February 21, 2006

BY ELECTRONIC MAIL

Laura M. Tarantino, Ph.D.
Director
Office of Food Additive Safety
Center for Food Safety and
Applied Nutrition (CFSAN)
Food and Drug Administration
5100 Paint Branch Parkway
College Park, Maryland 20740

Re: Use of Carbon Monoxide (CO) in Case-Ready Fresh Meat Packaging; Docket No. 2005P-0459

Dear Dr. Tarantino:

The American Meat Institute (AMI) submits this letter in response to the Citizen Petition (petition) submitted by Kalsec, Inc. (Kalsec) concerning the use of carbon monoxide (CO) in fresh meat packaging. 1 AMI represents the interests of packers and processors of beef, pork, lamb, veal, and turkey products and their suppliers throughout North America. Together, AMI's members produce 95 percent of the beef, pork, lamb, and veal products and 70 percent of the turkey products produced in the United States. In that regard, the technology at issue and the above-referenced petition directly affect AMI's members.

The petition has several glaring flaws in its legal reasoning and its application of the facts. Moreover, the petition appears to be part of a public relations campaign to create unnecessary confusion within the industry and inappropriately affect consumer confidence in meat products. Accordingly, AMI urges the Food and Drug Administration (FDA), in consultation with the Food Safety and Inspection Service (FSIS)

---

1 FDA Docket No. 2005P-0459 (Citizen Petition of Kalsec, Inc.) (Nov. 15, 2005).

of the U.S. Department of Agriculture (USDA), to review the petition and related submissions thoroughly but expeditiously and reaffirm the agencies' consistent position that the appropriate use of CO in fresh meat packaging raises no safety or other concerns.

The issues surrounding the use of CO in a modified atmosphere packaging (MAP) system have been considered by FDA as well as FSIS several times and its use is generally recognized as safe (GRAS) and lawful.2 Indeed, just weeks before the petition was filed FDA issued correspondence regarding the GRAS status of CO in the context of its limited use in fresh meat packaging.3 Notwithstanding these several, comprehensive reviews of CO for the type of application at issue here, the petition includes an assertion that CO intended for use in fresh meat packaging is an unapproved "color additive."

This assertion is unfounded on both legal and factual grounds. In that regard, the petition contains a lengthy discussion as to why petitioner believes the use of CO in this circumstance makes it a color additive, but in doing so fails to acknowledge a critical FDA decision that directly conflicts with that position. Indeed, for more than 25 years FDA has concluded that substances that merely "fix" color but do not "impart" color to food are not "color additives"; petitioner's repeated assertions that CO, as used in the packaging systems at issue, imparts color simply do not make it so. 4

---

2 See FDA Response Letter, GRAS Notice No. GRN 00143 (July 29, 2004) (advising that FDA had "no questions" concerning Precept Foods' determination that CO is GRAS under the intended conditions of use in fresh meat packaging); FDA Response Letter, GRAS Notice No. GRN 00083 (Feb. 21, 2002) (advising that FDA had "no questions" concerning the Pactiv Corporation's determination that CO is GRAS under the intended conditions of use in fresh meat packaging); FSIS Directive 7120.1, Safe and Suitable Ingredients Used in the Production of Meat and Poultry Products (identifying CO as suitable under its intended conditions of use in MAP systems for fresh meat and poultry). AMI will not repeat the lengthy discussion articulated by Precept's counsel in their January 23, 2006 letter challenging the petition's legal arguments. See Letter from Gary Jay Kushner and Ann Mileur Boeckman to Dr. Laura M. Tarantino (Jan. 23, 2006);

3 See FDA Response Letter, GRAS Notice No. GRN 00167 (Sept. 29, 2005) (advising that FDA had "no questions" concerning the conclusion of Tyson Foods, Inc. that CO is GRAS under the intended conditions of use in fresh meat packaging).

4 See the 1980 *Federal Register* notice addressing the color additive status of nitrites in bacon and other meats, in which FDA revisited its 1979 determination that nitrites impart color and stated that it "agrees that its tentative conclusion was

For example, in its recently filed reply, petitioner asserts that CO changes meat from the "naturally purple" color of "freshly slaughtered meat" to bright red and suggests that this is proof that CO is a color additive.5 Petitioner fails to note, however, that any exposure of meat to the oxygen levels found within normal ambient air on a processing line at a meat packing or processing plant elicits a very rapid chemical reaction that results in a color change of the meat from that "naturally purple" color to bright red. Proof of that is evident from a casual walk through a grocery store in front of the meat case, which reveals that packages of meat that are exposed to ambient air or are packaged in oxygen permeable packaging are red, not purple, in color. Thus the use of CO to package meat, as described in the GRAS notices, functions to maintain the red color of meat that is typical and "natural" when meat is processed in an environment that includes oxygen. In short, the petition's contention that CO imparts color relies not only on a flawed legal basis, but an erroneous application of the facts.

The petition also asserts that CO may not be used in this context because it "conceals damage and inferiority," citing an April 28, 2004, letter from FSIS articulating certain concerns that agency had regarding the Precept (notably not the earlier Pactiv GRAS letter) data. Interestingly, the petitioner, in attempting to argue that the use of CO is deceptive, conveniently ignores an interesting part of the language it chooses to use from the letter, *i.e.*, that the "Precept Foods MAP system stabilizes the color of meat…" in repeated assertions that CO "imparts" color.

Also significant is the conspicuous absence of any reference in the petition to the June 2, 2004, letter from FSIS to FDA that is a "follow up to our previous letter dated April 28, 2004…." That June 2 letter reiterates that FSIS had certain concerns and had requested additional data. The letter goes on to discuss the data submitted on two separate occasions by Precept and closes with the following statement:

> 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 **will not mislead consumers** into believing that they are purchasing a product that is fresher or of greater

---

incorrect and now concludes that nitrites do not 'impart' color to bacon within the meaning of section 201(t)(1) of the act." 45 Fed. Reg. 77043, 77044 (Nov. 21, 1980).

5 See February 1, 2006, letter from Kalsec to Linda Tarantino, page 5.

> value than it actually is or increase the potential for masking spoilage. (Emphasis added.)6

In short, the petition uses the April 28 letter to argue that FSIS had concerns about consumer deception but does not acknowledge the latter correspondence in which FSIS asserts that its concerns were addressed through the submission of additional data. Moreover, the petition conveniently ignores the FSIS assertion in the April 28 letter that CO "stabilizes color" rather than imparts color, a position that undercuts the petition's color additive contentions.

An additional practical consideration directly relevant to the petition's assertion that the use of CO in MAP systems is the fact that since the first Agency Response Letter, which was issued almost four years ago, millions of packages of meat products using this technology have been purchased by consumers. Significantly, the complaints submitted to the interested companies and their customers are virtually nonexistent. Given that products sold utilizing this technology are almost always branded, there is no incentive to do anything, including selling product that appears to be "fresh" but is spoiled and unusable, that would discourage consumers from buying those products in the future.

Finally, through these several unfounded assertions attempting to associate CO MAP systems with questions about food safety and consumer deception, the petition has created unwarranted confusion in the marketplace that adversely affects not only the companies utilizing the technology, but their customers and consumers in general. Accordingly, AMI respectfully requests that FDA, in consultation with FSIS, reaffirm the agencies' long-standing and consistent position regarding the use of CO MAP systems in a thorough and expeditious manner.

---

6 Letter from Dr. Robert Post, Food Safety and Inspection Service to Dr. Lane Highbarger, Center for Food Safety and Applied Nutrition (June 2, 2004).

We would be pleased to discuss these comments with you. Please contact me if there are any questions or if additional information would be useful.

Sincerely,

Mark Dopp
Senior Vice President, Regulatory Affairs and General Counsel

cc: Dr. Andrew C. von Eschenbach, Acting Commissioner of Food and Drugs,
Dr. Barbara J. Masters, Administrator, FSIS
Sheldon Bradshaw, Chief Counsel, FDA
Dr. Robert E. Brackett, Director, CFSAN
Dr. Robert C. Post, Director, Labeling & Consumer Protection Staff, FSIS
Scott Gottlieb, Deputy Commissioner for Policy, FDA
Michael Landa, Deputy Director for Regulatory Affairs, CFSAN
Dr. Robert L. Martin, Deputy Division Director, OFAS, FDA
Dr. Rudolph Harris, Supervisor, OFAS, FDA
Dr. Robert L. Buchanan, Senior Science Advisor, CFSAN
Lane Highbarger, Consumer Safety Officer, OFAS, FDA
Dr. Bill Jones, Chemist, FSIS
Philip Derfler, Assistant Administrator, FSIS