



June 2, 2008

The Honorable Michael O. Leavitt  
U.S. Department of Health and Human  
Services  
200 Independence Avenue, S.W.  
Washington, D.C. 20201

The Honorable Ed Schafer  
U.S. Department of Agriculture  
1400 Independence Ave., S.W.  
Washington, DC 20250

Dear Secretary Leavitt and Secretary Schafer:

In January 2006, consumer groups sent letters to the Food and Drug Administration (FDA) and the Department of Agriculture (USDA) requesting that the government rescind its “no objection” to the use of carbon monoxide (CO) in case-ready meat as a GRAS (generally recognized as safe) substance. In those letters we based our concerns on the following criteria:

1. Carbon monoxide artificially colors meat, thus masking the true color and freshness of the meat. This is deceptive and poses food safety risks because consumers have historically relied heavily upon color to judge the freshness and safety of meat.
2. The science behind the decision is questionable and flimsy, conducted by the interested parties without peer review.
3. Carbon monoxide-treated meat is allowed a much longer shelf life than traditionally packaged meat, or meat in modified atmosphere packages without carbon monoxide. This is problematic because older meat is more likely to have higher levels of spoilage bacteria, and any pathogenic bacteria present also have a greater opportunity to proliferate.
4. Older meat is also more likely to have been temperature abused before reaching the consumer. And although FDA and USDA advise consumers to maintain meat at proper temperatures, the bright red color produced by carbon monoxide may disguise meat that has not been temperature controlled.
5. The decision by your agencies to accept the use of CO in meat was made without the benefit of public dialogue and input<sup>1</sup>.

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<sup>1</sup> Carbon monoxide in fresh meat is a color additive as defined under 21 U.S.C. § 201(t), and is therefore unlawful until FDA publishes a rule, after notice and comment rulemaking, establishing that its use is safe and suitable. 21 U.S.C. § 721.

6. Using carbon monoxide to color meat (that is its only benefit) has already been banned in Europe, after thorough scientific review, because of concerns that it may present a health hazard by masking spoilage.
7. The American public is concerned that meat treated with CO looks fresher and could appear safer than it actually is.

In the two-and-a-half year time span since we first made entreaties to your agencies, CO-treated meat has been shipped into the marketplace without even a label describing to consumers that the product has an artificial color and warning them that they must use factors other than color and odor in their purchasing decisions to minimize risk to their health and safety.

Most recently, a letter sent to Wenonah Hauter, Executive Director of Food & Water Watch, from Alfred Almanza, Administrator of the Food Safety and Inspection Service, highlights and exacerbates the unacceptable response of your two agencies to this matter.

Administrator Almanza describes a situation in which the agency exclusively relies on communications with the company involved in evaluating spoilage data when studies already in the hands of both agencies irrefutably demonstrate that spoilage does occur prior to the “use-by or “freeze-by” date<sup>2</sup>. Instead of accepting the biased claims of the company involved, USDA should have insisted on independent, peer-reviewed studies. We find FDA’s and USDA’s reliance on the companies involved, that have a tremendous financial stake in this process, untenable and in complete contradiction of your duties to ensure a safe food supply and protect consumers.

What is occurring under your watch is a complete abdication of the agencies’ food safety responsibilities and obligation to uphold existing law. There are no legal grounds on which carbon monoxide can be used in fresh meat without rulemaking open to the public.<sup>3</sup> A full and thorough rulemaking process where all evidence can be thoroughly and objectively reviewed in a transparent manner is long overdue.

There is no disagreement on the following point: Treating packaged meat with CO produces a new, bright red pigment, carboxymyoglobin, and is therefore a food additive. This new color lasts indefinitely, even after extreme temperature abuse and beyond the point where spoilage will occur.

Even USDA has acknowledged the risk of misrepresentation to consumers by noting that the use of carbon monoxide “with case ready fresh cuts of meat and ground beef could potentially mislead consumers into believing that they are purchasing a product that is fresher or of greater value than it actually is and may increase the potential for masking

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<sup>2</sup> “Seeing red: Spoiled meat may look fresh,” *Consumer Reports*, July 2006, p 51; and Attachment A to comments submitted by Kalsec, Inc. to FDA Docket No. 2005P-0459, Citizen Petition Requesting FDA to Enforce Ban on Carbon Monoxide in Case-Ready Fresh Meat Packaging, June 14, 2006.

<sup>3</sup> Even if CO is deemed to affect meat color in a manner other than as a color additive, then rulemaking would be required to establish a food additive regulation because this use of CO is not GRAS, as evidenced by the fact that it has been banned in Europe due to safety concerns. Substances that are not GRAS must be regulated as food additives. 21 U.S.C. § 201(s).

spoilage.”<sup>4</sup> Despite this acknowledged risk, the agencies are relying exclusively on company data.

A proper regulatory process includes transparency, an opportunity for public input and consideration of all available scientific evidence. However, neither USDA nor FDA followed such a process. Instead, the agencies allowed the GRAS process to be misused to circumvent thorough evaluation of CO through notice and comment rulemaking as required by law.

As a result of record numbers of foodborne illness outbreaks and food recalls, consumers are becoming increasingly concerned about the federal government’s ability and commitment to protect them from harmful food. Consumers want more disclosure about food-processing practices, not obfuscation, as is occurring with carbon monoxide-treated meat. Rather than taking action to address the deception posed to consumers and possible violation of the Federal Meat Inspection Act, FDA and USDA have chosen to ignore the voices of Congress and consumer groups requesting a thorough review of the their decision-making process and the use of carbon monoxide in meat. The two agencies responsible for enforcing food safety laws, protecting the food supply and ensuring that consumers are not misled and deceived have failed to discharge their responsibilities.

We implore you to ban the use of carbon monoxide in fresh meat packaging and to take the necessary steps toward a thorough legal and scientific review.

Sincerely,

Chris Waldrop  
Consumer Federation of America

Jean Halloran  
Consumers Union

Wenonah Hauter  
Food & Water Watch

Mark Cohen  
Government Accountability Project

Sally Greenberg  
National Consumers League

Nancy Donley  
Safe Tables Our Priority

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<sup>4</sup> Letter from Robert C. Post, PhD, Director, Labeling and Consumer Protection Staff, to Dr. Lane Highbarger, Office of Food Additive Safety, CFSAN, FDA, April 28 2004.

CC: Senator Mike Enzi  
Senator Edward Kennedy  
Congressman Joe Barton  
Congressman Nathan Deal  
Congressman John Dingell  
Congressman Frank Pallone  
Congressman John Shimkus  
Congressman Bart Stupak