Appendix L
Reduced Oxygen Packaging

“Reduces Oxygen Packaging” means 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 surrounding, 21% oxygen atmosphere.

Concerns

There are serious concerns regarding the use of reduced oxygen packaging. Although these packages inhibit spoilage organisms, they also create an environment ideal for the growth of some pathogens. The extended shelf life provides more time for toxin production or pathogen growth. Lower oxygen levels favor facultative (Listeria) and anaerobic (Clostridium) pathogens over aerobic spoilage organisms, and toxins could be produced by pathogens before any spoilage occurs.

Pathogens of Concern

CLOSTRIDIUM BOTULINUM is the name of a group of bacteria commonly found in soil; sediments from streams lakes and coastal waters; intestinal tracts of fish and mammals; and the gills and viscera of crabs and other shellfish. Surveillance sampling showed 21.7 - 66.7% of fish samples are contaminated with Clostridium botulinum. These rod-shaped organisms grow best in low oxygen conditions. The bacteria form spores which allow them to survive in a dormant state until exposed to conditions that can support their growth. The classic symptoms of botulism include double vision, blurred vision, drooping eyelids, slurred speech, difficulty swallowing, dry mouth, and muscle weakness. These are all symptoms of the muscle paralysis caused by the bacterial toxin. If untreated, these symptoms may progress to cause paralysis of the arms, legs, trunk and respiratory muscles. All forms of botulism can be fatal and are considered medical emergencies.

LISTERIA MONOCYTOGENES is found in soil and water. Vegetables can become contaminated from the soil or from manure used as fertilizer. Animals can carry the bacterium without appearing ill and can contaminate foods of animal origin such as meats and dairy products. The bacterium has been found in a variety of raw foods, such as uncooked meats and vegetables, as well as in processed foods that become contaminated after processing, such as soft cheeses and cold cuts at the deli counter. Unpasteurized (raw) milk or foods made from unpasteurized milk may contain the bacterium. A person with listeriosis has fever, muscle aches, and sometimes gastrointestinal symptoms such as nausea or diarrhea. If infection spreads to the nervous system, symptoms such as headache, stiff neck, confusion, loss of balance, or convulsions can occur. Infected pregnant women may experience only a mild, flu-like illness; however, infections during pregnancy can lead to miscarriage or stillbirth, premature delivery, or infection of the newborn.

Minimal Growth Requirements

<table>
<thead>
<tr>
<th>Property</th>
<th>Clostridium botulinum</th>
<th>Clostridium botulinum</th>
<th>Listeria monocytogenes</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Group I proteolytic</td>
<td>Group II non- proteolytic</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Type A, B, F</td>
<td>Type B, E, F</td>
<td></td>
</tr>
<tr>
<td>Inhibitory pH</td>
<td>4.6</td>
<td>5.0</td>
<td>4.1-9.6</td>
</tr>
<tr>
<td>Inhibitory NaCl</td>
<td>10%</td>
<td>5%</td>
<td>≤ 10%</td>
</tr>
<tr>
<td>Minimum $a_w$</td>
<td>0.94</td>
<td>0.97</td>
<td>0.90-0.93</td>
</tr>
<tr>
<td>Temp. optimum</td>
<td>98°F</td>
<td>86°F</td>
<td>31°F to 113°F</td>
</tr>
<tr>
<td>Temp. range</td>
<td>50-118°F</td>
<td>38-113°F</td>
<td>28-122°F</td>
</tr>
<tr>
<td>Toxin production</td>
<td>≥ 50°F</td>
<td>≥ 50 °F</td>
<td></td>
</tr>
</tbody>
</table>
Multiple Barriers

The hurdle concept, or the use of multiple barriers, is frequently used to control pathogen growth or toxin production in reduced oxygen packages. It involves the use of a barrier (e.g., pH, water activity, chemicals) at a strength that, by itself, would not inhibit pathogen growth or toxin production, but will be effective in the presence of other sub-inhibitory limiting factors. Combining a number of these barriers at sub-inhibitory levels can effectively add up to a full barrier that prevents bacterial growth.

Secondary Barriers with Refrigeration at 41°±2°F

- pH ≤ 4.6
  - Natural
  - Acidification
  - Fermentation
- water activity ≤ 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)

Fish can only be vacuumed packed in a food establishment if it is frozen before, during and after packaging. The reason is because a high percentage of fish are contaminated with Clostridium botulinum spores which will germinate and produce toxin at refrigeration temperatures (at 38°F or above).

Laboratory testing is necessary to verify that the barriers have effectively prevented bacterial growth and toxin production. Accredited labs may be found in the yellow pages.

Links

http://www.fda.gov/Food/FoodSafety/RetailFoodProtection/ManagingFoodSafetyHACCPPrinciples/Operators/default.htm

http://www.fda.gov/Food/FoodSafety/RetailFoodProtection/IndustryandRegulatoryAssistanceandTrainingResources/ucm095463.htm