

# *Regulatory Status of Carbon Monoxide for Meat Packaging*

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Gases used in modified atmosphere packaging (MAP) for fresh meat products are regulated by the U.S. Food and Drug Administration (FDA) and the U.S. Department of Agriculture (USDA). FDA regulates the safety of packaging gases pursuant to the Federal Food, Drug, and Cosmetic Act (FFDCA); USDA's Food Safety and Inspection Service (FSIS) regulates the suitability of gases for use with meat products, as required by the Federal Meat Inspection Act (FMIA). Packaging gases that have been found to be safe and suitable for use in meat packaging include carbon dioxide (CO<sub>2</sub>), nitrogen (N<sub>2</sub>), oxygen (O<sub>2</sub>), and carbon monoxide (CO).

From an FDA perspective, the status of any material used in food packaging, as well as the procedures that must be followed to provide for its use, depend on the legal category into which the substance falls. An important category and the legal basis for marketing many substances for use in food or in contact with food is the category for generally recognized as safe (GRAS) substances. By law, a substance is GRAS if it is determined to be generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures (or, in the case of a substance used in food prior to January 1, 1958, through either scientific procedures or experience based on common use in food) to be safe under the conditions of its intended use . . . (FFDCA § 201 (s)). A GRAS determination thus requires two key elements: (1) evidence that a substance is safe for its intended use, and (2) a basis for concluding that such evidence of safety is available to and accepted by qualified scientific experts (62 Fed. Reg. 18937, 18940 (Apr. 17, 1997)). Safety requires a showing that there is a reasonable certainty in the minds of competent scientists that the substance is not harmful under the in-

tended conditions of use (21 C.F.R. § 170.3(i); 62 Fed. Reg. at 18948).

Under the FFDCA, a substance determined to be GRAS may be marketed on that basis, without FDA pre-market review or approval. For substances used in meat or poultry products, however, FDA is usually notified of self-determinations of GRAS status and provided an opportunity to object. Notifications of GRAS status are typically detailed scientific submissions explaining the basis for concluding that a particular intended use of a substance meets the statutory GRAS criteria. GRAS notifications affecting meat and poultry products are reviewed by both FDA (to assess safety and the GRAS criteria) and FSIS (to assess whether the notified substance is suitable for use in FSIS-regulated products). An FSIS suitability determination requires consideration of whether a substance proposed for use in meat or poultry products may cause the products to be adulterated or misbranded under the relevant statutes. For example, one important issue FSIS considers in suitability determinations is whether a substance will make a meat product appear to be better or of greater value than it is.

CO is presently used at low levels in low oxygen MAP systems for fresh meat for the purpose of stabilizing natural meat color. This use of CO has been determined to be GRAS in several packaging applications for fresh meat products. Since 2002, FDA has favorably reviewed three GRAS notifications for CO in fresh meat packaging; two additional notifications are presently pending. FSIS has reviewed and deemed suitable the three FDA-evaluated uses (and is presumably reviewing the pending notifications), as well as several additional applications related to those uses. In MAP applications employing barrier packaging, where low levels of CO will remain in the package until it is opened by the consumer, a use-or-freeze by date is included as a condition of use.

In November 2005, a Michigan manufacturer of ingredients intended to improve the performance of high oxygen systems (Kalsec, Inc.) asked FDA to withdraw the agency's favorable responses to the completed GRAS notifications for CO. In support of this request, the manufacturer submitted a petition detailing several allegations regarding the regulatory status of CO for its intended use in meat packaging: the

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petition alleged that CO is an unapproved color additive, is prohibited by the FDA regulation on combustion product gas, is not safe for use in fresh meat packaging, makes meat appear to be better than it is, will mask spoilage, and should be labeled. Based on FDA and FSIS precedent, however, substances that merely stabilize color are not color additives ; CO and combustion product gas are not equivalent; and packaging gases are not labeled as ingredients. The safety of CO in fresh meat packaging is based on, among other factors, the history of use of low oxygen MAP

systems (including packaging with CO), the low concentrations at which CO is used, and the absence of a relationship between meat color and safety. The GRAS notifications and history of use also establish that CO is used to maintain the color of wholesome products for a defined shelf life and will, in the unlikely event of abuse, evidence signs of spoilage by means such as off odors, slime, and bulging packages. To date, FDA has defended its decisions on CO in the press and is presently reviewing the petitioner's allegations. A formal response is forthcoming.