

ATTACHMENT 6



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

FEB 21 2002

Eric Greenberg
Ungaretti and Harris
3500 Three First National Plaza
Chicago, IL, 60602-4405

Re: GRAS Notice No. GRN 000083

Dear Mr. Greenberg:

The Food and Drug Administration (FDA) is responding to the notice, dated August 29, 2001, that Ungaretti and Harris submitted on behalf of Pactiv Corporation (Pactiv) in accordance with the agency's proposed regulation, proposed 21 CFR 170.36 (62 FR 18938; April 17, 1997; Substances Generally Recognized as Safe (GRAS)). FDA received the notice on September 4, 2001, and designated it as GRAS Notice No. GRN 000083.

The subject of the notice is carbon monoxide (CO). The notice informs FDA of the view of Pactiv Corporation (Pactiv) that CO is GRAS, through scientific procedures, for use as a component of a gas mixture in a modified atmosphere packaging (MAP) system. The level of CO in this MAP system is 0.4 percent. The other components of the MAP system are carbon dioxide (30 percent) and nitrogen (69.6 percent). The MAP system would be used for packaging fresh cuts of case ready muscle meat and ground case ready meat to maintain wholesomeness, provide flexibility in distribution, and reduce shrinkage of the meat. The case ready meats would be removed from the MAP system prior to retail display.

As part of its notice, Pactiv includes letters from a panel of individuals (Pactiv's GRAS panel) who evaluated the data and information that are the basis for Pactiv's GRAS determination. Pactiv considers the members of its GRAS panel to be qualified by scientific training and experience to evaluate the safety of substances added to food. Pactiv's GRAS panel evaluated information and data on the chemical identity, manufacture and processing, conditions of proposed use, and estimated daily intakes of CO used in a MAP system for meat. Pactiv's GRAS panel also evaluated studies (published and unpublished) of the effects of CO used in a MAP system for meat. Members of the GRAS panel reviewed and evaluated the publicly available information summarized in the GRAS notice. Based on the data and information reviewed, Pactiv's GRAS panel concludes that CO, when produced in accordance with current good manufacturing practice and meeting appropriate food grade specifications, is GRAS, through scientific procedures under the conditions of its intended use.

The notice describes publicly available information pertaining to the identity and characteristic properties of CO. Carbon monoxide (Chemical Abstracts Service Registry Number 630-08-0) is a colorless, odorless, gas. The notice includes a list of properties of CO and identifies the

manufacturer who currently supplies CO to Pactiv. Pactiv intends to use CO at a minimum purity of 99.99 percent ("commercial grade"). Pactiv includes a list of specifications for CO with limits on the levels of other gases and considers CO of this purity to be "food grade."

The notice describes information about existing regulations and notices regarding food substances that contain CO as a significant component:

- Wood smoke, which includes CO as a component, is permitted by regulation as an ingredient in meat and poultry products under regulations issued by the U.S. Department of Agriculture (9 CFR 318.7(c)(4), 381.147(c)(4) and 424.21(c)).
- Combustion-product gas, which includes CO as a component at a maximum level of 4.5 percent by volume, is approved for use in the production of beverages and other foods (except fresh meat) under FDA's regulations (21 CFR 173.350).
- Tasteless smoke, which includes CO as a primary component, is the subject of GRN 000015 for use on raw tuna, before it is frozen, to preserve its taste, aroma, texture, and color. In response to GRN 000015, FDA had no questions regarding the notifier's conclusion that tasteless smoke is GRAS under the intended conditions of use.

The notice describes the estimated consumption of CO per meal as a consequence of its intended use as a component in a MAP system for storing meat. Assuming that 30 percent of the CO present in the MAP is absorbed into the meat and that there is an 85 percent reduction of CO due to cooking the meat, Pactiv calculates a realistic intake estimate to be 0.084 milligrams (mg) CO per meal. Pactiv also calculates a worst case intake estimate to be 1.88 mg CO per meal, assuming that 100 percent of the CO present in the MAP is absorbed into the meat and that there is no reduction in CO during cooking. Pactiv cites published articles to support the assumptions used in the realistic exposure estimate and to support the conclusion that exposure to CO is safe at this level.

The notice describes published reports of studies demonstrating the technical effect and safety of using CO as a component of a MAP system (similar to the MAP system that is the subject of GRN 000083) for storing meat. These reports include published data (microbial growth profiles and odor and color data) from meat stored in MAP containing CO, CO₂, and N₂, and meat stored in MAP containing only CO₂ and N₂. Pactiv concludes that the presence of CO in MAP systems allows the meat to maintain a desirable red color during storage. In addition, CO neither affects the ability of the MAP system to slow the growth of a variety of microorganisms, nor affects the characteristic odor of meat spoilage.

The notice describes an unpublished study using the MAP system that is the subject of GRN 000083. The study examined the effects of the system on initial meat color, stability of color during display, and the relationship between color deterioration and microbial growth. The notice also includes unpublished pictures that compare the ageing (color deterioration) of meats stored for 20 days in an environment of CO, CO₂, and N₂, to the ageing of fresh cut meat and the ageing of meat stored in a high oxygen environment. From these data, Pactiv concludes that once meat is removed from a MAP system containing CO, its color deteriorates at a similar rate to

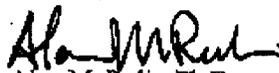
that of meat that has not been exposed to CO. Pactiv also concludes that the use of CO in a MAP system does not result in red color life extension that could mask microbial spoilage of the meat.

Based on the information provided by Pactiv, as well as other information available to FDA, the agency has no questions at this time regarding Pactiv's conclusion that CO is GRAS under the intended conditions of use. The agency has not, however, made its own determination regarding the GRAS status of the subject use of CO. As always, it is the continuing responsibility of Pactiv to ensure that food ingredients that the firm markets are safe, and are otherwise in compliance with all applicable legal and regulatory requirements.

During its evaluation of GRN 000083, OFAS consulted with the Labeling and Consumer Protection Staff of the Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture regarding the use of CO in meat products. Based on the information submitted by Pactiv, FSIS has concluded that the MAP system (ActiveTech™ 2001) as described in Pactiv's notice, and used under the conditions stated in Pactiv's notice, would be acceptable for packaging red meat cuts and ground meat. In FSIS' view, Pactiv has demonstrated that this MAP 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 MAP gases (e.g., nitrogen), there are no labeling issues in regard to meat cuts and ground meat packaged using this MAP. Additionally, when considering the use of a food ingredient or additive in a meat product, FSIS historically has treated each livestock species separately. However, in this case, the data submitted by Pactiv can be extrapolated to all species of livestock. If you have any additional questions, you should direct your inquiry to Dr. Robert Post, Director, Labeling and Consumer Protection Staff, Office of Policy, Program Development and Evaluation, Food Safety and Inspection Service, 300 12th Street, SW, Room 602, Washington, DC 20250-3700. The telephone number of his office is (202) 205-0279 and the FAX number is (202)205-3625.

In accordance with proposed 21 CFR 170.36(f), a copy of the text of this letter, as well as a copy of the information in your notice that conforms to the information in proposed 21 CFR 170.36(c)(1), is available for public review and copying on the homepage of the Office of Food Additive Safety (on the Internet at <http://www.cfsan-fda.gov/~lrd/foodadd.html>).

Sincerely,



Alan M. Rulis, Ph.D.

Director

Office of Food Additive Safety

Center for Food Safety

and Applied Nutrition