



COMMONWEALTH of VIRGINIA

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STATE HEALTH COMMISSIONER

Department of Health

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June 8, 2007

MEMORANDUM

PIM# 07-02

TO: District Directors
Environmental Health Managers
Division of Food and Environmental Services Staff

THROUGH: Robert B. Stroube, M.D., M.P.H.
State Health Commissioner

FROM: Gary J. Hagy, Director
Division of Food and Environmental Services

SUBJECT: Reduced Oxygen Packaging (ROP) for Cook-Chill and Sous-Vide Processing
Without a Variance

The attached PIM addresses the standard methods and procedures for conducting Reduced Oxygen Packaging (ROP) using cook-chill or sous-vide processing without a regulatory variance. This PIM is based on information provided by the Food and Drug Administration and information from the Conference for Food Protection.

This PIM outlines the ten-step process that operators can use to conduct cook-chill or sous-vide ROP without a regulatory variance. If cook-chill or sous-vide operations are identified during inspections, operators should be educated about this new ten-step process before any violations are cited for ROP without a variance. Restaurants should be advised either through mass mailings, faxes, or during routine inspections. If the operator is unable to follow this ten-step process, then the facility must apply for a regulatory variance as required by 12 VAC 5-421-860.

Please insert this document in your PIM manual and distribute copies to all persons in your district working in your foodservice protection program. Please note the effective date is June 8, 2007.

If you have any questions, please contact your food and dairy consultants.

Attachment

Program: Foodservice Protection

Subject: Reduced Oxygen Packaging (ROP)—Cook-chill and sous-vide processing

Issue: Implementing methods and standards for cook-chill and sous-vide ROP without a regulatory variance

Authority: Food Regulations § 12 VAC 5-421-10 Definitions “reduced oxygen packaging”; § 12 VAC 5-421-870 Reduced oxygen packaging, criteria; and § 12 VAC 5-421-860 Variance requirement.

Public Health Rationale:

New technology and standard processing methods outlined in the 2005 FDA Food Code make it possible to safely conduct cook-chill and sous-vide ROP operations without a regulatory variance. This will enable institutions that feed thousands daily as well as individual restaurants without ice banks or blast chillers to conduct these processes safely.

Background: In the 2005 FDA Food Code, the definition of ROP was expanded to mean “a process that involves a food for which the hazards of *Clostridium botulinum* or *Listeria monocytogenes* require control in the final packaged form.” This change was needed since two new methods of ROP were also included; cook-chill and sous-vide packaging. Cook-chill packaging is defined as “cooked food is hot filled into impermeable bags which have the air expelled and are then sealed or crimped closed. The bagged food is rapidly chilled and refrigerated at temperatures that inhibit the growth of psychrotrophic pathogens.” Sous-vide packaging is defined as “raw or partially cooked food is placed in a hermetically sealed, impermeable bag, cooked in the bag, rapidly chilled, and refrigerated at temperatures that inhibit the growth of psychrotrophic pathogens.”

During ROP, the control of pathogens of concern (*Clostridium botulinum* and *Listeria monocytogenes*) is usually accomplished using multiple hurdles or barriers to growth. The primary barrier includes cold holding potentially hazardous foods below 41°F along with a secondary barrier. Secondary barriers can be reducing the water activity below 0.91, lowering the pH below 4.6, curing the food, or having high levels of competing organisms on raw foods. However, with the addition of cook-chill and sous-vide ROP, these foods no longer have a reliable secondary barrier. A different approach is necessary to assure food safety since temperature control is now the only barrier in place. Raising this barrier to bacterial growth by lowering the food storage temperature for these two processes provides a safeguard. New technology in the form of thermocouple data loggers, recording charts, and nickel-sized data loggers also assures this barrier will continuously be monitored. In the current Virginia Food Regulations (12 VAC 5-421-860), ROP with only one barrier requires a regulatory variance. The standard processing methods established in the 2005 FDA Food Code along with new

technology now make it possible to conduct ROP with only one barrier both safely and without a regulatory variance.

Interpretation: Except for fish, a food establishment may package food using a cook-chill or sous-vide ROP without obtaining a regulatory variance if the food establishment implements a Hazard Analysis Critical Control Point (HACCP) plan that contains the following ten items:

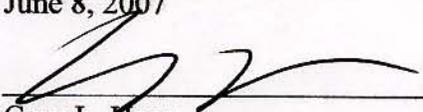
1. The food is prepared and consumed on the premises, or prepared and consumed off the premises but within the same business entity with no distribution or sale of the bagged product to another business entity or consumer;
2. The food is cooked to heat all parts of the food to a temperature and for a time specified in 12 VAC 5-421-700;
3. The food is protected from contamination after cooking as specified in 12 VAC 5-421-450 through 12 VAC 5-421-690;
4. The food is placed in a package or bag with an oxygen barrier before cooking, or placed in a package or bag immediately after cooking and before reaching a temperature below 135°F;
5. Except for frozen food that is not shelf-life restricted, the food is cooled to 41°F in the package or bag as specified under 12 VAC 5-421-800-A, and then cooled as follows:
 - a. Cooled to 34°F within 48 hours of reaching 41°F and held in a refrigerator at 34°F for no longer than 30 days; or
 - b. Cooled to 34°F within 48 hours of reaching 41°F and if removed from a storage unit that maintains 34°F, held at 41°F or less for no more than 72 hours before consumption; or
 - c. Cooled to 38°F or less within 24 hours of reaching 41°F and held there for no more than 72 hours from packaging at which time the food must be consumed or discarded; or
 - d. Held frozen with no shelf life restriction until consumed and used.
6. The food is held in a refrigeration unit that is equipped with an electronic system that continuously monitors time and temperature and is visually examined for operation twice daily;
7. If transported off-site to a satellite location of the same business entity, the food is equipped with verifiable electronic monitoring devices to ensure that times and temperatures are monitored during transportation;

8. The food is labeled with the product name and the date packaged;
9. Records are required to confirm that cooling and cold holding refrigeration time/temperature parameters as required in this HACCP plan are maintained and are
 - a. Made available to the regulatory authority upon request, and
 - b. Held for 6 months;
10. Written operational procedures are in place that:
 - a. Prohibit contacting food with bare hands; and
 - b. Identify a designated work area and method by which physical barriers or methods of separation of raw foods and ready-to-eat foods minimize cross-contamination, and access to the processing equipment is limited to responsible trained personnel familiar with the potential hazards of the operation; and
 - c. Delineate cleaning and sanitization procedures for food contact surfaces; and
 - d. Describe a training program that ensures the individual responsible for ROP understands the concepts required for a safe operation.

Responsibility: The local Environmental Health Specialist Senior is responsible for the application of this interpretation in foodservice establishments.

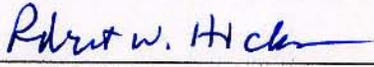
Effective Date: June 8, 2007

Approved by:



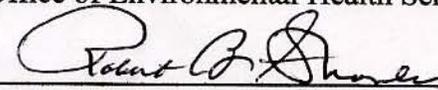
Gary L. Hagy
Director
Division of Food and Environmental Health Services

Approved by:



Robert W. Hicks
Director
Office of Environmental Health Services

Approved by:



Robert B. Stroube, M.D., M.P.H.
State Health Commissioner