United States Department of Agriculture
Food Safety and Inspection Service
Office of Policy and Program Development
Washington, D.C. 20250/3700
US

Dr. Lane Highbarger
Office of Food Additive Safety
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paintbranch Parkway, HFS-255
College Park, MD 20740

APR 28 2004

Dear Dr. Highbarger:

In accordance with the procedures described in the Memorandum of Understanding (MOU) between the Food Safety and Inspection Service (FSIS) and the Food and Drug Administration (FDA), we have reviewed GRAS Notice No. GRN 000143, submitted by Precept Foods, LLC, for the use of *"Carbon monoxide"* as a component of a modified atmosphere packaging (MAP) system for packaging case-ready fresh cuts of beef and pork as well as ground beef and ground pork. The carbon monoxide will be used at the targeted concentration of 0.4 percent of the modified atmosphere.

In the previous carbon monoxide MAP systems evaluated by FSIS and FDA, the carbon monoxide modified atmosphere was either introduced into an outer bag containing meat packaged into conventional retail display packages or directly into the package containing the meat where the container had a film layer that needed to be removed prior to retail sale, thus allowing exposure of the meat to the atmosphere before the consumer received the product. In both types of systems the meat is removed from the carbon monoxide modified atmosphere when presented for retail sale and allowed to equilibrate with the atmosphere outside the package. As a result, the heme pigment of the meat will change over time as though it had not been exposed to carbon monoxide. In the Precept Foods MAP system, carbon monoxide (0.4 percent) mixed with nitrogen (0-80 percent) and carbon dioxide (20-100 percent) is introduced directly into the retail display packages containing the meat. The carbon monoxide modified atmosphere remains in contact with the meat until opened by the consumer at home.

Under the tenets of the Federal Meat Inspection Act (FMIA), FSIS is responsible for determining the efficacy and suitability of food ingredients and additives in meat products as well as prescribing safe conditions of use. Suitability relates to the effectiveness of the additive in performing the intended purpose of use and the assurance that the conditions of use will not result in an adulterated product or one that misleads consumers.

Historically, when considering the use of a food ingredient or additive in a meat product FSIS has treated each livestock species separately. From FSIS's perspective, data must normally be generated for each species of livestock to which an application of an ingredient is desired. The effect generated by the use of carbon monoxide in the modified atmosphere system is due to the reaction of carbon monoxide with the heme pigment in the muscle myoglobin to form carboxymyoglobin. In this situation, we would expect the effect to be the same regardless of the species of livestock. Consequently, FSIS feels that, in this case, the data submitted by Precept Foods using ground and whole muscle cuts of beef can be extended to all species of livestock.

In evaluating the initial petition, submitted by Pactiv Corporation, for the use of a carbon monoxide MAP system with fresh meat, both FSIS and FDA expressed concern that the use of carbon monoxide with fresh meat may cause the meat to retain its fresh color longer than meat not so treated, thereby misleading the consumer and increasing the potential for masking spoilage. Pactiv conducted tests on beef cuts and ground beef using their "ActiveTech 2001" modified atmosphere system, to specifically address these concerns. Experiments were conducted to determine color stability during display and the relationship between color deterioration and microbial population (i.e., was color life extended beyond the microbial soundness of the product). Data showed that retail packages of meat would deteriorate in color beginning almost immediately after removal of the modified atmosphere. The color of the products from the modified atmosphere system declined similar to baseline products exposed to oxygen, allowing for a retail display life of 3 to 4 days. Furthermore, the longer the product was stored under the modified atmosphere the faster the deterioration when that atmosphere was removed. Also, product in packages exposed to mild temperature abuse exhibited faster discoloration than product in packages not exposed to temperature abuse, when the modified atmosphere was removed. The carbon monoxide in the "ActiveTech 2001" MAP system did not result in color life extension once the packages were displayed for retail sale and microbial loads did not reach unsafe levels while the color of the meat was still acceptable to consumers. Therefore, the concern we originally expressed for the Pactiv notification is not presented here.

Precept Foods has submitted data showing that their carbon monoxide MAP system did not inhibit the growth of spoilage organisms. However, the data also show that the carbon monoxide modified atmosphere minimizes the degradation of product color that can occur prior to microbial spoilage. Thus, product that may have microbial levels sufficient to cause spoilage may appear to be acceptable to the consumer. Therefore, as an added safety measure, Precept Foods has proposed the use of an open date code, applied at the time of packaging in the Federal establishment, which would inform consumers when a product should be used by or frozen. Precept Foods asserts that this validated "use or freeze by date" will help avoid a health or safety issue since meat in the MAP system held under refrigeration beyond the specified "use or freeze by date" will exhibit noticeable signs of spoilage, i.e., an objectionable odor and bulging of the retail package. The open date code would not exceed 35 days for muscle cuts and 28 days for ground meat. Apparently, these open date codes were established based upon tests showing that there were no signs of spoilage in boneless beef strip steaks and top round steaks packaged in barrier plastic trays and stored under this modified atmosphere for 42 days at 38-40°F.
We would like to point out that the steaks used for these tests were injected with a solution that contained potassium lactate and sodium diacetate. Potassium lactate and sodium diacetate are regulated by FSIS (viz. 9 CFR, 424.21(c)) as antimicrobial agents to inhibit microbial growth in meat and poultry products. Thus, the results obtained using steaks injected with a solution containing antimicrobial agents would not be indicative of the spoilage pattern associated with whole muscle cuts of meat not containing any added substances. Furthermore, no samples were tested to establish a spoilage pattern for ground meat products stored under this modified atmosphere.

In regard to the discussion above about the effects of Precept or microbial spoilage, FSIS regulations (viz. 9 CFR, 424.23(a)) prohibits the use of any substance in or on meat if it conceals damage or makes the product appear to be better or of greater value than it is. The Precept Foods MAP system stabilizes the color of the meat and, therefore, by affecting one of the sensory properties (i.e., appearance) used in assessing the quality of a meat product has the potential to

mislead consumers into believing that the product they are purchasing is fresher than it actually is. The true quality of the meat purchased would not be readily apparent until the consumer opened the package at home and detected an objectionable odor. Although Precept Foods stated in their July 2, 2003, submission to FSIS that product testing needs to be done to prove that off odors will exist when product is unsafe we were unable to locate any such test results in that submission. Finally, FSIS has never regulated nor considered "use or freeze by dates" as being sufficient for food safety.

In summary, it is our opinion that the use of the Precept Foods MAP system described in GRAS Notice No. GRN 000143 for use with case-ready fresh cuts of meat and ground meat could potentially mislead consumers into believing they are purchasing a product that is fresher or of greater value than it actually is and may increase the potential for masking spoilage.

If you need any additional information regarding this response, do not hesitate to contact Mr. Bill Jones, Chemist, or myself at Area Code (202) 205-0279.

Sincerely,

for Robert C. Post, Ph.D., Director
Labeling and Consumer Protection Staff