Scientific Contributions

Carbon Monoxide in Meat Packaging: Update from United States

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Over the last 4 years, the use of low-oxygen technologies for case ready meats has evolved rapidly in the United States. In 2002, the Food and Drug Administration (FDA) and the United States Department of Agriculture (USDA) offered no objection to the use of small amounts of carbon monoxide (CO) in the secondary packaging of case ready meats. In 2004, the use of CO in modified atmosphere packaging (MAP) was also reviewed with no objections. Since that time, FDA and USDA have reviewed the use of CO in meat on at least two more occasions, and have found no objection.

The benefits of this technology are clear. The use of low oxygen packaging with CO will allow for distribution life consistent with other forms of low oxygen packaging. Additionally, color and flavor degradation will be avoided with these atmospheres. This packaging format, combined with USDA mandated open code dating of packaging, offers great convenience and superior product quality to the retailer and consumer. This topic is pertinent to the Canadian Meat Industry, as it may be a technology to consider for use in Canada at a future date.

Recently, this technology and the processes used by FDA to review this technology have been called to question. The purpose of the following document is to demystify some of the attention that is being given to this topic. The following document was prepared by Randy Huffman and Janet Riley of the American Meat Institute. The material is taken from a submission to the FDA by the law firm Hogan and Hartson. The detailed, technical response is available from the Food and Drug Administration Docket Office.

Carbon Monoxide in Meat Packaging: Myths and Facts

Background: A petition submitted to the Food and Drug Administration (FDA) by Kalsec, Inc., maker of a line of herbal extracts that retard the effects of oxidation and thus maintain the color and flavor of meat, makes numerous erroneous allegations about carbon monoxide (CO) used in some modified atmosphere packaged (MAP) meat products that are processed and packaged centrally at meat plants. Case-ready MAP using CO as one of the protective gases has been permitted for use by the FDA and the Food Safety and Inspection Service (FSIS) of the U.S. Department of Agriculture since February, 2002. In the almost four years leading up to Kalsec's petition submission, the marketplace has increasingly adopted the use of low-oxygen CO packaging systems in place of MAP systems using high-oxygen in combination with herbal extracts, such as those supplied by Kalsec. This shift appears to have triggered an aggressive effort to challenge the use of the low-oxygen CO MAP systems, and attempt to block their use through erroneous regulatory arguments.

Arguments detailed in the FDA petition include both errors and omissions. This Myths and Facts backgrounder helps detail both the facts and the missing information. When all relevant information is considered, it is clear that FDA acted appropriately when it did not object to the classification of CO in meat packaging as "Generally Recognized as Safe."

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Myth: Packaging systems that use specific gases are new and untested systems.

Fact: Packaging systems containing a variety of different gases have been used on food products for many years. These packaging systems are referred to as modified atmosphere packaging or MAP, and the range of products packaged in MAP include produce like bagged salads, pre-cut vegetables, and fruits, snack foods such as potato chips and pastries, seafood and a variety of beverage products. These and other products are packaged with food grade gases to maintain an attractive appearance that appeals to consumers. CO systems for meat have been available for approximately four years.

Red meat products are somewhat like sliced apples. Their color can change rapidly – even though the product is still safe and wholesome. In fact, retail stores often discount red meat products that have changed color but are still safe and wholesome – and well within their shelf life. These detrimental effects to foods, including apples and meat, are the result of chemical changes caused by oxygen. But by eliminating the oxygen from the package and adding minute amounts of CO along with other protective gases to the headspace of the red meat packages, products like ground beef can maintain their appealing red color throughout their shelf life.

Myth: *CO* is a color additive requiring FDA to regulate it as such.

Fact: CO is a color stabilizer that maintains the typical red color of fresh meat when the gas mixture is applied to the package. FDA has evaluated the issue of CO use in meat products on at least three separate occasions and in each case has necessarily concluded that CO is not a color additive.

Myth: FDA erred when it permitted *CO* to be classified as "Generally Recognized as Safe" because FDA determined that nitrite imparts color to meat and therefore is an unapproved color additive. This precedent applies to *CO*.

Fact: FDA does not consider nitrite to "impart color" to meat, as implied by the petition, so the nitrite precedent provides no support for the petitioner's claim that CO should be a color additive. In 1979, FDA made a preliminary decision regarding the status of nitrite as a color additive; however, the petition conveniently omits a 1980 FDA determination that reversed the 1979 proposal. In the 1980 determination, FDA said it "agrees that its tentative conclusion was incorrect and now concludes that nitrites do not impart color to bacon...". In other words, FDA returned to its long standing position that substances that maintain color and do not impart color are not color additives. In a follow-up letter dated February 1, 2006, the petitioner continued to focus improperly on the interaction between meat tissue and CO, claiming that this interaction could "generate" color, especially when CO is used at high levels. A substance is "color additive" only if it changes color in a noticeable way under its intended conditions of use.

The bottom line: CO as used in the meat industry does not impart color and is not a "color additive"; it is used at low levels that maintain or stabilize the natural red color of oxygenated meat.

Myth: FDA permitted GRAS status for *CO* despite objections by USDA.

Fact: In a letter dated June 2, 2004, USDA's Food Safety and Inspection Service said that in the agency's opinion, MAP using CO (as described in GRAS Notice 143) "for use with case-ready fresh cuts of meat and ground meat will not mislead consumers into believing that they are purchasing a product that is fresher or of greater value than it actually is or increase the potential for masking spoilage."

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It is true that FSIS on April 28, 2004 identified questions and concerns in a preliminary response sent to FDA. However, FSIS' June 2, 2004, letter said that those questions and concerns had been resolved based upon additional data and information provided to them. This "back and forth" dialogue between the regulatory agency and the applicant is typical of the review process and speaks to its thorough and robust nature.

Myth: Combustion product gas regulations prohibit *CO* in meat packaging.

Fact: Combustion product gas is made by the controlled combustion in air of butane, propane or natural gas. This mix of gases – which includes CO – is not approved for use on fresh meat. However, the purified CO gas used in packaging is not covered, much less prohibited, under this rule. The CO covered by FDA and FSIS-reviewed GRAS notices is not a product of combustion.

Myth: *CO* in meat packaging is deceptive to consumers and may mask spoilage.

Fact: All low-oxygen, CO packages include a clearly defined use-by date that indicates the date by which product should be consumed. Under the rare circumstance in which a package may be temperature abused and spoilage occurs prematurely before the use-by date, several signs would alert consumers. When spoilage bacteria multiply, packages begin to bulge. When opened, a strong spoilage odor will be readily apparent. Meat also may have a slippery or slimy texture. These are all typical signs of spoilage that consumers should equate with meat that should not be consumed.

The FDA and USDA both reviewed data related to this issue in the GRAS applications. The data submitted show that when products were temperature abused in a sufficient manner to cause spoilage, these products evidenced the tell-tale signs of spoilage: odor, gas formation (bulging package) and slime formation.

Myth: *CO* in meat packaging extends the normal shelf life of red meat.

Fact: CO does not extend the shelf life of red meat; CO simply helps to retain the natural appearance of meat products throughout the established shelf life. The most important factor influencing shelf life is bacterial growth and ultimately risk of spoilage. The use of CO in MAP meat products has no impact on bacterial growth and therefore cannot extend shelf life. It is important to note that the shelf-life of products covered by the FDA and FSIS-reviewed GRAS notices for CO are no longer than those used for other low oxygen systems judged to be safe.

Myth: *CO* in meat packaging increases the risk that consumers will be exposed to *Clostridium botulinum* and other pathogens like *Listeria monocytogenes*.

Fact: *Clostridium botulinum* is a very rare bacterium and has never been associated with the consumption of a fresh, unprocessed meat product regardless of package type. The Centers for Disease Control tracks botulism cases very closely and indicates that approximately 110 cases occur each year. Only one quarter of those cases are linked to food products. Those small numbers of cases have been associated with home-canned foods – not fresh meat.

If low-oxygen, vacuum packaging (which has been in use for at least 40 years in meat processing) did increase the risk of botulism, one would have expected a steady increase in cases as use of the packaging technology has increased. That is clearly not the case and the misinformation provided in the petition related to this issue calls into question the scientific credibility of the claims made in the petition.

The use of low-oxygen CO MAP has no effect on the presence or growth of *Listeria monocytogenes* in fresh meat products. *L. monocytogenes* is a pathogen that is considered a risk in ready to eat foods, including sliced lunch meats and deli

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salads, and not fresh meat. This pathogen has been the subject of intense scrutiny by both USDA as well as other global regulatory bodies, and several comprehensive risk assessments have been conducted on the risk of *L. monocytogenes* from food. In no case has fresh meat been considered a significant source of foodborne Listeriosis risk. *L. monocytogenes* is easily destroyed by the normal heat associated with cooking. It is unscientific and illogical to suggest that CO would change or increase the risk of Listeria in fresh meat products, again calling into question the credibility of claims made in the petition.

Myth: *CO* packaging systems offers no benefit to consumers.

Fact: CO package systems offer significant benefits to consumers. First, these systems are exclusively used in centralized processing facilities under close scrutiny of federal inspectors. Tamper evident packaging is used in MAP meat products, which provides an added layer of benefit to the consumer. Also, because these products maintain their appeal throughout the shelf life, they do not lose their marketability. When products become unmarketable due to purely cosmetic issues during their shelf life, this can add costs to the system, which in turn can raise meat prices.

The fact that each year, consumers spend a fraction of their disposable income on meat – and less than any other nation in the world – can be attributed to efficient, effective systems like CO packaging systems.

Myth: Consumers need to be extra vigilant when they handle meat packaged using *CO* systems.

Fact: Consumers need to use the same handling practices for all fresh meat products regardless of their packaging system. These practices are detailed in the federal safe handling label that appears on every package.

Consumers also need to follow the use-by date on packages. Data collected by the Food Marketing Institute show that consumers pay close attention to use-by dates on meat, poultry and dairy products.

Note: Information for this document was taken from the January 23, 2006, submission by Hogan & Hartson to the Food & Drug Administration. This detailed, technical response is available from the Food and Drug Administration Docket Office.