self-service. In these instances, the label provides an important source of information for consumers to answer questions about ingredients, allergens, weight, and manufacturer.

List of Ingredients

A list of ingredients on the label enables a consumer to make an informed decision about a packaged food product. Therefore it is important that the list of ingredients accurately describe all of the ingredients present in the food. In some instances, an ingredient itself may be composed of two or more ingredients, or sub-ingredients. The 21 CFR 101.4(b)(2), calls for the sub-ingredients to be declared on the label - d. One example includes parenthetically listing the individual sub-ingredients in descending order of predominance after the common or usual name of the main ingredient, as illustrated here:

- Bread pudding: bread (*wheat flour, water, yeast, salt, honey*), milk, eggs, and sugar

Another example is to incorporate the common or usual name of each sub ingredient into the list of ingredients in descending order of predominance in the finished food without listing the ingredient itself, as illustrated here :

- Bread pudding: milk, wheat flour, water, eggs, sugar, yeast, salt, and honey.

Food Allergen Labeling

The Food Allergen Labeling and Consumer Protection Act of 2004 (Public Law 108-282) require that all affected packages of food labeled on or after January 1, 2006 identify on the label the names of the food sources of any major food allergens (i.e., the following eight foods and any protein derived from them: milk, egg, fish, Crustacean shellfish, tree nuts, wheat, peanuts, and soybeans) used as ingredients in the food. Providing the name of the food source on the label of packaged foods alerts consumers to the presence of a major food allergen and may prevent an inadvertent exposure. The names of the food sources are the same as the names of the eight foods that are major food allergens, with the exception that for fish, crustacean shellfish, and tree nuts, their respective food source names are the specific species of fish (e.g., bass, flounder, or cod), the specific species of crustacean shellfish (e.g., crab, lobster, or shrimp), and the specific types of tree nuts (e.g., almonds, pecans, or walnuts).

Nutrition Labeling

Certain requirements in the CFR relating to aspects of nutrition labeling became effective in May, 1997. The following attempts to provide guidance regarding those requirements and exemptions as they relate to the retail environment and to alert regulators to authority that has been given to them by the Nutrition Labeling and Education Act (NLEA) of 1990. The statute and the CFR should be reviewed to ensure a comprehensive understanding of the labeling requirements.

I. The following foods need not comply with nutrition labeling in 21 CFR 101 and 9 CFR 317 Subpart B if they do not bear a nutrient claim, health claim, or other nutrition information:

(A) Foods packaged in a food establishment if:

(1) The food establishment has total annual sales to consumers of no more than $500,000 (or no more than $50,000 in food sales alone), and

(2) The label of the food does not bear a reference to the manufacturer or processor other than the food establishment;

(B) Low-volume food products if:

(1) The annual sales are less than 100,000 units for which a notification claiming exemption has been filed with FDA's Office of Nutritional Products Labeling and Dietary Supplements Food Labeling by a small business with less than 100 full-time equivalent employees, or

(2) The annual sales are less than 10,000 units by a small business with less than 10 full-time equivalent employees;

(C) Foods served in food establishments with facilities for immediate consumption such as restaurants, cafeterias, and mobile food establishments, and foods sold only in those establishments;

(D) Foods similar to those specified in the preceding bullet but that are sold by food establishments without facilities for immediate consumption such as bakeries and grocery stores if the food is:

(1) Ready-to-eat but not necessarily for immediate consumption,

(2) Prepared primarily in the food establishment from which it is sold, and

(3) Not offered for sale outside the food establishment;

(E) Foods of no nutritional significance such as coffee;

(F) Bulk food for further manufacturing or repacking; and

(G) Raw fruits, vegetables, and fish.

II. Game animal meats shall provide nutrition information which may be provided by labeling displayed at the point of purchase such as on a counter card, sign, tag affixed to the food, or some other appropriate device.

III. Food packaged in a food processing plant or another food establishment, shall meet the requirements for food labels and enforcement by the regulatory authority is authorized in the NLEA, Section 4. State Enforcement.

Canthaxanthin and Astaxanthin

Canthaxanthin and Astaxanthin are color additives for salmonid fish. According to the FDA Regulatory Fish Encyclopedia, the family Salmonidae includes pink salmon, coho salmon, sockeye salmon, chinook salmon, Atlantic salmon, chum salmon, rainbow trout, cutthroat trout, and brown trout. These color additives may be in the feed that is fed to aquacultured fish. When those fish are placed into a bulk container for shipment, the bulk container will bear a label declaring the presence of canthaxanthin. 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.

Family Style Service

The permit holder is required to fully disclose how the family-style of service will be provided to consumers prior to their being seated for service. Disclosure must be in the form of a prominently displayed sign containing descriptive language in a letter height of at least 1 inch so it is easily readable by consumers at the location where consumers wait to be seated and then again, verbally by the host, hostess or server prior to consumers being seated. Once served, any leftover food on the table must be discarded.

Consumer Advisory **Consumption of Raw or Undercooked Animal Foods.**

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.

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 Rule -.04 of the Chapter. **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. 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.

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.

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 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 Rule -.04(5)(a) 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 Rule -.04(5)(a)1.-2. 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 may differ from the language in the codified provision. 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.

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.

Expired Foods.

Prepackaged sandwiches, eggs, infant formula, shucked oysters, and milk cannot be served, sold, or used after the manufacturer’s expiration date or the sell-by date.. In addition, time/temperature control safety foods that are labeled as “keep refrigerated” and that are for sale or service to the consumer or used as an ingredient in other foods shall be immediately discarded and shall not be sold, served, or used after the manufacturer’s expiration date or the sell-by date. This does not apply to food with a label that reads “keep refrigerated after opening”. This does not apply to “keep refrigerated after opening,” or similar statements since these products are typically held as shelf-stable products, not requiring refrigeration at the point of sale.This is consistent with Georgia Department of Agriculture.

Disposition **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 **Pasteurized Foods, Prohibited Re-Service, and Prohibited Food.**

The Chapter provisions that relate to highly susceptible populations are combined within the following paragraphs for ease of reference and to add emphasis to special food safety precautions that are necessary to protect those who are particularly

vulnerable to food-borne illness and for whom the implications of such illness can be dire.

As a safeguard for highly susceptible populations from the risk of contracting food-borne 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 food-borne 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, this Manual will be modified or interim interpretive guidance will be issued regarding food-borne 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.

In lieu of meeting the requirements of 21 CFR 120, juices that are produced as commercially sterile products (canned juices) are acceptable for service to a highly susceptible population. Persons providing pureed meals to highly susceptible populations may also wish to use fruit and vegetables that are produced as commercially sterile products (canned fruit or vegetables) as a means of enhancing food safety.

Salmonella often survives traditional preparation techniques. It survives in a lightly cooked omelet, French toast, stuffed pasta, and meringue pies. In 1986 there was a large multistate outbreak of Salmonella Enteritidis traced to stuffed pasta made with raw eggs and labeled fully cooked. Eggs remain a major source of these infections, causing large outbreaks when they are combined and undercooked as was the case in the 1986 outbreak linked to stuffed pasta. Therefore, special added precautions need to be in place with those most susceptible to food-borne illness.

Operators of food service establishments serving highly susceptible populations may wish to discuss buyer specifications with their suppliers. Such specifications could stipulate eggs that are produced only by flocks managed under a Salmonella Enteritidis control program that is recognized by a regulatory agency that has animal health jurisdiction. Such programs are designed to reduce the presence of Salmonella Enteritidis in raw shell eggs. In any case, the food service establishment operator must use adequate time and temperature controls within the establishment to minimize the

risk of a food-borne illness outbreak relating to Salmonella Enteritidis.

Since 1995, raw seed sprouts have emerged as a recognized source of food-borne illness in the United States. The FDA and CDC have issued health advisories those persons who are at a greater risk for foodborne disease should avoid eating raw alfalfa sprouts until such time as intervention methods are in place to improve the safety of these products. Further information is available at the FDA website, http://www.fda.gov, by entering “sprouts” in the search window.

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the 1986 outbreak linked to stuffed pasta. Therefore, special added precautions need to be in place with those most susceptible to foodborne illness.

Operators of food establishments serving highly susceptible populations may wish to discuss buyer specifications with their suppliers. Such specifications could stipulate eggs that are produced only by flocks managed under a ***Salmonella* Enteritidis** control program that is recognized by a regulatory agency that has animal health jurisdiction. Such programs are designed to reduce the presence of ***Salmonella* Enteritidis** in raw shell eggs. In any case, the food establishment operator must use adequate time and temperature controls within the establishment to minimize the risk of a foodborne illness outbreak relating to ***Salmonella* Enteritidis**.

Although the Chapter's allowance for a variance is applicable to all provisions, variance requests related to the preparation of food for highly susceptible populations will be considered with particular caution and scrutiny. With all variances, the hazard(s) must be clearly identified and controlled by a HACCP plan that is instituted in conjunction with a standard operating plan that implements good retail practices. Variances that will impact a highly susceptible population must be considered in light of the fact that such a population is at a significantly higher risk of contracting foodborne illnesses and suffering serious consequences including death from those illnesses, than is the general population. Rule -.04(9)(a)2. requires a HACCP plan for the use of raw shell eggs when eggs are combined in food establishments serving highly susceptible populations. A variance is not required since the HACCP plan criteria are specific, prescriptive, and conservative and require a cooking temperature and time to ensure destruction of ***Salmonella* Enteritidis**.

Re-service of food

The Chapter addresses two issues concerning persons in isolation:

1. Contamination from an isolated patient to others outside.

The re-service of any food including unopened, original, intact packages in sound condition, of non-temperature controlled for safety food from a person in isolation or quarantine for use by anyone else (other patients, clients, or consumers) is <u>not</u> permitted. The "isolation or quarantine" terminology in the Chapter provisions refers to a patient-care setting that isolates the patient, thereby preventing spread of key pathogens to other patients and healthcare workers. Once food packages come to a contact isolation room, they stay there until the patient uses or discards them. If packages of food are still in the room when the patient is discharged or moved from isolation, they must be discarded.

2. Contamination from the outside into a room with a patient in a “protective environment” isolation setting which protects the patient from contacting pathogens from other patients, healthcare workers, or other persons.

Packages of food from any patients, clients or other consumers should not be re-served to persons in protective environment isolation. Precautions similar to the isolation setting apply to this setting, i.e., once an unopened, original, intact package of condiment is delivered to this patient, the package stays there until used or discarded. New (not re-served) packages of food should be delivered to this patient each time.

To summarize the key difference between the two scenarios:

- Food packages served to patients in contact isolation may not be re-served to other patients because of the potential for disease transmission to other patients.

- Patients in protective environments should not be re-served with food packages from other patients because of the potential for disease transmission to the protective environment patient.

511-6-1-.05 EQUIPMENT AND UTENSILS

Multiuse **Characteristics.**

Multiuse equipment is subject to deterioration because of its nature, i.e., intended use over an extended period of time. Certain materials allow harmful chemicals to be transferred to the food being prepared which could lead to foodborne illness. In addition, some materials can affect the taste of the food being prepared. Surfaces that are unable to be routinely cleaned and sanitized because of the materials used could harbor foodborne pathogens. Deterioration of the surfaces of equipment such as pitting may inhibit adequate cleaning of the surfaces of equipment, so that food prepared on or in the equipment becomes contaminated.

Inability to effectively wash, rinse and sanitize the surfaces of food equipment may lead to the buildup of pathogenic organisms transmissible through food. Studies regarding the rigor required to remove biofilms from smooth surfaces highlight the need for materials of optimal quality in multiuse equipment.

Cast Iron, Use Limitation.

Equipment and utensils constructed of cast iron meet the requirement of durability as intended in section RULE - .05. However, the surface characteristics of cast iron tend to be somewhat porous which renders the material difficult to clean. On the other hand,