Information Sheet on Reduced Oxygen Packaging
Oklahoma City-County Health Department
4900 Richmond Square
Oklahoma City, OK 73118
405-425-4347
www.occhd.org/fe

Reduced oxygen packaging (ROP) encompasses a large variety of packaging methods where the internal environment of the package contains less than the normal oxygen level of 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 typically require oxygen to live (aerobes). As such foods packaged under ROP could appear to be fresh and safe when in fact they contain deadly toxins or large populations of disease causing bacteria.

The state of reduced oxygen is achieved in different ways. Oxygen can be withdrawn from the package with or without having another gas, such as nitrogen or carbon dioxide replacing it. Fresh produce and raw meat or poultry continue to breathe and use oxygen after they are packaged. Bacterial activity also plays a role here. Additionally, the process of cooking drives off oxygen (the bubbling is oxygen gas coming off) and leaves a reduced oxygen level in the food, thus, microenvironments of reduced oxygen are possible even without packaging that has a barrier to oxygen transmission.

Packaging material that readily allows the transmission of oxygen is usually designated by an Oxygen Transfer Rate of 10,000 cm^2/m^3/24 hours or greater. However, this type of packing material only applies to packaging fish unless challenge study is conducted to support a specific oxygen transmission rate as non-ROP for other foods.

Most foodborne disease organisms are anaerobes or bacteria that thrive in reduced oxygen environments or facultative anaerobes that are able to multiply under either aerobic or anaerobic conditions. Therefore special controls are necessary to control their growth. Refrigerated storage temperatures of less than 41°F may be adequate to prevent growth and/or toxin production of some disease causing microorganisms but some types of *Clostridium botulinum* are able to multiply well below 41°F. For this reason, *Clostridium botulinum* becomes one of the organisms of concern for ROP. Controlling its growth will control the growth of other foodborne illness causing bacteria as well.

The control of *Clostridium botulinum* when using ROP is usually accomplished using multiple hurdles or barriers to growth. Secondary barriers that will control the growth of *Clostridium botulinum* when used in conjunction with a food storage temperature of 41°F or less include water activity (Aw) of 0.91 or less;

acidity (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 raw meats. *Clostridium botulinum* will not produce toxin below an water activity (Aw) of 0.91. Nitrite, used in meat and poultry curing, inhibits the outgrowth of *Clostridium botulinum* spores. Most foodborne pathogens do not compete well with other microorganisms, so foods that have a high level of spoilage organisms or lactic acid producing bacteria can safely be packaged using ROP. Additionally, naturally fermented cheeses 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 factors that together act as a secondary barrier to disease causing bacterial 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, production of organic acids, and natural antibiotics or bacteriocins, such as nisin by lactic acid bacteria, salt (NaCl) added during processing, low moisture content, added preservatives, and live competing cultures.

Very few outbreaks have occurred that were associated with cheese. However, the few outbreaks of foodborne illness associated with cheeses or cheese products could be traced in large part to temperature abuse with storage at uncontrolled air temperatures. 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 <u>may not be packaged</u> under reduced oxygen because of their ability to support the growth of *Listeria monocytogenes (Listeria)* under modified atmosphere conditions. When a food to be packaged under reduced oxygen conditions cannot reliably depend on secondary barriers, such as water activity (Aw), acidity (pH), nitrite in cured meat products, high levels of competing microorganisms or intrinsic factors in certain cheeses, time/temperature becomes the critical controlling factor for growth of *Clostridium botulinum*.

An example of critical steps is easily seen in cook-chill processing where foods are cooked then sealed in a barrier bag while still hot and sous vide processing where foods are 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 of 41°F or less to inhibit growth and/or toxin production of any surviving disease causing organisms is essential. Since there are no other controlling factors for *Clostridium botulinum* in a cook-chill or sous vide packaging system, temperature control must be continuously monitored electronically and visually examined twice daily to verify that refrigeration temperatures are adequate.

New technology makes it relatively easy to continuously and electronically monitor temperatures of refrigeration equipment used to hold cook chill and sous vide products at 41°F or less. Thermocouple data loggers can connect directly with commonly available thermocouple probes and be recorded via computers. Recording charts are also commonly used. Temperature monitors and alarm systems will activate an alarm or dialer if temperatures rise above preset limits (41°). Nickel-sized data loggers are available to record temperatures which 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. A Hazard Analysis Critical Control Point (HACCP) plan is essential when using ROP processing procedures. *Clostridium botulinum* is a potential and deadly hazard which must be controlled in most foods unless the food is a low acid canned food produced within the regulations outlined in 21 CFR Part 108 or 113 or an acidified food produced under 21 CFR 114.

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. It must be stressed that the current Oklahoma Food regulations only addresses *Clostridium botulinum* as a hazard in ROP packaging. However, Listeria is a concern and should be considered also when using ROP. When an establishment intends to use ROP technology, the operator must submit an application for a variance as outlined in Chapter 257 providing evidence that the ROP methodology to be used is safe.

Unfrozen, raw fish and other seafood are specifically excluded from ROP because these products have a natural association with *Clostridium botulinum* type E which grows at or above 37-38°F. Fish and seafood that are frozen before, during and after the ROP packaging process are allowed.

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