



**TEXAS DEPARTMENT OF STATE HEALTH SERVICES
PUBLIC SANITATION AND RETAIL FOOD SAFETY
GROUP
GUIDANCE DOCUMENT FOR REFRIGERATED FOODS
IN REDUCED OXYGEN PACKAGING**

INTRODUCTION

While reduced oxygen packaging may extend the shelf life of certain foods, the process can also create a serious public health hazard if the proper control parameters are not followed. These control parameters must include recognized barriers that prevent the growth of infectious or toxigenic microorganisms combined with proper temperature control of the product at all times and carefully monitored rotation of the processed food. Retail establishments should only engage in this practice after a thorough evaluation of the potential hazards has resulted in the establishment having adequate safeguards against food contamination.

We must recognize that products packaged in a reduced oxygen package atmosphere may pose a serious public health threat even though the food may not exhibit the usual organoleptic (taste/smell) or visual signs relied on by consumers to warn them that the food is no longer edible.

DEFINITIONS

Acceptable product list – A list of foods, which because of their characteristics will present a barrier to the growth of *Clostridium Botulinum*.

Barrier – A safety factor of a physical, biological or chemical nature which inhibits or minimizes the growth of microorganisms including those which may be infectious or toxic.

Critical Control Point - A point or procedure in a specific food system where loss of control may result in an unacceptable health risk.

Hazard Analysis Critical Control Point (HACCP) Program - A written document that delineates the formal procedures for following the Hazard Analysis Critical Control Point principles developed by The National Advisory Committee on Microbiological Criteria for Foods.

Lot – a unique run of processed or packaged product with a specifically designated date and processing operation.

Processing – To manufacture, compound, intermix or prepare food products for sale or for customer service.

Retail Food establishment – A facility where food products are processed, prepared, stored or handled, and then sold or offered for human consumption at a retail level with such sales being made primarily to the consumer.

Reduced Oxygen Packaging - The reduction of the amount of oxygen in a package by removing oxygen, displacing oxygen and replacing it with another gas or combination of gases, or otherwise controlling the oxygen content to a level below that normally found in the atmosphere (approximately 21% at sea level). It is a process that involves a food for which the hazards of *Clostridium botulinum* or *Listeria monocytogenes* require control in the final packaged form. ROP includes cook chill packaging, controlled atmosphere packaging, modified atmosphere packaging, Sous vide packaging, and vacuum packaging.

TYPES OF REDUCED OXYGEN PACKAGING

Cook Chill - A method of packaging food in which cooked food is hot filled into impermeable bags which have the air expelled and are then sealed or crimped closed. Bagged food is rapidly chilled and refrigerated at temperatures that inhibit the growth of psychrotrophic pathogens.

Vacuum –Packaging - A method of packaging food in which air is removed from a package of food and the package is hermetically sealed so that a vacuum remains inside the package.

Sous Vide - A method of packaging food in which raw or partially cooked food is vacuum packaged in an impermeable bag, cooked in the bag, rapidly chilled, and refrigerated at temperatures that inhibit the growth of psychotropic pathogens.

Modified Atmosphere Packaging (MAP) - A method of packaging food in which the atmosphere of a package of food is modified so that its composition is different from air but the atmosphere may change over time due to the permeability of the packaging material or the respiration of the food. Modified atmosphere packaging includes: reduction in the proportion of oxygen, total replacement of oxygen, or an increase in the proportion of other gases such as carbon dioxide or nitrogen.

Controlled Atmosphere Packaging (CAP) - A method of packaging food in which the atmosphere of a package of food is modified such that until the package is opened, its composition is different from air, and continuous control of that atmosphere is maintained, such as by using oxygen scavengers or a combination of total replacement of oxygen, non-respiring food, and impermeable packaging material.

REDUCED OXYGEN PACKAGING BARRIERS

The primary reduced oxygen packaging barrier is Refrigeration as specified in section §228.75 (a) and (b). All Time/temperature control for safety food requires refrigeration. Few treatments reliably destroy all pathogenic microorganisms in food except heat sterilization and irradiation. Other inhibitory factors used in combination with refrigeration can be equally effective at preventing spoilage and growth of foodborne illness pathogens.

Secondary barriers with refrigeration at $\leq 41^{\circ}$:

- pH or acidity ≤ 4.6
 - Natural
 - Acidification
 - Fermentation
- Water activity (a_w) ≤ 0.91
 - Dried products (jerky, dry fermented sausage)
 - High salt or sugar concentration
- Cured meat or poultry products
 - Salt added at 3.5%
 - Nitrite (inhibits spore germination and toxin production by *Clostridium botulinum*)

ROP CRITICAL LIMITS

(no variance required but Haccp plan is required)

41° with secondary barrier = 30 day shelf life

34° No secondary barrier = 30 day shelf life or

41° No secondary barrier = 7 day shelf life

*continuous electronic monitoring of temperature

REGULATORY AUTHORITY APPROVAL

An approved variance may be obtained from the regulatory authority before packaging time/temperature control for safety (TCS) food using a reduced oxygen packaging method except where the growth of and toxin formation by *Clostridium botulinum* and the growth of *Listeria monocytogenes* are controlled. If the establishment is packaging time/temperature controlled for safety food using a reduced oxygen packaging method and controlling the growth and toxin formation of *Clostridium botulinum* and *Listeria monocytogenes*, the establishment shall implement an approved HACCP Plan.

Exemption: A HACCP plan is not required when a food establishment uses a reduced oxygen packaging method to package TCS food that is always labeled with the production time and date, held at 41°F or less during refrigerated storage and removed from its package in the food establishment within 48 hours after packaging.

COOK CHILL OR SOUS VIDE

A food establishment that packages TCS food using cook-chill or sous vide process shall provide to the regulatory authority prior to implementation, a HACCP plan. They must also ensure 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 packaged product to another business entity or the consumer;
- cooked to heat all parts of the food to a temperature as required
- protected from contamination before and after cooking

- placed in package with oxygen barrier and sealed before cooking, or
- placed in package and sealed immediately after cooking and before reaching an internal temperature below 57 degrees Celsius (135 degrees Fahrenheit);
- cooled to 5 degrees Celsius (41 degrees Fahrenheit) in the sealed package or bag
 - Cooled to 1°C (34°F) within 48 hours of reaching 5°C (41°F) and held at that temperature until consumed or discarded within 30 days after the date of packaging;
 - Held at 5°C (41°F) or less for no more than 7 days, at which time the food must be consumed or discarded; or
 - Held frozen with no shelf life restriction while frozen until consumed or used.
- held in a refrigeration unit that is equipped with an electronic system that continuously monitors time and temperature and is visually examined for proper operation twice daily,
- if transported off-site to a satellite location of the same business entity, equipped with verifiable electronic monitoring devices to ensure that times and temperatures are monitored during transportation, and
- labeled with the product name and the date packaged

All records must be maintained to confirm that cooling and cold holding refrigeration time/temperature parameters are being met. Records must be made available to the regulatory authority and held for at least 6 months. The establishment must also implement the written operational procedures and a training program.

CHEESE

A food establishment that packages cheese using a ROP method shall:

- limit the cheeses packaged to those that are commercially manufactured in a food processing plant with no ingredients added in the food establishment and that meet the Standards of Identity as specified in 21 CFR 133.150 Hard cheeses, 21 CFR 133.169 Pasteurized process cheese or 21 CFR 133.187 Semisoft cheeses;
- have a HACCP plan
- labels the package on the principal display panel with a “use by” date that does not exceed 30 days from its packaging or the original manufacturer’s “sell by” or “use by” date, whichever occurs first; and
- discards the reduced oxygen packaging cheese if it is not sold for off-premises consumption or consumed within 30 calendar days of its packaging.