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United States Department of Agriculture

Food Safety and Inspection Service

Office of Policy, Program Development and Evaluation

Washington, D.C. 20250

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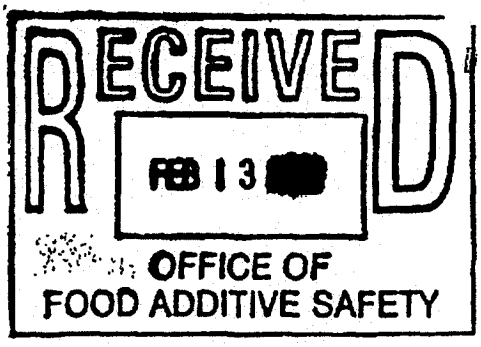

Mr. Lane Highbarger, Ph.D.
Office of PreMarket Approval
CFSAN, Food and Drug Administration
200 C Street, S.W., HFS-206
Washington, DC 20204

Dear Dr. Highbarger:

In accordance with the procedures described in the Memorandum of Understanding (MOU), we have reviewed GRN 000083, submitted by Pactiv Corporation, for the use of *"Carbon monoxide"* as a component of a modified atmosphere system for packaging fresh cuts of muscle meat and ground meat.

In the "ActiveTech 2001" modified atmosphere system, meat products are packaged into conventional retail display packages which are subsequently placed within an outer bag made of an oxygen barrier polymer film. An oxygen-absorbing sachet is attached to the inside of the outer bag. Prior to sealing the outer bag the air is replaced by flushing with a gas blend composed of 30 percent carbon dioxide, 0.4 percent carbon monoxide, and 69.6 percent nitrogen.

During the initial 24 hours after packaging, the oxygen-absorbing sachet consumes any remaining oxygen in the package, thus creating and maintaining an oxygen-free environment for the packaged meat during storage. As the oxygen is removed, the carbon monoxide reacts with the myoglobin to produce carboxymyoglobin. Since the oxymyoglobin is converted directly to carboxymyoglobin rather than metmyoglobin, the red color of the meat is retained during storage. When the outer bag is removed, eliminating the modified atmosphere, and the product is displayed for retail sale, the myoglobin will begin its natural conversion to metmyoglobin.

Two of the components of the system, nitrogen and carbon dioxide, are currently acceptable for use as components of modified atmosphere packaging for meat products. The Federal meat inspection regulations (i.e., Title 9 of the Code of Federal Regulations (CFR), Section 424.21 (c)) permit the use of nitrogen gas to exclude oxygen in sealed containers. Carbon dioxide is listed in 21 CFR, Section 184.1240, as being Generally Recognized as Safe (GRAS) as a propellant, aerating agent, and gas defined in Section 170.3 (o) (25). Title 21 CFR, Section 170.3 (o) (25) defines "propellants, aerating agents, and gases" as gases used to supply force to expel a product or used to reduce the amount of oxygen in contact with the food in packaging.

The Federal meat inspection regulations, viz., 9 CFR 424.21 (c), do not currently allow for the use of carbon monoxide in the preparation of meat food products. Carbon monoxide is considered in the allowance for combustion gas as a food additive used in the processing and packaging of certain foods (21 CFR 173.350). However, 21 CFR 173.350 (c) specifically precludes the use of combustion gas for use with fresh meat. This exclusion is because of concerns that the treatment of meat with combustion product gases may cause the meat to

retain its fresh red color longer than meat not so treated, thereby misleading the customer and increasing the potential for masking spoilage.

Under the tenets of the Federal Meat Inspection Act, the Food Safety and Inspection Service (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.

As mentioned above, both the Food and Drug Administration (FDA) and FSIS have expressed concerns 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 has conducted tests on beef cuts and ground beef, using the "ActiveTech 2001" modified atmosphere system, to specifically address these concerns.

Pactiv conducted experiments 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). Beef samples were exposed to the "ActiveTech 2001" modified atmosphere system for up to 35 days at either 35°F or 43°F. Data show that retail packages of meat will 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 (i.e., 43°F) exhibited faster discoloration than product in packages not exposed to temperature abuse, when the modified atmosphere was removed. The carbon monoxide in the modified atmosphere 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.

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 application is desired. The effect generated by the use of carbon monoxide in this modified atmosphere system is due to the reaction of carbon monoxide with the heme pigment in the muscle myoglobin to form carboxymyoglobin. 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 Pactiv can be extrapolated to apply to all species of livestock.

Based on the information submitted by Pactiv, FSIS has concluded that the modified atmosphere packaging system (ActivTech 2001) as described in the Pactiv petition, and used under the conditions stated in the petition, would be acceptable for packaging red meat cuts and ground meat. Pactiv has demonstrated that this modified atmosphere system complies with FDA's definition of a processing aid that appears in labeling regulations (21 CFR 101.100 (a) (3)). There is no lasting functional effect in the food and there is an insignificant amount of carbon monoxide present in the finished product under the proposed conditions of use. As such, similar

to uses of other modified atmosphere packaging gases (e.g., nitrogen) there are no labeling issues in regard to meat cuts and ground meat packaged using this modified atmoshpere system.

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

Sincerely,

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