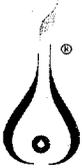


KALSEC

June 14, 2006

BY FEDERAL EXPRESS

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FSIS, United States Department of Agriculture
Room 602 Annex Bldg.
1400 Independence Avenue, SW
Washington, DC 20250-3700



Re: Use of Carbon Monoxide in Fresh Meat Packaging Violates the Federal Meat Inspection Act and USDA Regulations and Policy

Dear Dr. Post:

This submission is made on behalf of Kalsec, Inc. ("Kalsec") and establishes why carbon monoxide is not suitable for use in fresh meat packaging. It further establishes that the U.S. Department of Agriculture ("USDA") may lawfully permit the use of carbon monoxide in fresh meat packaging only by rules issued through notice and comment rulemaking, pursuant to the Federal Meat Inspection Act ("FMIA"), USDA Food Safety and Inspection Service ("FSIS") regulations, and the requirements of the Administrative Procedure Act ("APA");¹ and that USDA

¹ First, USDA is obligated to engage in rulemaking to permit the use of an unapproved color additive in meat. See 21 U.S.C. 601(m)(2)(D) (stating that meat is "adulterated" if it includes a color additive not approved under 21 U.S.C. 379e), 601(n)(9)(B) (stating that meat without a standard of identity is "misbranded" unless its label bears, "in case it is fabricated from two or more ingredients, the common or usual name of each such ingredient; except that spices, flavorings, and colorings may, when authorized by the Secretary, be designated as spices, flavorings, and colorings without naming each: Provided, That to the extent that compliance with the requirements of clause (B) of this subparagraph (9) is impracticable, or results in deception or unfair competition, exemptions shall be established by regulations promulgated by the Secretary." (emphasis added)). See also 9 C.F.R. 424.(b)(3) ("No food ingredient, the intended use of which is to impart color in any meat or poultry product, shall be used unless such use is approved in 21 C.F.R. Chapter I as a color additive (21 C.F.R. Parts 73, 74, 81, and 82) or in a regulation in this chapter.").

Second, rulemaking is necessary to overcome the existing ban on carbon monoxide's use in fresh meat packaging imposed by regulation. See 21 C.F.R. 173.350 (prohibiting the use of combustion product gas in fresh meat packaging). See also, e.g., *Sprint Corp. v. FCC*, 315 F.3d 369, 374 (D.C. Cir. 2003) ("new rules that work substantive changes in prior regulations are subject to the APA's procedures" at 5 U.S.C. 553 for notice-and-comment rulemaking); *U.S. Telecom. Assn. v. FCC*, 400 F.3d 29, 38 (D.C. Cir. 2005) (an agency's action which (continued...)

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must immediately enforce the existing ban on such use of carbon monoxide, notwithstanding FSIS Directive 7120.1, including by rescinding all favorable suitability determinations permitting the use of carbon monoxide,² withholding the mark of inspection from meat in packaging systems containing carbon monoxide,³ and refusing to allow the processing of meat packaged in atmospheres containing carbon monoxide.⁴

“substantively changes a preexisting legislative rule . . . can be valid only if it satisfies the notice-and-comment requirements of the APA”).

Third, FSIS has historically made suitability determinations concerning color-altering substances through rulemaking. *See, e.g.*, 9 C.F.R. 424.21(c) (“miscellaneous”) (permitting the use of specified substances to “delay discoloration” of fresh beef, lamb, and pork cuts); 53 Fed. Reg. 49848, 49849 (December 12, 1988) (final rule regarding ascorbic acid, erythorbic acid, citric acid, sodium ascorbate, and sodium citrate as color maintainers on fresh pork cuts to extend color and appearance); 58 Fed. Reg. 45238 (August 27, 1993) (final rule regarding citric acid as a color preserver on cured pork products). *See also* 21 U.S.C. 621 (“[S]aid Secretary shall, from time to time, make such rules and regulations as are necessary for the efficient execution of the provisions of this chapter . . .”). Established principles of administrative law prohibit USDA from reversing its treatment of color-altering substances without enumerating its justification for this significant deviation from agency precedent. *See, e.g., Independent Petroleum Ass’n v. Babbitt*, 92 F.3d 1248, 1258 (D.C. Cir. 1996) (“An agency must treat similar cases in a similar manner unless it can provide a legitimate reason for failing to do so.”).

² *See* FSIS, Safe and Suitable Ingredients Used in the Production of Meat and Poultry Products, FSIS Directive 7120.1, Amendment 7 (April 10, 2006) (“FSIS Directive 7120.1”), available at http://www.fsis.usda.gov/OPPDE/rdad/FSISDirectives/7120.1_Amend_7.pdf.

³ 21 U.S.C. 606 (“[S]aid inspectors shall mark, stamp, tag, or label as ‘Inspected and passed’ all such products found to be not adulterated; and said inspectors shall label, mark, stamp, or tag as ‘Inspected and condemned’ all such products found adulterated. . . .”); 9 C.F.R. 500.3 (“FSIS may take a withholding action or impose a suspension without providing the establishment prior notification because: (1) The establishment produced and shipped adulterated or misbranded product as defined in 21 U.S.C. 453 or 21 U.S.C. 602”); FSIS, Guidance on Ingredients and Sources of Radiation Used to Reduce Microorganisms on Carcasses, Ground Beef, and Beef Trimmings (“FSIS Guidance on Ingredients”), <http://www.fsis.usda.gov/Frame/FrameRedirect.asp?main=http://www.fsis.usda.gov/OPPDE/rdad/FRPubs/00-022N/IngridGuid.htm> (last visited June 9, 2006) (“The USDA mark of inspection for meat and poultry products reflects a determination by FSIS that the food product is not adulterated, and thus that all ingredients used to make the product must be safe and suitable for the product to receive the mark.”).

⁴ 21 U.S.C. 607(e) (“If the Secretary has reason to believe that any marking or labeling or the size or form of any container in use or proposed for use with respect to any article subject to this subchapter is false or misleading in any particular, he may direct that such use be withheld unless the marking, labeling, or container is modified in such manner as he may prescribe so that it will not be false or misleading.”); 9 C.F.R. 500.1(a) and 500.2(a) (granting FSIS the authority to take a regulatory control action, such as the refusal to allow the processing of a specifically identified product, because of product adulteration or misbranding).

I. Executive Summary Concerning Why Carbon Monoxide is Not Suitable in Fresh Meat Packaging

On November 15, 2005, Kalsec filed a citizen petition (“Kalsec Citizen Petition”) with the Food and Drug Administration (“FDA”) which requests that FDA take immediate action to prohibit the use of carbon monoxide in the packaging of fresh meat, including by terminating FDA’s unlawful responses to all Generally Recognized As Safe (“GRAS”) notifications accepted by FDA for such use (such as those submitted by Pactiv Corp. (“Pactiv”) and Precept Foods, L.L.C. (“Precept”)),⁵ and taking all such further action as is necessary to effectively implement and enforce an immediate ban on carbon monoxide in fresh meat packaging. On February 1, 2006 and June 9, 2006, Kalsec made further submissions to FDA in support of the citizen petition. The Kalsec Citizen Petition and the Kalsec February 1, 2006 Comments to FDA are attached to this letter.⁶ This letter incorporates those submissions by reference, as well as presents new data⁷ and provides further details not previously included in the administrative record that establish why carbon monoxide is not suitable in fresh meat packaging.

⁵ While Kalsec’s submissions have focused on the Pactiv and Precept GRAS notifications (the first two GRAS notifications for the use of carbon monoxide in fresh meat packaging, GRAS Notice Nos. GRN 000143 and 000083, respectively), the Kalsec Citizen Petition and this submission are directed at all uses of carbon monoxide in fresh meat packaging. See FSIS Directive 7120.1, *supra* note 2.

⁶ The Kalsec Citizen Petition (Docket No. 2005P-0459/CP1) (Attachment A) and the Kalsec February 1, 2006 Comments (Docket No. 2005P-0459/RC1) (Attachment B) are available at <http://www.fda.gov/ohrms/dockets/dockets/05p0459/05p-0459-cp00001-toc.htm> and <http://www.fda.gov/ohrms/dockets/dockets/05p0459/05p-0459-rc00001-toc.htm>, respectively.

⁷ Appended hereto as Attachment C are scientific reports from limited unpublished studies that were sponsored by Kalsec and conducted by S&J Laboratories of Portage, Michigan (“June 2006 Scientific Reports”). These studies were designed to evaluate selected microbial and sensory characteristics of ground beef sold at retail in packaging containing carbon monoxide gas (carbon monoxide modified atmosphere packaging, or “CO-MAP”), compared to ground beef sold in high oxygen modified atmosphere packaging (“high oxygen MAP”). Additional studies evaluated microbial features of CO-MAP ground beef and ground beef sold at retail in other common types of packaging that do not contain carbon monoxide. Although the results from the Kalsec-sponsored studies are limited, and involved a relatively small number of ground beef samples purchased from various retail stores in a local region, the findings lend further support to the scientific evidence raising food safety and consumer deception concerns relating to the use of carbon monoxide in fresh meat packaging. Several key findings merit close evaluation FSIS. Notably, the commercially available CO-MAP ground beef samples tested were shown to have significantly higher bacterial counts at the time of purchase than the high oxygen MAP ground beef. In some of the CO-MAP ground beef samples, the high bacteria levels were indicative of spoilage, even though the meat was within the labeled “use or freeze by” date listed on the package.

Consumer Reports magazine recently reported similar findings in a limited study of carbon monoxide-packaged ground beef. *Seeing Red: Spoiled Meat May Look Fresh*, Consumer Reports 51 (July 2006) (Attachment D) (“By their use- or freeze-by date, seven [out of ten] (continued...)”)

For the reasons set forth in detail below, irrespective of any action FDA may take in response to the Kalsec citizen petition, and notwithstanding FSIS Directive 7120.1, Kalsec urges USDA to take immediate action to prohibit the use of carbon monoxide in fresh meat packaging in compliance with the FMIA and APA requirements, as well as well-established USDA regulations and policy restricting the use of substances in fresh meat that have an effect on meat color. As described in the Kalsec petition, carbon monoxide “binds to myoglobin and forms cherry red carboxymyoglobin.”⁸ This pigment is “spectrally similar” to the oxymyoglobin that naturally develops on fresh meat exposed to air.⁹ While meat is in an atmosphere of carbon monoxide gas, it appears to retain its bright red color indefinitely.¹⁰ This color that simulates the appearance of freshness appears to persist regardless of the degree of temperature abuse or level of microbial contamination, and it has functional and distinct effects in the finished meat product.

As is documented in the published literature and FSIS’s own statements, carbon monoxide can mask the natural signs of aging, deterioration, and spoilage that consumers depend upon when making meat quality and safety decisions. The Kalsec petition raises concerns that the use of carbon monoxide in case-ready fresh meat packaging needlessly threatens consumer confidence in the safety and integrity of the entire case-ready meat supply. Because product labels do not disclose the use of carbon monoxide to chemically alter meat color, consumers cannot tell whether carbon monoxide has been added to any particular meat package, putting at risk the reputation of case-ready meat generally. Kalsec serves the case-ready meat business as a supplier of rosemary extract used in oxygen-containing packaging systems. Kalsec believes that case-ready meat packaging offers substantial safety and consumer benefits,¹¹ and should be embraced by retailers and consumers alike. Kalsec urges USDA to take the actions requested to prevent serious harms to public health and consumer confidence in the integrity of the U.S. case-ready meat supply posed by this use of carbon monoxide.

Under the FMIA, Congress charged USDA with the responsibility for determining the suitability of all food ingredients and additives in meat products, and for prescribing safe and suitable conditions of a substance’s use.¹² In exercising this authority, FSIS

samples were fresh but two packages of ground beef from one company were spoiled; an additional sample was on the brink of spoilage a day before the stamped date.”).

⁸ Oddvin Sørheim *et al.*, *The Storage Life of Beef and Pork Packaged in an Atmosphere with Low Carbon Monoxide and High Carbon Dioxide*, 52 *Meat Science* 157, 162 (1999) (Attachment A at Attachment 18) (citation omitted).

⁹ *Id.*

¹⁰ See June 2006 Scientific Reports, *supra* note 7.

¹¹ See Kalsec February 1, 2006 Comments, *supra* note 6, at 9-10.

¹² 21 U.S.C. 601(m), (n) (defining adulterated and misbranded meat), 606 (requiring USDA inspectors to affirmatively determine that meat prepared for food commerce is not adulterated prior to marking the meat “inspected and passed”). See also 9 C.F.R. 424.23(a) (“No substance (continued...)”).

is obligated to ensure that a substance's "conditions of use will not result in an adulterated product or one that misleads consumers."¹³ This letter explains in detail how carbon monoxide is not suitable in fresh meat packaging because it poses a serious risk of consumer deception. Key points are highlighted as follows:

- Carbon monoxide renders meat adulterated and misbranded under the FMIA and FSIS's implementing regulations. The color-altering effect of carbon monoxide can mask meat spoilage and deterioration, and has the potential to cause meat to appear to be of better value than it is and mislead consumers. Published scientific literature conclusively documents the color-altering effect of carbon monoxide, as well as the inadequacy of other signs of spoilage to compensate for the loss of color as a visual cue of product quality and wholesomeness. The record fails to establish that "use or freeze by" dates adequately protect consumers, particularly when meat color suggests freshness. In addition, use of carbon monoxide in fresh meat packaging violates the FMIA's prohibition against the use of unapproved color additives in meat absent formal notice and comment rulemaking.
- This use of carbon monoxide in fresh meat packaging is banned by FDA's combustion product gas regulation. As FSIS has stated, this regulation is expressly designed to address concerns that the treatment of meat with gases such as carbon monoxide may mislead consumers and mask spoilage by causing meat to retain a bright red color longer than meat not so treated.
- This use of carbon monoxide is precluded by FSIS's longstanding restrictive policy toward color-altering substances. FSIS typically bans color-altering substances. When FSIS has not prohibited a color-altering substance outright, it has historically prescribed narrow conditions of use, after engaging in formal notice and comment rulemaking, to ensure that the color-altering effect did not outlast a product's shelf life and to require that the product label disclose the presence of the substance.

may be used in or on any meat if it conceals damage or inferiority or makes the product appear to be better or of greater value than it is."), 317.8(a) ("No product shall be wholly or partly enclosed in any wrapper, packaging, or other container that is so made, formed, or filled as to be misleading."), 500.8(a) (FSIS may rescind or refuse approval of false or *misleading* marks, labels, or sizes or *forms of any container for use with any meat* or poultry product under section 7 of the FMIA or under section 8 of the PPIA.) (emphasis added); FSIS Guidance on Ingredients, *supra* note 3 ("All ingredients and sources of radiation must be determined to be safe and suitable before they can be used in the production of meat and poultry products.").

¹³ See FSIS, Guidance on the Procedures for Joint Food Safety and Inspection Service (FSIS) and Food and Drug Administration (FDA) Approval of Ingredients and Sources of Radiation Used in the Production of Meat and Poultry Products ("FSIS MOU Guidance"), <http://www.fsis.usda.gov/OPPDE/rdad/FRPubs/00-022N/ApprovalofIngredients.htm> (last visited June 9, 2006).

- Consumer deception and safety concerns identified by FSIS in a letter to FDA on April 28, 2004 preclude lawful use of carbon monoxide in any retail package of fresh meat. The key concerns that FSIS identified after its initial evaluation of one company's intended use of carbon monoxide (the gas's potential to mislead consumers into believing meat is fresher than it actually is and mask spoilage, the inability of consumers to detect organoleptic signs of spoilage prior to purchasing carbon monoxide-treated meat, and the insufficiency of "use or freeze by" dating) have not been addressed. These serious concerns can only be adequately addressed through notice and comment rulemaking.
- New data from limited unpublished studies that were sponsored by Kalsec and conducted by S&J Laboratories of Portage, Michigan, raise serious questions about the shelf life and adequacy of the open date codes accepted as conditions of use for carbon monoxide in fresh meat packaging to assure that consumers purchase wholesome meat. These studies found that, on average, the commercially available carbon monoxide-treated ground beef samples tested had a statistically significant higher bacterial count, on the date of purchase or within a day of purchase, than commercially available samples of ground beef packaged in high oxygen modified atmosphere packaging that were tested. Some of the carbon monoxide-treated ground beef samples tested within their "use or freeze by" dates were found to have bacterial counts indicative of spoilage, whereas none of the high oxygen modified atmosphere packaging ground beef samples tested within their "sell by" dates had bacterial counts indicative of spoilage.
- If carbon monoxide is to be permitted in fresh meat packaging at all, it must at least be identified on the product label, in compliance with the FMIA and FSIS regulations. Carbon monoxide must be identified on the label for several independent reasons: the absence of labeling has the potential to mislead consumers in violation of the FMIA's misbranding prohibition; carbon monoxide is an ingredient that qualifies for no exception from statutorily-mandated ingredient labeling; failure to identify carbon monoxide on the label contravenes firm FSIS policy to alert consumers when natural meat color has been altered; and the presence and purpose of carbon monoxide in fresh meat packaging is a material fact that must be declared on the meat label under the FMIA.
- Further, USDA may lawfully permit the use of carbon monoxide in fresh meat packaging only through notice-and-comment rulemaking. USDA must engage in formal rulemaking for several independent reasons: to permit the use of an unapproved color additive in meat; to overcome the ban on carbon monoxide's use in fresh meat packaging currently imposed by regulation; and to comply with tenets of administrative law requiring agencies to justify a significant deviation from agency precedent. Rulemaking will allow public participation of stakeholders to ensure that all material data and information are considered (including critical data related to consumer behavior under real-world conditions of use).

Allowing carbon monoxide to alter the color of meat controverts federal laws and regulations governing meat, as well as well-established FSIS policy. Accordingly, Kalsec urges FSIS to uphold the FMIA and its own policies by prohibiting use of carbon monoxide in fresh meat packaging.

II. Carbon Monoxide's Color-Altering Effect Adulterates and Misbrands Meat under the FMIA and FSIS Regulations

Carbon monoxide is not suitable for use in fresh meat packaging because it masks deterioration and spoilage and it is a prohibited unapproved color additive. As such, allowing its use in fresh meat packaging violates the FMIA's adulteration and misbranding provisions as well as the Act's implementing regulations.

Federal law charges USDA with the responsibility for permitting the use of substances in meat products only under conditions that are suitable. "Suitable" conditions are those that will not render a product adulterated or misbranded, and are therefore non-deceptive, safe, and effective.¹⁴ Meat is adulterated under the FMIA if "*damage or inferiority has been concealed in any manner[,]* or if any substance has been added thereto or mixed or packed therewith so as to ... make it appear *better or of greater value than it is.*"¹⁵ Meat is misbranded if "*its container is so made, formed, or filled as to be misleading.*"¹⁶

Congress intended for the FMIA and the 1967 Wholesome Meat Act amendments to the FMIA to safeguard against consumer deception risks such as those posed by this use of carbon monoxide. Congress enacted legislation governing meat due in part to concerns that substances affecting meat color were "potentially deceptive"¹⁷ because they made meat "appear

¹⁴ See, e.g., Letter from Robert C. Post, Ph.D., Director, FSIS Labeling and Consumer Protection Staff, to Lane Highbarger, Ph.D., Office of Premarket Approval, Center for Food Safety and Applied Nutrition ("CFSAN"), FDA 2 (February 13, 2002) ("FSIS 2002 Letter") (Attachment E) ("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.").

¹⁵ 21 U.S.C. 601(m)(8) (emphasis added). See also 9 C.F.R. 301.2(8), 424.23(a).

¹⁶ 21 U.S.C. 601(n)(4). See also 9 C.F.R. 301.2 (defining "misbranded," subsection (4)), 317.8(a).

¹⁷ *Amend the Meat Inspection Act: Hearings on H.R. 1314, H.R. 1321, and H.R. 6168 Before the Subcomm. on Livestock and Grains of the H. Comm. on Agriculture, 90th Cong. 18 (1967)* (statement of Rodney E. Leonard, Deputy Assistant Secretary of Agriculture).

to have a normal color”¹⁸ or “cancel[led] out the ... appearance of decaying or unhealthy meat.”¹⁹

Given the plain language of the FMIA’s adulteration and misbranding provisions as well as Congress’s intent motivating them, carbon monoxide renders meat adulterated and misbranded under the tenets of the FMIA in three key respects: it makes meat appear to be of better value than it is; it masks the normal spoilage indicator of discoloration; and it is an unapproved color additive, for which the “processing aid” exemption to ingredient status does not apply.

A. This Use of Carbon Monoxide Makes Meat Appear to be of Better or of Greater Value than It Is, Violating the FMIA and FSIS Regulations

By masking the normal appearance of aging and deteriorating meat (i.e., discoloration), this use of carbon monoxide on its face violates the statutory prohibition against concealing product inferiority. It adulterates meat by making meat appear to be of “better or of greater value than it is.”²⁰ As FSIS states in guidance, substances adulterate or misbrand meat by “making products look better or of greater value *than untreated products*...”²¹ Because the presence of carbon monoxide is not declared on the product label, consumers could be misled to believe that a product packaged with carbon monoxide (bearing a persistent bright red color) is more fresh than an otherwise identical product (bearing its true, more brown coloration).²²

¹⁸ *Id.* at 39 (statement of Rep. Neal Smith).

¹⁹ 113 CONG. REC. 33842 (1967) (statement of Sen. Mondale, speaking on behalf of the Senate Committee on Agriculture).

²⁰ 21 U.S.C. 601(m)(8); 9 C.F.R. 301.2(8), 424.23(a).

²¹ FSIS MOU Guidance, *supra* note 13 (emphasis added). *See also* 21 U.S.C. 601(m)(8) (defining “adulterated”), 601(n)(4) (defining “misbranded”); 9 C.F.R. 301.2 (“adulterated,” subsection (8)), 424.23(a) (prohibiting adulteration), 301.2 (“misbranded,” subsection (4)), 317.8(a) (prohibiting misbranding).

²² *See, e.g.*, J. Brad Morgan, *Extending Shelf-Life of Beef Cuts Utilizing Low Level Carbon Monoxide in Modified Atmosphere Packaging Systems*, Project Summary Prepared on behalf of the Cattlemen’s Beef Board by the National Cattlemen’s Beef Association Center for Research & Knowledge Management, (July 2003) (Attachment B at Attachment 3), *available at* <http://www.fda.gov/ohrms/dockets/dockets/05p0459/05p-0459-rc00001-04-Attach-03-Morgan-vol2.pdf> (“U.S. retailers *fail to capture at least one billion dollars of revenue annually* from fresh beef sales, *due to product discoloration*. The findings of this study suggest that CO MAP could contribute to longer shelf life for T-bone steaks, sirloin steaks and ground beef patties. This packaging system also appears to reduce oxidation over storage and retail display time versus the other two packaging systems, and *sensory panelists found the cuts packaged in CO more acceptable than the High-Oxygen MAP cuts*. This is important to the Beef Industry in that *longer shelf life can contribute more to the bottom line of the retailer* and consistent eating experiences by the consumer contribute to customer satisfaction and continued willingness to purchase.”) (emphasis added).

B. This Use of Carbon Monoxide Masks Discoloration, Violating FSIS Policy

Longstanding FSIS policy prohibits the use of substances in meat that “mask[] normal spoilage indicators.”²³ FSIS policy establishes further that meat “discoloration” constitutes a critical “normal spoilage indicator.”²⁴

FSIS policy is well justified in the case of carbon monoxide. Scientific literature confirms that carbon monoxide “may mask spoilage, because the stable cherry red colour can last beyond the microbiological shelf life of the meat.”²⁵

C. This Use of Carbon Monoxide Constitutes Use of an Unapproved Color Additive, Violating the FMIA and FSIS Regulations

Carbon monoxide is prohibited from use in fresh meat packaging because it is an unapproved color additive. In submissions to FDA, Kalsec has comprehensively demonstrated that carbon monoxide is an unapproved color additive under the statutory definition of the term, consistent with FDA’s regulation of numerous substances that impart color through chemical reaction with a substance in the food to which it is applied.²⁶ Kalsec has submitted published scientific literature that documents how carbon monoxide produces a new pigment not found naturally in meat.²⁷

The FMIA deems meat adulterated if the product bears or contains any unapproved food or color additive.²⁸ Due to the consumer deception concerns presented by substances that alter the color of fresh meat, FSIS regulation prohibits the use of ingredients intended to impart color to meat absent approval in 21 C.F.R. Chapter I as a color additive or by express FSIS regulation.²⁹

²³ FSIS MOU Guidance, *supra* note 13.

²⁴ FSIS Guidance on Ingredients *supra* note 3.

²⁵ Sørheim *et al.*, *supra* note 8, at 157. See also June 2006 Scientific Reports, *supra* note 7.

²⁶ See Kalsec Citizen Petition, *supra* note 6, at 8-10; Kalsec February 1, 2006 Comments, *supra* note 6, at 2-4.

²⁷ Sørheim *et al.*, *supra* note 8, at 162 (“CO binds to myoglobin and forms cherry red carboxymyoglobin. This pigment is spectrally similar to the bright red oxymyoglobin which normally develops at the surface of fresh meat in air.”) (citation omitted).

²⁸ 21 U.S.C. 601(m)(2)(D).

²⁹ 9 C.F.R. 424.21(b)(3) (“No food ingredient, the intended use of which is to impart color in any meat or poultry product, shall be used unless such use is approved in 21 C.F.R. Chapter I as a color additive (21 C.F.R. Parts 73, 74, 81, and 82) or in a regulation in this chapter.”).

No legal exemptions to color additive status apply to carbon monoxide in fresh meat packaging. Federal regulation, FSIS policy and precedent, and federal case law preclude carbon monoxide's status as a processing aid in fresh meat packaging.

FSIS has made clear that, in the absence of an authorizing color additive regulation, substances imparting color may be used in meat only when the substance satisfies the requirements for "processing aids" within the meaning of section 101.100(a)(3) of FDA regulations.³⁰ FSIS guidance states that to qualify as a "processing aid," a substance must have "no lasting effect" in the treated food, and there must be an "insignificant amount" of the substance present in the finished food product under the proposed conditions of use.³¹ FSIS elaborates that processing aids "are ordinarily removed from the final food, and any residuals that may carry over to the final product are not expected to exhibit any technical effect."³²

In FSIS's response to the GRAS notification submitted by Pactiv, FSIS explains its policy related to determinations about what substances are processing aids exempt from requirements applicable to ingredients.

Notwithstanding the serious weaknesses in the Pactiv GRAS notification (which are discussed more fully below), under the intended conditions of use of carbon monoxide in the Pactiv system the carbon monoxide gas is added to the retail meat package, but is purported to dissipate through the gas permeable packaging before consumer sale, thus allegedly having no technical or functional effect in the finished food product sold to consumers.³³ In Pactiv's

³⁰ See FSIS Guidance on Ingredients, *supra* note 3 ("Even though FSIS has no definition of 'processing aid' in its labeling regulations, the Agency, through the Labeling and Consumer Protection Staff (LCPS), which serves as FSIS' focal point on the use and labeling of food ingredients, makes judgments on a case-by-case basis using FDA's definition of a processing aid to decide whether the use of a substance is as a processing aid or as an ingredient of a food."); FSIS 2002 Letter, *supra* note 14, at 2. See also 21 U.S.C. 101.100(a)(3)(c) (stating that the term "processing aids" includes "[s]ubstances that are added to a food for their technical or functional effect in the processing but are present in the finished food at insignificant levels and do not have any technical or functional effect in that food.").

³¹ See FSIS Guidance on Ingredients, *supra* note 3; FSIS 2002 Letter, *supra* note 14, at 2 (stating that a substance is not a processing aid where "[t]here 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.").

³² FSIS Guidance on Ingredients, *supra* note 3.

³³ FDA's Agency Response Letter to the Pactiv GRAS notification states that the carbon monoxide-containing "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." Letter from Alan M. Rulis, Director, CFSAN Office of Food Additive Safety, to Eric Greenberg, Ungaretti and Harris (February 21, 2002) ("Agency Response Letter to GRAS Notice No. GRN 000083"), available at <http://www.cfsan.fda.gov/~rdb/opa-g083.html>.

modified atmosphere packaging system, gas permeable retail-ready packages are placed inside an impermeable outer bag in which the air is replaced with a mixture of nitrogen, carbon dioxide, and 0.4% carbon monoxide. At retail, the individual gas permeable packages are removed from the outer bag and placed on store shelves. The Pactiv GRAS notification contains data purporting to show that color begins to deteriorate after removal of the outer bag and placement of the meat in retail display. The Pactiv notification also includes data that purport to demonstrate that the color of treated meat would deteriorate if exposed to temperature abuse. Based on these data, Pactiv's GRAS notification asserts that the intended use of carbon monoxide in this packaging system is that of a processing aid, because the carbon monoxide has no technical or functional effect in the finished food presented to consumers. The Pactiv notification discusses the published literature that expresses concerns that the coloring effect of carbon monoxide can mask spoilage, and argues that such concerns are not present in its packaging system. The notification states that Pactiv's system "does not mask spoilage of the meat" because it "does not involve use of a modified atmosphere including CO in the retail package."³⁴

While the Pactiv GRAS notification ultimately is unsuccessful, it attempts to establish that its proposed use of carbon monoxide qualifies as a "processing aid." It emphasizes the opportunity for carbon monoxide to dissipate through the gas permeable package before retail sale. Were it the case that evidence had, in fact, shown that carbon monoxide constituted a processing aid because it had no technical or functional coloring effects in the finished food, then it would have qualified as a "secondary direct food additive." Pactiv could have shown that its intended use of carbon monoxide was a processing aid if the carbon monoxide "did not result in color life extension once the [meat] 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,"³⁵ and if it could have shown that there was "no lasting functional effect in the food and there [was] an insignificant amount of carbon monoxide present in the finished product under the proposed conditions of use."³⁶

In contrast to substances that FSIS has determined have no lasting functional effect on meat, FSIS has determined that organic acids that are used in meat for technical effects – such as "color preservati[on]" – are not processing aids. Instead, FSIS concluded that when organic acids are used as color preservers, they are "ingredients of the product since they are in the finished meat food product at a detectable level, and they exhibit a continuing technical effect in or on the meat food product."³⁷ These color preservers are not processing aids because

³⁴ GRAS Notification of Pactiv Corporation, August 29, 2001, at 22 ("GRAS Notice No. GRN 000083").

³⁵ FSIS 2002 Letter, *supra* note 14, at 2.

³⁶ *Id.*

³⁷ FSIS Guidance on Ingredients, *supra* note 3.

“sensory characteristics (i.e., color and odor) of the product” show that the product characteristics are “altered as compared to untreated” meat.³⁸

In addition, courts have established that substances affecting color or otherwise making a product appear to be of greater value than it is cannot satisfy FDA’s definition of a processing aid at 21 C.F.R. 101.100(a)(3)(ii)(c). In *United States v. Randazzo*, the defendant argued that the sodium hydroxide it added to shrimp “did no more than bring out or restore the allegedly natural pink color of the shrimp and that the ingredient was exempted from listing as a ‘processing aid.’”³⁹ However, the jury found that this use of the substance did not satisfy the processing aid definition, and the First Circuit affirmed the jury verdict convicting the defendant of misbranding violations, *inter alia* because of the failure to list the sodium hydroxide as an ingredient.⁴⁰ Similarly, in *Sea Snack Foods, Inc. v. United States*, FDA found that the company’s use of sodium hydroxide caused water retention, which altered the shrimp’s weight in such a manner that consumers purchasing the product would pay for shrimp but receive water, and therefore ruled that the sodium hydroxide did not qualify as a processing aid exempt from labeling requirements.⁴¹ The court found that FDA acted within its discretion in reaching this conclusion.⁴²

Finally, in *Stauffer Chemical Company v. Food and Drug Administration*, FDA had ruled that the use of sodium tripolyphosphate (“STPP”) in the processing of canned tuna was not an incidental additive, where the data showed that STPP has several effects which persist in the finished food, including that the treated canned tuna is lighter in color.⁴³ The court noted that, because the higher, more expensive grades of tuna are lighter in color, the use of STPP may enable tuna processors to market canned tuna at a higher grade than would be lawful.⁴⁴ While the court concluded it lacked jurisdiction in that case because the plaintiff had failed to exhaust its administrative remedies, it also concluded that there were no genuine issues of material fact and that the defendant was entitled to judgment as a matter of law, because this use of STPP does not qualify as an incidental additive used as a processing aid under 21 C.F.R. 101.100(a)(3)(ii)(c).⁴⁵ These cases make clear that the use of a substance such as carbon monoxide that affects the color of a food and makes it appear to be of greater value than it is cannot satisfy the definition of a processing aid.

³⁸ *Id.*

³⁹ 80 F.3d 623, 632 (1st Cir. 1996).

⁴⁰ *Id.* at 627, 633.

⁴¹ [1988-1989 Transfer Binder] Food Drug Cosm. L. Rep. (CCH) ¶ 38,062 at 37,901 (D.D.C. 1987).

⁴² *Id.* at 38,902.

⁴³ [1980-1981 Transfer Binder] Food Drug Cosm. L. Rep. (CCH) ¶ 38,065 at 38,304-38,305 (C.D. Cal. 1980).

⁴⁴ *Id.*

⁴⁵ *Id.* at 38,305-38,306.

According to FSIS policy, the proponent of the use of an ingredient has the burden to provide data showing that a substance does not have a continuing effect on the meat product.⁴⁶ “Specifically, the supporting data must show that the fresh color of the meat is not preserved. The product will exhibit normal spoilage indicators (e.g., discoloration); and that there is no extension of shelf life as compared to products” to which the substance is not applied.⁴⁷

Proponents seeking to use carbon monoxide in fresh meat packaging have failed to establish that this use of carbon monoxide functions as a processing aid. Carbon monoxide in fresh meat packaging is an ingredient under federal regulation, FSIS policy and precedent, and federal case law. As described above, FSIS noted that a substance is a processing aid if it “did not result in color life extension once the [meat] 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.”⁴⁸ Under this definition, carbon monoxide does not qualify for the processing aid exemption when in either retail packaging or gas permeable packaging.

In packaging systems that do not attempt to remove carbon monoxide from the retail package prior to display, the use of carbon monoxide cannot qualify as a processing aid because it has a lasting technical effect in the meat product:

- This use results in color life extension after packages are displayed for retail sale: the gas gives meat the bright red appearance associated with freshness, regardless of product age, until the package seal is broken by consumers.⁴⁹
- Under this use, microbial loads reach levels considered indicative of spoilage while the color of the meat is is still acceptable to consumers: the gas gives meat the bright red appearance associated with freshness, regardless of product temperature abuse or level of microbial contamination.⁵⁰

In retail packaging systems (such as the Precept Foods, L.L.C. (“Precept”) and Tyson Foods, Inc. (“Tyson”) systems), carbon monoxide is used precisely to have a continuing effect on the color of treated meat. The function of carbon monoxide in anaerobic modified atmosphere packaging is to prevent discoloration that would otherwise normally occur. Notably, Precept’s submissions make no attempt to demonstrate that discoloration will occur upon spoilage, but rather contend that color is not a relevant sign of spoilage.⁵¹ Because carbon

⁴⁶ FSIS Guidance on Ingredients, *supra* note 3.

⁴⁷ *Id.*

⁴⁸ FSIS 2002 Letter, *supra* note 14, at 2.

⁴⁹ June 2006 Scientific Reports, *supra* note 7.

⁵⁰ *Id.*

⁵¹ *See, e.g.*, Precept’s April 11, 2006 Comments, at 9.

monoxide is intended or permitted to remain functional in the retail package, it constitutes neither a processing aid nor a secondary direct food additive.

Likewise, carbon monoxide in packaging systems that do attempt to remove meat from an atmosphere of carbon monoxide prior to retail display (such as the system used by Pactiv), fails to qualify for the processing aid exception. The carbon monoxide in the Pactiv system does not satisfy the definition of a processing aid stated in FDA regulations: “[s]ubstances that are added to a food for their technical or functional effect *in the processing* but are present in the finished food at insignificant levels and do not have any technical or functional effect in that food.”⁵²

- First, the gas is not a processing aid because it is plainly intended to have a functional effect on the meat, given that a modified atmosphere without carbon monoxide could be used and still give meat the benefits of case-ready packaging. The color-altering effect of carbon monoxide has a technical effect on the meat, even if this effect is intended to occur during distribution and storage of the meat while it remains in the outer bag. The ingredient definition and exemptions thereto relate to whether the substance has an effect on the meat food product to which it is applied, not whether the substance has any effect on the consumer.
- Second, an expert report dated May 2001 submitted in support of the Pactiv GRAS notification (“the Kansas State study”) acknowledges that carbon monoxide in the Pactiv system does have some effect on color life extension for certain cuts of meat.⁵³ The Pactiv GRAS notification contains conflicting information about the rate at which carboxymyoglobin converts to other pigment forms and allows color deterioration to occur once meat packages are removed from the outer bag.⁵⁴ These contradictory data fail to establish that the carbon

⁵² 21 C.F.R. 101.100(a)(3)(ii)(c).

⁵³ The Kansas State study, Kathy Hachmeister *et al.*, Evaluation of Beef Steaks and Ground Beef in the Pactiv Active Tech Packaging System: Effects of Carbon Monoxide in the Package Atmosphere (Final Report for Pactiv Corp.) (May 2001), concludes, at 3, that “color life for tenderloin and inside round steaks (and to a lesser extent ground beef) was slightly longer than their baseline counterparts, especially when stored at 35° F vs. 43° F.”

⁵⁴ The Pactiv GRAS notification states that when the “outer bag was removed, the product’s conversion to oxymyoglobin occurred in 60-90 minutes and then had a typical bright red color,” suggesting that the carboxymyoglobin disappears an hour or so after the barrier bag is removed. GRAS Notice No. GRN 000083, *supra* note 34, at 28. This conclusion appears to have been drawn from the expert report submitted in support of that notification by Kathy Hachmeister *et al.*, Kansas State University. The Kansas State study actually reported, however, that “[c]olor of products exposed to CO was a typical bright red when the outer MAP bag was removed and products were allowed to bloom for 60 to 90 minutes.” Kansas State study, at 3. This report does not claim, or provide any evidence, that carboxymyoglobin was converted to oxymyoglobin within the 60-90 minute time frame. The report does not contain any information as to the identity of the pigments on the meat surface or description of experiments to make such (continued...)

monoxide has no functional effect in the finished meat package presented to the retail consumer at the point of purchase.

- Third, the carbon monoxide in the Pactiv system cannot be a processing aid because it is not added during processing; rather, it is added to meat after processing (as well as packaging) has been completed.

Proponents of this use of carbon monoxide have not met their burden of establishing that the gas does not have a technical effect on meat, and therefore, could qualify as a processing aid. Indeed, the letters issued by FDA to both Precept and Pactiv, expressing no objection at this time to the companies' assertions that carbon monoxide in fresh meat packaging is GRAS, note that carbon monoxide "is included in the modified atmosphere to help maintain the characteristic color of fresh meat"⁵⁵ and functions to give meat "a desirable red color during storage."⁵⁶ This technical, coloring effect in meat must be considered that of a color additive, and as such, it may only lawfully be permitted pursuant to approval granted by USDA or FDA through notice and comment rulemaking.⁵⁷

In sum, carbon monoxide is not suitable for use in fresh meat packaging under the FMIA's adulteration and misbranding provisions, which were in part designed expressly to preclude the use of substances that deceptively alter the color of meat. By masking meat aging and deterioration, carbon monoxide in fresh meat packaging has the potential to make meat products appear to be of greater value than untreated, otherwise identical products. Carbon monoxide further adulterates meat by masking a principal indicator of spoilage: discoloration. In addition, using carbon monoxide in fresh meat packaging constitutes the use of an unapproved

measurements. To the contrary, the Pactiv GRAS notification cites published literature reporting the half-life of carboxymyoglobin in carbon monoxide-treated meat subsequently exposed to air as approximately three days. See Oddvin Sørheim *et al.*, *Technological, Hygienic and Toxicological Aspects of Carbon Monoxide Used in Modified-Atmosphere Packaging of Meat*, 8 Trends Food Sci. Tech. 307, 310 (September 1997) (Attachment A at Attachment 14) ("CO is lost from previously CO-treated meat during storage in the absence of CO, with a half life of ~3d [days]."), cited in GRAS Notice No. GRN 000083, *supra* note 34, at 19. This slow conversion of carboxymyoglobin is supported elsewhere in the literature. See, e.g., D.L. Gee & W.D. Brown, "Stability of Carboxymyoglobin in Refrigerated Ground Beef," 26(1) J. Agric. Food Chem. 273-274 (1978) (Attachment F) (measuring the concentration of carboxymyoglobin, metmyoglobin, and myoglobin plus oxymyoglobin in ground beef initially exposed to an atmosphere of 1% carbon monoxide and then stored in air in a lighted environment, and calculating the half-life of carboxymyoglobin on ground beef in air at about 2.1 days).

⁵⁵ Letter from Laura M. Tarantino, Director, Office of Food Additive Safety, CFSAN, to Gary J. Kushner & Anne M. Boeckman, Hogan & Hartson at 2 (July 29, 2004) ("Agency Response Letter to GRAS Notice No. GRN 000143"), available at <http://www.cfsan.fda.gov/~rdb/opa-g143.html>.

⁵⁶ GRAS Notice No. GRN 000083, *supra* note 34, at 2.

⁵⁷ See *supra* note 1.

color additive, an act prohibited by the FMIA and FSIS regulation. The processing aid exemption to ingredient status does not apply because this use of carbon monoxide has a continuing technical effect in meat products. Accordingly, the use of carbon monoxide in fresh meat packaging is unlawful.

III. Existing Food Additive Regulations Prohibit Carbon Monoxide in Fresh Meat Packaging

The FMIA obligates USDA to prohibit the use of substances in fresh meat that are banned by FDA food additive regulations.⁵⁸ As detailed in the Kalsec petition and a subsequent submission to FDA,⁵⁹ section 173.350 of FDA food additive regulations provide that combustion product gas, including carbon monoxide gas, may be used in food packaging “for the purpose of removing and displacing oxygen” only under prescribed conditions of use, one of which is that the gas not be used in “fresh meats.”⁶⁰

As FSIS’s February 13, 2002 Letter to FDA correctly stated in commenting on the use of carbon monoxide characterized in the Pactiv GRAS notification,⁶¹ section 173.350 prohibits the use of combustion product gas in fresh meat packaging “because of concerns that the treatment of meat with combustion product gases *may cause the meat retain its fresh red color longer than meat not so treated*, thereby misleading the customer and increasing the potential for masking spoilage.”⁶²

⁵⁸ 21 U.S.C. 601(m)(2)(C) (declaring meat “adulterated” if it “bears or contains any food additive which is unsafe within the meaning of section 348 of this title”).

⁵⁹ See Kalsec Citizen Petition, *supra* note 6, at 23-25; Kalsec February 1, 2006 Comments, *supra* note 6, at 6-8.

⁶⁰ 21 C.F.R. 173.350(a)-(c) (emphasis added):

(a) The food additive combustion product gas may be safely used in the processing and packaging of the foods designated in paragraph (c) of this section *for the purpose of removing and displacing oxygen* in accordance with the following prescribed conditions.

(b) The food additive meets the following specifications: (1) Carbon monoxide content not to exceed 4.5 percent by volume. (2) The ultraviolet absorbance in isooctane solution in the range 255 millimicrons to 310 millimicrons not to exceed one-third of the standard reference absorbance when tested as described in paragraph (e) of this section.

(c) It is used or intended for use to displace or remove oxygen in the processing, storage, or packaging of beverage products and other food, *except fresh meats*.

⁶¹ GRAS Notice No. GRN 000083, *supra* note 34.

⁶² FSIS 2002 Letter, *supra* note 14, at 1-2 (emphasis added).

More specifically, these well-established concerns about the coloring effects of combustion product gas plainly relate to carbon monoxide, because carbon monoxide is the only combustion product gas that affects meat color in the manner of concern identified by FSIS. In view of the prohibition in section 173.350, USDA may not lawfully permit the use of carbon monoxide in fresh meat under section 601(m)(2)(C) of the FMIA absent formal rulemaking as required by the APA.⁶³

IV. Carbon Monoxide is Not Suitable under FSIS's Restrictive Policy Toward Color-Altering Substances in Fresh Meat

FSIS's heightened concern about – and accordingly restrictive treatment of – substances that alter the color of meat is firmly established by regulation and policy. FSIS regulations, precedents, and guidance consistently demonstrate the agency's vigilance in guarding against the potential for consumer deception posed by color-altering substances.

FSIS regulation prohibits the use of substances “that conceal damage or inferiority or make the product appear better or of greater value.”⁶⁴ Consistent with this prohibition, FSIS has authorized no substances for use in fresh meat classified as “coloring agents” and no substances with the stated intent to “preserve color” in the agency's regulations and Directive enumerating substances permitted for use in meat products.⁶⁵ To the contrary, FSIS has affirmatively and repeatedly banned substances that alter the color of fresh meat. FSIS has even banned substances that have a history of safe use in food generally and have been declared by FDA to be GRAS.

For example, FSIS bans sorbic acid and its salts by regulation⁶⁶ because these substances inhibit the development of select aerobic bacteria that produce visual cues of spoilage (e.g., mold and surface growth) while they simultaneously permit the growth of other organisms associated with serious health hazards. Sorbic acid thus makes meat products appear “better and

⁶³ See, e.g., *Sprint Corp. v. FCC*, 315 F.3d 369, 374 (D.C. Cir. 2003) (“new rules that work substantive changes in prior regulations are subject to the APA's procedures” at 5 U.S.C. 553 for notice-and-comment rulemaking); *U.S. Telecom. Assn. v. FCC*, 400 F.3d 29, 38 (D.C. Cir. 2005) (an agency's action which “substantively changes a preexisting legislative rule ... can be valid only if it satisfies the notice-and-comment requirements of the APA”).

⁶⁴ 9 C.F.R. 424.23(a),(b).

⁶⁵ 9 C.F.R. 424.21(c); FSIS Directive 7120.1, *supra* note 2. It appears that the only color-affecting substances that FSIS allows on fresh meat are ascorbic acid, erythorbic acid, citric acid, sodium ascorbate, and sodium citrate to “delay discoloration” of fresh beef, lamb, and pork cuts. 9 C.F.R. 424.21(c) (“miscellaneous”). Notably, however, FSIS did not permit the use of ascorbic acid or related substances until first engaging in formal notice and comment rulemaking, and FSIS permits use of these substances only when they are identified on the product label. 59 Fed. Reg. 12536, 12536, 12538 (March 17, 1994).

⁶⁶ 9 C.F.R. 424.23(a)(3).

of greater value than they are in view of their decomposing condition.”⁶⁷ Similarly, the use of carbon monoxide in fresh meat packaging adulterates the meat because it gives meat a fresh appearance regardless of the meat’s actual age, while simultaneously permitting the growth of organisms that accompany the normal aging and deterioration of meat.⁶⁸

FSIS banned the use of sodium sulfite in meat products⁶⁹ because “it masks the spoilage and color change due to aging.”⁷⁰ FDA also acknowledged over fifty years earlier the reason for this ban: “[d]ue to the effect of sulfites in meat products . . . old and dull colored meat can be rendered red and fresh looking”⁷¹

Similarly, FSIS concluded that paprika adulterates fresh meat “by preserving the red color characteristic of fresh meat even after the articles have begun to spoil.”⁷² Notably, FSIS bans the use of paprika in fresh meat despite the fact that FDA declared paprika safe for food generally. Like sodium sulfite and paprika, carbon monoxide in fresh meat packaging gives meat the red color of fresh meat, masking meat’s age and level of wholesomeness.

FSIS determined that paprika does not adulterate sausages, in contrast, because “consumers *expect sausages to contain paprika* or oleoresin paprika and *do not rely on the red color of the sausages as an indicator of the freshness or quality* of these products.”⁷³ Consumer expectations concerning fresh meat differ significantly. Well-documented evidence establishes that color is a critical – if not the primary – factor that consumers consider when making decisions about the freshness and quality of fresh meat.⁷⁴ Indeed, FSIS has itself recognized that

⁶⁷ 35 Fed. Reg. 15552, 15553 (October 3, 1970).

⁶⁸ See Sørheim (1999), *supra* note 8, at 157 (“CO may mask spoilage because the stable cherry red colour can last beyond the microbiological shelf life of the meat.”); June 2006 Scientific Reports, *supra* note 7.

⁶⁹ 9 C.F.R. 424.23(a)(3) (prohibiting the use of sulfurous acid and the salts of sulfurous acid in or on any meat because they conceal damage or inferiority or make products appear of better or of greater value than they are).

⁷⁰ See News Release, FSIS, Pittsburgh Firm and Meat Packers Fined \$12,000 (July 21, 1998), available at <http://www.fsis.usda.gov/oa/news/1998/cr98-10.htm>.

⁷¹ See Letter from Joseph Callaway, Jr., Acting Chief, Division of State Cooperation, FDA, to Wayne B. Adams, Acting State Food and Drug Commissioner, Nevada 3 (October 14, 1943) (Attachment A at Attachment 3).

⁷² 33 Fed. Reg. 15027, 15027 (October 8, 1968) (proposed rule).

⁷³ *Id.* at 15028 (emphasis added). See also 9 C.F.R. 424.23(a)(2).

⁷⁴ See, e.g., M.C. Hunt *et al.*, American Meat Science Association Comm. on Guidelines for Meat Color Evaluation, Guidelines for Meat Color Evaluation, 44 Proc. Reciprocal Meat Conf. App. 1, 3 (1991) available at <http://www.meatscience.org/Pubs/factsheets/M9110228.pdf>, (“The color of muscle foods is critically appraised by consumers and often is their basis for product selection or rejection.”); National Pork Board/American Meat Science Association Facts: (continued...)

meat discoloration is a “normal spoilage indicator”⁷⁵ and that “product color was the first test for wholesomeness” for consumers examining fresh pork cuts.⁷⁶ FSIS in fact advises consumers to be alert to meat color as an indication of spoilage: “With spoilage there can be a change in color [of meat] – often a fading or darkening.”⁷⁷ By creating a chemical that produces a bright red color similar to the color of naturally fresh meat, carbon monoxide in meat packaging deprives consumers of color cues that would normally indicate spoilage and freshness.

In those occasions in which FSIS has determined a ban was unnecessary, the agency has done so only after mandating that the product label disclose the presence of the substance, and typically after proceeding through notice and comment rulemaking to prescribe conditions of use to ensure that the substance either constituted a processing aid or its effect on color did not outlast a product’s shelf life.⁷⁸ FSIS also has historically emphasized the need for

Modified Atmosphere Packaging (MAP): Microbial Control and Quality, at 3 (Attachment G), (1998) (“Meat color is the single greatest appearance factor that determines whether or not a meat cut will be purchased”) (citation omitted); L.I. Kohls *et al.*, *A Comparison of Five Different Modified Atmosphere Package Methods for Retail Display-Ready Ground Beef*, Animal Sciences Research Report, Colorado State University, 73, 73 (2001), available at <http://ansci.colostate.edu/dp/msfs/lik011.pdf>, at 1 (“Consumers view color as one of the most important attributes of fresh beef when making a decision to purchase retail product. Color, therefore, determines appeal of the product in the retail case and consumer acceptability.”); L.E. Jeremiah *et al.*, *Beef Color as Related to Consumer Acceptance and Palatability*, 37 *J. Food Sci.* 476, 476 (1972) (Attachment A at Attachment 11) (“Consumer studies have shown that physical appearance of a retail cut in the display case is the most important factor determining retail selection of meat products. Consumers select meat cuts primarily for leanness and then for appearance and freshness, with judgments for the latter two attributes based primarily on brightness of color.”) (citations omitted); Q. Liu *et al.*, *Titration of Fresh Meat Color Stability and Malondialdehyde Development with Holstein Steers Fed Vitamin E-Supplemented Diets*, 74 *J. Anim. Sci.* 117, 117 (1996) (Attachment A at Attachment 12) (“Meat color is the main factor affecting beef product acceptability at retail points of purchase.”) (citation omitted).

⁷⁵ FSIS MOU Guidance, *supra* note 13.

⁷⁶ 53 Fed. Reg. at 49849.

⁷⁷ Fact Sheets, FSIS, Safe Food Handling: The Color of Meat and Poultry, http://www.fsis.usda.gov/Fact_Sheets/Color_of_Meat_&_Poultry/index.asp (last visited June 9, 2006). See also Fact Sheets, FSIS, Meat Preparation: Beef ... From Farm to Table (June 2003), http://www.fsis.usda.gov/Fact_Sheets/Beef_from_Farm_to_Table/index.asp (“Beef that has turned brown during extended storage may be spoiled, have an off-odor, and be tacky to the touch.”).

⁷⁸ See 59 Fed. Reg. at 12536 (final rule regarding ascorbic acid, erythorbic acid, citric acid, sodium ascorbate, and sodium citrate as color preservers on beef, lamb, and pork cuts); 58 Fed. Reg. at 45238 (final rule regarding citric acid as a color preserver on cured pork products); 53 Fed. Reg. at 49849 (final rule regarding ascorbic acid, Erythrobic acid, citric acid, sodium ascorbate, and sodium citrate in fresh pork cuts); FSIS Directive 7120.1, *supra* note 2, at 16 (permitting erythorbic acid “to delay discoloration in ground beef and ground beef patties” under (continued...))

data concerning consumer behavior when determining suitable conditions of a substance's use, particularly when a substance affects meat color. None of these safeguards have been implemented with regard to the use of carbon monoxide.

For example, FSIS narrowly restricted the use of ascorbic acid and other substances on fresh pork cuts used "to maintain the fresh appearance of such meat"⁷⁹:

- FSIS sought public comment and thoroughly analyzed data about consumer behavior before making its suitability determination and prescribing restrictions concerning the use of antioxidants that maintain the color of fresh pork cuts. As FSIS explained, "due to the potential *significance of color maintenance* through the use of added substances, this rule is being published as an interim final rule *with request for comments so that commercial experience and public comment can be obtained* and considered prior to confirmation of the rule as final."⁸⁰
- Critical to FSIS's suitability analysis was its conclusion that data established that the substances did not extend the fresh color and appearance of the meat beyond the meat's microbiological shelf life. FSIS prescribed conditions of use to "ensure that the substances will not be applied in excessive amounts and that *color maintenance will not exceed microbiological shelf life*."⁸¹
- FSIS further required that the substances be identified on the product label.⁸²

It is worth underscoring how this precedent reflects the importance that FSIS has placed on evaluating data related to the behavior of consumers under real-world conditions when FSIS has made suitability determinations. When FSIS analyzed the suitability of ascorbic acid on fresh pork cuts, the agency evaluated data from consumer tests "to determine the habits of consumers when purchasing fresh pork, as well as methods used by consumers to evaluate freshness and wholesomeness."⁸³ FSIS evaluated data concerning "typical duration of refrigerated and frozen storage by consumers."⁸⁴ In addition, FSIS evaluated data from an independent study that it commissioned to examine the treatment of the meat "under commercial and retail conditions rather than laboratory conditions."⁸⁵ As FSIS precedent recognizes, such

prescribed conditions, including the requirement that the "[p]roduct must be descriptively labeled."

⁷⁹ 53 Fed. Reg. at 49849.

⁸⁰ 51 Fed. Reg. 30052, 30052 (August 22, 1986).

⁸¹ 53 Fed. Reg. at 49849.

⁸² *Id.* at 49850.

⁸³ *Id.* at 49849.

⁸⁴ *Id.*

⁸⁵ *Id.*

data are critical to a determination whether a substance that alters the color of meat has the potential to mislead consumers or endanger consumer safety.

FSIS later extended the conditions of use imposed on ascorbic acid and related substances to fresh beef and lamb cuts. Significantly, FSIS did so only after again determining that evidence demonstrated such conditions would result in the preservation of a fresh color and appearance for a length of time that did not exceed a product's microbiological shelf life.⁸⁶ FSIS again mandated that the substances be declared on the product label.⁸⁷

Unlike FSIS's assurance with meat cuts treated with ascorbic acid that "discoloration of the cuts would occur before the onset of microbiological spoilage,"⁸⁸ no evidence has established that meat stored in retail packaging containing carbon monoxide discolors before the onset of spoilage. Quite the opposite: the coloring effect of carbon monoxide on fresh meat in retail packaging appears to continue indefinitely.⁸⁹

FSIS's treatment of citric acid is another example of the agency's restrictive policy concerning substances affecting the color of meat. By rulemaking FSIS imposed restrictions on the use of citric acid (a "color preserver") on cured pork to assure that the substance did "not preserve the product's cure color beyond 3 days nor reverse gray-colored meat to a pink color."⁹⁰ FSIS prescribed these conditions of use to assure that citric acid did not pose "concern for masking any indicators of spoilage."⁹¹

As with the purpose of the substances at issue in the precedents described above, the purpose of carbon monoxide in fresh meat packaging is to alter meat's normal coloration. Thus, allowing carbon monoxide to color fresh meat contradicts FSIS regulation and longstanding policy. The allowance of carbon monoxide in fresh meat packaging contravenes prior regulatory action concerning substances that serve a virtually identical function as carbon monoxide. Adequate explanation has not been given to justify such a marked deviation from

⁸⁶ 59 Fed. Reg. at 12536, 12538. *See also id.* at 12537-38 ("This would ensure that these substances applied to the surface of the meat cuts to delay discoloration would not be applied in excessive amounts; therefore, the discoloration of the cuts would occur before the onset of microbiological spoilage.").

⁸⁷ 59 Fed. Reg. at 12536 (requiring the substances be identified in the ingredients listings for fresh beef, lamb, and pork cuts, and removing the requirement for qualifying statements on fresh pork cut labels).

⁸⁸ *Id.* at 12538.

⁸⁹ June 2006 Scientific Reports, *supra* note 7.

⁹⁰ 58 Fed. Reg. at 45238.

⁹¹ *Id.*

FSIS's established policy toward color-altering substances, as is required under established principles of administrative law.⁹²

V. Proponents Fail to Establish the Suitability of Carbon Monoxide under the FMIA and FSIS Regulations

The Kalsec petition urges FSIS to enforce the FMIA by rescinding suitability determinations permitting the use of carbon monoxide in fresh meat packaging. USDA must enforce the existing ban on carbon monoxide in fresh meat packaging because of the significant risk that consumers will be misled under real world conditions of use as to the freshness or safety of carbon monoxide-treated meat. Proponents of carbon monoxide in fresh meat packaging have not met their burden of establishing the gas's suitability for such use.

FSIS identified the substantial risks posed by this use of carbon monoxide in a letter to FDA on April 28, 2004. After evaluating the Precept GRAS notification's intended use of carbon monoxide in fresh meat retail packaging, FSIS initially informed FDA that the agency concluded this use "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."⁹³

The key concerns FSIS cites include this use of carbon monoxide's potential to mislead consumers into believing a product is fresher than it actually is and mask spoilage, the inability of other organoleptic indicators of spoilage to safeguard consumers from deception, and the insufficiency of "use or freeze by" dating:

- FSIS states that the data included in Precept's its GRAS notification show that carbon monoxide "minimizes the degradation of product color that can occur prior to microbial spoilage. Thus, a product that may have microbial levels sufficient to cause spoilage may appear to be acceptable to the consumer."⁹⁴
- FSIS observes with respect to odor that "[t]he true quality of the meat purchased would not be readily apparent until the consumer opened the package at home and detected an objectionable odor."⁹⁵

⁹² See, e.g., *Independent Petroleum Ass'n v. Babbitt*, 92 F.3d 1248, 1258 (D.C. Cir. 1996) ("An agency must treat similar cases in a similar manner unless it can provide a legitimate reason for failing to do so.").

⁹³ Letter from Robert C. Post, Ph.D., Director, FSIS Labeling and Consumer Protection Staff, to Lane Highbarger, Ph.D., Office of Food Additive Safety, CFSAN, at 3 (April 28, 2004) ("FSIS April 28, 2004 Letter") (Attachment A at Attachment 4).

⁹⁴ *Id.* at 2.

⁹⁵ *Id.* at 3.

- FSIS asserts the inadequacy of date labeling, stating that “FSIS has never regulated nor considered ‘use or freeze by dates’ as being sufficient for food safety.”⁹⁶

In response to FSIS’s serious concerns, Precept submitted reports of three privately-generated studies, according to the materials provided to Kalsec in response to its FOIA request for all materials associated with the Precept GRAS notification. These reports were written by personnel from the Excel Corporation and the Hormel Corporation, the parent companies of the Precept joint venture.⁹⁷ On June 7, 2004, FSIS sent a subsequent letter to FDA after reviewing the additional data submitted by Precept.⁹⁸ This subsequent letter cites data provided by Precept concerning the shelf life of fresh meat stored in packaging containing carbon monoxide. FSIS stated that the data indicated that meat remained wholesome before the “use or freeze by” dates proposed in Precept’s submissions expired.

While the three privately-generated studies obtained from Kalsec’s FOIA request appear to have generated the data discussed in FSIS’s subsequent letter, the reports of these studies do not resolve the three key concerns that FSIS posed in its original letter to FDA,⁹⁹ and each study suffers from serious methodological flaws. The studies document that the red color of the carbon monoxide-treated meat does not deteriorate even when the meat has spoiled. The studies fail to show that odor or “use or freeze by” date labeling overcomes the loss of the most important cue to consumers of freshness.

The consumer deception and safety concerns originally raised by FSIS preclude lawful use of carbon monoxide in any retail package of fresh meat. The inadequacy of data provided by Precept’s submissions reveal concerns about this use of carbon monoxide that are broadly applicable to all similar uses of this gas.

⁹⁶ *Id.*

⁹⁷ Nancy Rathje & Graciela Catano, Use of Carbon Monoxide in Lid Stock on Ground Beef, Project # 23034, Excel Report (February 14, 2003) (“February 14 Excel Report”); Liza John *et al.*, Ground Beef Abuse Study in Peelable, Low Oxygen and Carbon Monoxide Lidstock Tray, Excel Report (May 13, 2003) (“May 13 Excel Report”); Dave Ruzek, Precept Foods/MAP Packaging, R&D Project # PF002.00, Hormel Report (June 6, 2003) (“June 6 Hormel Report”). Studies were provided to Kalsec in response to its FOIA request, and are marked “Confidential information.”

⁹⁸ Letter from Robert C. Post, Ph.D., Director, FSIS Labeling and Consumer Protection Staff, to Lane Highbarger, Ph.D., Office of Premarket Approval, CFSAN (June 2, 2004) (“FSIS June 2, 2004 Letter”) (Attachment H). This letter was initially not provided to Kalsec in response to its FOIA request for all materials relating to the Precept GRAS notification, and was only obtained subsequent to the filing of The Kalsec Citizen Petition.

⁹⁹ Even if the studies provided in response to Kalsec’s FOIA request are not the studies described in the FSIS June 2, 2004 Letter, it is clear from the text of that letter that the studies described did not address the concerns FSIS had posed in its April 28, 2004 letter.

A. Temperature Abuse is Widespread and Presents Heightened Risks When Meat Color Suggests Freshness

The risks posed by temperature abuse are heightened where meat color – consumers’ “first test for wholesomeness”¹⁰⁰ – suggests freshness. As detailed above and in the June 2006 Scientific Reports, carbon monoxide gives meat the bright red appearance associated with freshness, regardless of product age or level of microbial contamination.¹⁰¹

The widespread prevalence of temperature abuse during distribution, retail, and consumer handling of fresh meat is well documented.¹⁰² As FDA has acknowledged, “[t]emperature abuse is common throughout distribution and retail markets.”¹⁰³ The potential for such abuse is compounded for meat packaged in modified atmospheres with an intended longer shelf life. Such meat has more opportunities to encounter abusive temperature variation during distribution and storage, thereby increasing the likelihood of microbial spoilage.¹⁰⁴

¹⁰⁰ 53 Fed. Reg. at 49849.

¹⁰¹ See, e.g., June 2006 Scientific Reports, *supra* note 7.

¹⁰² See, e.g., FDA, Food Code (2005), at 547, 550 (stating that “[t]emperature abuse is common throughout distribution and retail markets” and that “[c]onsumers often cannot, or do not, maintain adequate refrigeration of potentially hazardous foods at home Under the best of circumstances, home refrigerators can be expected to range between 5° and 10°C (41°-50°F.)”); Theodore P. Labuza & Bin Fu, *Use of Time/Temperature Integrators, Predictive Microbiology, and Related Technologies for Assessing the Extent and Impact of Temperature Abuse on Meat and Poultry Products*, 15 J. Food Safety 201, 202 (1995) (Attachment A at Attachment 5) (“Unfortunately, the existing distribution channel is not well equipped for the optimum control of temperature during the distribution and display of refrigerated foods. Temperature abuse is common throughout the distribution and retail markets, with the temperature in 21% of household refrigerators often higher than 10°C. Recent data suggested that 33% of retail refrigerated foods were held in display cases above 7°C and 5% were held above 13°C. Temperatures were even higher in southern market regions. Serious microbial stability problems exist because of the frequency of temperature abuse.”) (citations omitted); G.G. Greer *et al.*, *Evaluation of the Bacteriological Consequences of the Temperature Regimes Experienced by Fresh Chilled Meat During Retail Display*, 27 Food Research Int’l 371 (1994) (Attachment A at Attachment 7) (reporting survey of commercial retail cases finding that recommended temperatures of 4°C or below cannot be maintained throughout existing retail cabinets); Kalsec Citizen Petition, *supra* note 6, at 16-18.

¹⁰³ FDA, Food Code, *supra* note 102, at 547. See also G.G. Greer *et al.*, *supra* note 102 (cautioning that “[i]t must be assumed . . . for purposes of assessing risk, that occasionally temperatures of 10°C (50°F) or higher may occur for extended periods” in warehouses and transport vehicles in U.S. distribution chains and reporting a survey of commercial retail cases finding that recommended temperatures of 4°C or below cannot be maintained throughout existing retail cabinets) (Attachment A at Attachment 7).

¹⁰⁴ See, e.g., J.M. Farber, *Microbiological Aspects of Modified-Atmosphere Packaging Technology – A Review*, 54 J. Food Protection 58, 58 (January 1991) (Attachment A at (continued...))

Consumers can normally evaluate the color of meat to detect meat spoilage due to temperature abuse, even when date codes suggest that meat should still be wholesome. In contrast, when meat has been treated with carbon monoxide unbeknownst to consumers, color is not a reliable indicator of wholesomeness. Evidence has not established that consumers do, or even know to, examine meat products for other signs of spoilage when color indicates freshness. Consumer behavior data must therefore be presented and evaluated to ensure that consumers will not be misled about the quality or safety of meat treated with carbon monoxide given the dangerous reality of temperature abuse.

B. "Use or Freeze By" Dates are Inadequate

Evidence in the record does not establish that "use or freeze by" date labeling will ensure the safe handling and consumption of meat treated with carbon monoxide. As FSIS observed in its April 28, 2004 letter to FDA, "FSIS has never regulated nor considered 'use or freeze by dates' as being sufficient for food safety."¹⁰⁵ FSIS deems open date labeling insufficient to safeguard consumers because the usefulness of such labeling is dependent upon strict adherence to temperature control. As FSIS has stated, "[a]lthough many products bear 'Sell-By' dates, product dating is not a Federal requirement. While these dates are helpful to the retailer, they are reliable only if the food has been kept at proper temperature during storage and handling."¹⁰⁶ Consistent with this policy of not relying on "use or freeze by" labeling, FSIS does not appear to have considered the possibility of allowing the use of other substances, such as sodium sulfite or paprika, with "use by" labeling to help ameliorate their deceptive coloring effects.

The potential consumer deception and food safety risks presented by carbon monoxide use in fresh meat packaging could in fact be amplified by consumer reliance on the open date labeling provided. Inviting consumers to rely on open date codes may provide a false sense of security when the "use or freeze by" date has not passed and the meat still appears fresh, yet the bacterial counts have risen to a level constituting spoilage.

Attachment 6) (stating that microbiological safety issues have been raised about modified-atmosphere packaged foods mainly because of "the fact that the extended shelf life of many MAP products may allow extra time for . . . pathogens to reach dangerously high levels in a food.").

¹⁰⁵ FSIS April 28, 2004 Letter, *supra* note 93, at 3. FSIS's concern about "use or freeze by" dating is consistent with the view of the European Commission to the European Parliament that examined carbon monoxide in fresh meat packaging. The European Commission observed that many "consumers base their decisions on the general appearance of a meat product rather than on the written information given on the label." Letter from Robert J. Coleman, European Commission, to Mrs. Caroline F. Jackson, European Parliament, June 20, 2003 (Attachment I), at 2. For this reason, the European Commission rejected a proposal to include labeling that would inform the consumer that the color of the meat does not necessarily reflect its freshness, finding that even such extensive labeling would not solve the problem of consumer safety risk. *Id.*

¹⁰⁶ Fact Sheets, USDA, FSIS, Meat Preparation: Focus on Ground Beef (July 2002), http://www.fsis.usda.gov/Fact_Sheets/ground_beef_and_food_safety/index.asp.

An evaluation of consumer behavior data is needed to demonstrate that consumers would consistently consult and defer to date labeling where the color of meat suggests freshness. Evidence has not shown that “use or freeze by” dates can compensate for the loss of the color as an indicator of meat quality and safety (particularly when meat has experienced temperature abuse within the “use or freeze by” date).

C. The Published Scientific Literature Documents the Inadequacy of Spoilage Indicators Other than Color in the Types of Anaerobic Packaging Systems at Issue

Evidence in the record has not established that consumers do – or even know to – examine a meat package for organoleptic cues besides color to detect spoilage, particularly when color indicates freshness. To the contrary, evidence indicates that other potential indicators of spoilage besides color do not adequately ensure consumer safety or prevent meat adulteration. First, as documented in published literature, the spoilage organisms that might be expected to produce signals such as odor or slime are suppressed or altered in anaerobic packaging systems that contain carbon dioxide (like the Precept and Pactiv systems, which use carbon dioxide along with carbon monoxide and nitrogen). Second, carbon monoxide-treated meat produces an odor different from the odor consumers normally associate with spoilage, and no evidence has been presented that consumers will associate this new odor with spoilage. Third, a significant portion of the population at greatest risk for food-borne illness has a compromised sense of smell. Fourth, because meat in case-ready packaging cannot be touched or smelled prior to purchase, the meat is adulterated because it has the potential to conceal damage or inferiority at the point of purchase, regardless of whether consumers can detect signs of spoilage after opening the package.

First, whether consumers can detect meat spoilage when meat is a color that consumers normally associate with freshness is critical information in light of scientific literature demonstrating that carbon dioxide-containing anaerobic packaging systems suppress odor and slime. The literature demonstrating suppression of odor and slime in carbon dioxide-containing anaerobic packaging systems was extensively documented in Kalsec’s Citizen Petition and will not be repeated in detail here.¹⁰⁷ Notably, even the data submitted in support of the Precept

¹⁰⁷ See Kalsec Citizen Petition, *supra* note 6, at 20-21; J.M. Farber, *supra* note 104 (explaining that the byproducts of the metabolism of the lactobacilli produced in anaerobic carbon dioxide-containing modified atmospheres “are inoffensive compared to the typical spoilage odors produced by the pseudomonads” that thrive in oxygenated atmospheres); J.H. Silliker & S.K. Wolfe, *Microbiological Safety Considerations in Controlled-Atmosphere Storage of Meats*, 34 Food Tech. 59, 59 (March 1980) (Attachment A at Attachment 15) (describing the fact that carbon dioxide in low-oxygen atmospheres “selectively inhibits the growth of Gram-negative bacteria, such as pseudomonads and other related psychrotrophs which grow rapidly and produce off-odors and -flavors in raw meats and poultry. . . . The organoleptic changes attended by the growth of lactic acid bacteria [in low-oxygen, elevated carbon dioxide packaging atmospheres] are less noticeable than those produced by the Gram-negative bacteria which develop upon meat in air atmospheres.”); Carolyn Bristor Hintlian & Joseph H. Hotchkiss, *The Safety of Modified* (continued...)

GRAS notification found lower odor scores associated with higher microbial counts, as discussed in Section V(F)(2) below. This suggests that, even if odor were available to consumers assessing meat in unopened packages, odor would be a questionable indicator for detecting spoilage in fresh meat packaged with carbon monoxide. Regarding alleged slime formation upon spoilage, the record contains no evidence that slime forms on carbon-monoxide treated meat, or that any such formation will adequately alert consumers to product spoilage when color suggests freshness.

Second, as documented in the June 2006 Scientific Reports, any odor that could potentially be detected when meat spoils in a carbon monoxide-containing atmosphere would be a unique smell that is unlike the odor consumers are accustomed to associating with spoiled meat.¹⁰⁸ If consumers detected the odor, they might not attribute the smell to the meat, and even if they did, there is no evidence in the record establishing that consumers would reliably interpret this odor as a sign the meat is spoiled and unsafe to eat.

Third, of additional concern is the fact that a significant portion of the population most vulnerable to food-borne illness lacks an adequate sense of smell to detect the odor of spoiled meat packaged with carbon monoxide. While the elderly and pregnant women are among the populations at greatest risk for food-borne illness,¹⁰⁹ they are also more likely to

Atmosphere Packaging: A Review – Do Modified Atmospheres Enhance Pathogenesis But Delay Signs of Spoilage? 40 Food Tech. 70, 75 (December 1986) (Attachment A at Attachment 10) (“The presence of air in packaged foods supports the growth of aerobic spoilage organisms. . . . In refrigerated products, this noxious warning by spoilage organisms is a critical safety factor since it serves to alert the consumer of temperature abuse and to prevent the consumption of a product which may also contain pathogens. Because anoxic MAs can favor the growth of facultative anaerobes and/or obligate organisms, packaging of foods in oxygen-excluded MAs could result in the loss of this safety factor.”); Theodore P. Labuza & Bin Fu, *Use of Time/Temperature Integrators, Predictive Microbiology, and Related Technologies for Assessing the Extent and Impact of Temperature Abuse on Meat and Poultry Products*, 15 J. Food Safety 201, 202 (1995) (Attachment A at Attachment 5) (stating that the recent trend to use MAP technology, “made with ‘invisible’ processing methods, which are not perceived as processing by the consumer, creates a new paradigm shift for food safety control” because of the potential to mask organoleptic signs of spoilage) and 205 (“Sensory perceptions (e.g., meat color), evidence of metabolic by-products and types and levels of microorganisms are all valuable, and together give a full picture of food quality and safety.”).

¹⁰⁸ June 2006 Scientific Reports, *supra* note 7.

¹⁰⁹ See, e.g., Charles P. Gerba *et al.*, *Sensitive Populations: Who is at the Greatest Risk?* 30 Int'l J. Food Microbiol. 113 (1996) (Attachment J) (a literature review found that the elderly and pregnant women, along with the very young and the immunocompromised, were the groups at greatest risk of serious illness and mortality from water and foodborne enteric microorganisms, and that this segment of the population currently represents almost 20% of the population of the United States); K.C. Klontz *et al.*, *Age-Dependent Resistance Factors in the Pathogenesis of Foodborne Infectious Disease*, 9 Aging Clin. Exp. Res. 320 (1997) (Attachment K) (documenting that the young and the elderly have higher overall rates of infection with certain foodborne pathogens and are likely to experience more severe consequences of foodborne (continued...))

experience a diminished sense of smell.¹¹⁰ The large-scale National Geographic Smell Survey found that about 12% of octogenarians have completely lost their sense of smell.¹¹¹ About half of the elderly population suffers a severely compromised ability to detect mercaptans,¹¹² a fact that is particularly troubling because the main odorants produced during the spoilage of carbon monoxide-treated meat appear to be hydrogen sulfide (the parent compound from which mercaptans are derived), together with methyl mercaptan and ethyl mercaptan. The attributes and needs of the elderly population must be considered in any safety assessment, both because of this group's vulnerability and growing numbers.¹¹³

Fourth, in addition to the absence of evidence in the record supporting the assertion that consumers can detect spoilage in spite of conflicting color cues, any presentation of evidence concerning the development of odor would nevertheless fail to address a critical fact observed by FSIS in its April 28, 2004 letter to FDA: for meat packaged in carbon monoxide, "[t]he true quality of the meat purchased would not be readily apparent until the consumer opened the package at home and detected an objectionable odor."¹¹⁴ Thus, even if organoleptic

disease); Centers for Disease Control and Prevention, Foodborne Illness (October 11, 2005), http://www.cdc.gov/ncidod/dbmd/diseaseinfo/foodborneinfections_t.htm (identifying "[i]nfants, elderly, and the immunocompromised at greatest risk of serious illness and death" due to foodborne illness).

¹¹⁰ See, e.g., Avery N. Gilbert & Charles J. Wysocki, *The Smell Survey*, 172 Nat'l Geographic 514, 514 (1987) (publishing preliminary results of the extensive National Geographic Smell Survey, reporting that "[p]regnant women, commonly thought to be smell-sensitive, may actually experience a diminished sense of smell," and documenting the age-related decline in olfactory sensitivity) (Attachment L); Charles J. Wysocki & Marcia L. Pelchat, *The Effects of Aging on the Human Sense of Smell and Its Relationship to Food Choice*, 33(1) Crit. Rev. Food Sci. Nutr. 63, 63 (1993) (it has "become generally accepted that olfactory function declines with increasing age") (Attachment M); Charles J. Wysocki & Avery N. Gilbert, *National Geographic Smell Survey: Effects of Age Are Heterogenous*, 561 Ann. N. Y. Acad. Sci. 12 (1989) (describing age-related loss of smell, and particularly, losses in the ability to detect individual compounds and classes of compounds) (Attachment N).

¹¹¹ See Charles J. Wysocki & Avery N. Gilbert, *supra* note 110.

¹¹² See *id.*, at 17 ("For mercaptans, a steep decline in detection began more abruptly in the fifth decade."); Wysocki & Pelchat, *supra* note 110, at 63-64 ("Compared with young adults, elderly individuals show higher detection thresholds for a variety of odors. For example, in the case of mercaptans, which are used as warning odors in cooking gas, the decline in sensitivity to the odor with age is large enough to render the odor useless as a warning for about half of the elderly population.").

¹¹³ See, e.g., Gerba, *et al.*, *supra* note 109, at 117 ("It is projected that from 1980 to 2020, the number of individuals over 65 will double from 25 to 50 million. The fastest growing segment of the population will be the over-85 age group, which is projected to increase from 2.3 to 7.3 million.").

¹¹⁴ FSIS April 28, 2004 Letter, *supra* note 93, at 3 ("The true quality of the meat purchased would not be readily apparent until the consumer opened the package at home and detected an (continued...)

signs of spoilage are apparent to a consumer after opening the package at home, damage or inferiority could nevertheless be concealed at the point of purchase, rendering the meat adulterated under the FMIA.¹¹⁵

It is therefore unsurprising that FSIS has not been satisfied in the past to force consumers to rely on non-color organoleptic cues to determine meat freshness or wholesomeness. For example, FSIS banned the use of paprika in fresh meat because it “preserve[s] the red color characteristic of fresh meat even after the articles have begun to spoil”¹¹⁶ – despite the fact that a consumer could conceivably perceive odor or visible signs of deterioration besides discoloration to evaluate meat spoilage.

Because the published literature documents that odor and other alleged spoilage indicators do not compensate for the loss of the color signal as to the freshness and wholesomeness of meat packaged with carbon monoxide (and particularly for populations most vulnerable to foodborne illness), carbon monoxide is not suitable in fresh meat packaging.

D. New Data Lends Support to Potential Food Safety and Consumer Deception Concerns about the Use of Carbon Monoxide in Fresh Meat Packaging

Studies suggest that FSIS’s concerns expressed in its April 28, 2004 Letter to FDA about the inadequacy of “use or freeze by” dates and odor to safeguard consumers against deception and safety risks are well-founded. New data from Kalsec-sponsored studies lend support to the existing body of evidence documenting the potential food safety and consumer deception concerns about carbon monoxide use in fresh meat packaging.

Submitted as Attachment A to these comments are reports from unpublished studies that were sponsored by Kalsec and conducted by S&J Laboratories of Portage, Michigan.¹¹⁷ These limited studies were designed to evaluate selected microbial and sensory characteristics of ground beef sold at retail in packaging containing carbon monoxide (CO-MAP), compared to ground beef sold in high oxygen modified atmosphere packaging containing no carbon monoxide (high oxygen-MAP). Although the results from these studies are limited, and involved a relatively small number of ground beef samples purchased in a local region, the findings lend support to the scientific evidence documenting the food safety and consumer deception concerns that have been raised concerning the use of carbon monoxide in fresh meat packaging.

objectionable odor.”). *See also* Kalsec study (finding that odor from temperature abused, carbon monoxide-treated meat is not detectable until the meat package is opened).

¹¹⁵ 21 U.S.C. 601(m)(8).

¹¹⁶ 33 Fed. Reg. at 15027; 9 C.F.R. 424.23(a)(1).

¹¹⁷ June 2006 Scientific Reports, *supra* note 7.

As described in detail in the attached reports, key findings from these studies are as follows:

- On average, the commercially available CO-MAP ground beef samples tested were shown to have a statistically significant higher bacterial count, on the date of purchase or within a day of purchase, than commercially available ground beef packaged in high oxygen-MAP.
- Some of the CO-MAP ground beef samples tested within their “use or freeze by” dates were found to have bacterial counts indicative of spoilage (i.e., bacterial counts of $>10^7$ colony forming units (cfu) /gram). In contrast, none of the high oxygen-MAP ground beef samples tested within their “sell by” dates had bacterial counts indicative of spoilage.
- The artificial reddish pigment (carboxymyoglobin) formed by the reaction of carbon monoxide in the CO-MAP ground beef samples was found to be stable, giving the ground beef a red appearance after the meat had been temperature abused or become spoiled. In contrast, the high oxygen-MAP ground beef samples tested showed color loss during temperature abuse and became “discolored” when the bacterial levels reached around 1×10^5 to 1×10^6 cfu per gram.
- There was a significant difference in the odor profiles observed in the CO-MAP ground beef samples and high oxygen-MAP ground beef samples tested as they aged, when the packaging was opened. In the CO-MAP ground beef samples, a sulfury odor was observed, whereas in the high oxygen-MAP ground beef samples, a rancid odor more commonly associated with the spoilage of meat was observed. No aroma was observed in the CO-MAP ground beef samples or high oxygen-MAP ground beef samples before the packaging was opened.

These data contribute to the existing body of evidence supporting the potential for consumer deception attributable to the use of carbon monoxide in fresh meat products sold at retail. In CO-MAP ground beef samples tested, microbial levels were higher than in ground beef samples packaged in high oxygen MAP, and continued to maintain a red appearance of freshness even when subjected to temperature abuse and when bacterial counts were indicative of spoilage. The results seem to validate the concerns expressed by FSIS that meat packaged with carbon monoxide and having “microbial levels sufficient to cause spoilage may appear to be acceptable to the consumer.”¹¹⁸ In addition, these data support the concerns Kalsec has expressed in its petition and related submissions that carbon monoxide use in fresh meat packaging has the potential to deceive consumers by making bacterially contaminated meat appear to be fresher or of better quality than it actually is. The potential for deception is particularly egregious where meat packages containing carbon monoxide are labeled “All Natural,” as were some of the samples examined in the June 2006 Scientific Reports.

¹¹⁸ FSIS April 28, 2004 Letter, at 2.

These data also support the concerns Kalsec has expressed in its petition and related submissions concerning the potential for carbon monoxide use in fresh meat packaging to present food safety risks. In the CO-MAP ground beef samples tested, high levels of bacteria and significant growth rates were observed for both aerobic and anaerobic bacteria. While these studies did not evaluate pathogenic organisms that may occur in contaminated meat, it is reasonable to assume that conditions in CO-MAP ground beef that would allow for the significant growth of the spoilage organisms evaluated would also support increased growth of pathogenic organisms in contaminated meat.

Further, as some samples of the CO-MAP ground beef samples tested in the studies had bacterial levels indicative of spoilage before the “use or freeze by” date, to the extent these data can be considered representative, they raise further concerns regarding the reliance on the “use or freeze by” date labeling and 28 day shelf life specified in the GRAS notifications. Particularly in view of the 11-day shelf life for carbon monoxide treated meat that was documented by the European Commission Scientific Committee on Food and a recent Consumer Reports article finding that 3 out of 10 carbon monoxide-packaged ground beef samples examined were spoiled or “on the brink of spoilage” before their “use or freeze by” dates, these data suggest that the accuracy of the asserted 28 day shelf life of carbon monoxide-treated ground beef merits careful review.¹¹⁹

While the Kalsec-sponsored studies are limited and cannot fully explain the high levels of bacteria found in the CO-MAP ground beef samples that were tested, the preliminary findings are disconcerting and suggest that a careful evaluation of the microbiological safety issues presented by carbon monoxide use in fresh meat by FSIS is merited. A larger survey of commercially available ground beef should be conducted, so that the promise of high quality modified atmosphere packaging is not betrayed through the potentially deceptive practice of coloring meat with carbon monoxide. Such a study should be part of an FSIS-mandated notice and comment rulemaking process to correctly assess the conditions of use (if any) that would assure the safe and non-deceptive use of this technology. Unless and until such rulemaking occurs, FSIS should rescind any favorable suitability determinations permitting its use, withhold the mark of inspection from meat treated with carbon monoxide, and refuse to allow the processing of meat packaged in atmospheres containing carbon monoxide because proponents have not established that use of carbon monoxide is suitable.

E. Risk of Consumer Deception Persists

Even assuming that ideal conditions of meat storage, selection, and use could exist in the real world, use of carbon monoxide would still not be suitable in fresh meat

¹¹⁹ See Scientific Committee on Food, European Commission, Opinion of the Scientific Committee on Food on the Use of Carbon Monoxide as Component of Packaging Gases in Modified Atmosphere Packaging for Fresh Meat, SCF/CS/ADD/MSAd/04, at 3 (December 18, 2001) (“Opinion of the Scientific Committee on Food”) (Attachment A at Attachment 16); Consumer Reports, *supra* note 7.

packaging because it would violate a fundamental tenet of the FMIA: a substance (here, carbon monoxide) may not mislead consumers into believing that the product they are purchasing is better or of greater value (here, more fresh or wholesome) than it actually is. The purpose of adding carbon monoxide to fresh meat packaging is to make the meat appear more red and fresh than it would appear otherwise. Absent the declaration of carbon monoxide on the package label, it is difficult to understand how it could be genuinely asserted that carbon monoxide in fresh meat packaging does not “potentially mislead consumers into believing they are purchasing a product that is fresher or of greater value than it actually is”¹²⁰

The unsuitability of the use of carbon monoxide in packaging systems described in the Precept and Pactiv GRAS notifications is discussed with greater particularity below. Addressing these specific notifications is illustrative because Precept and Pactiv were the first companies to receive FDA letters expressing no objection to GRAS notifications concerning the use of carbon monoxide in retail-ready and gas permeable packaging, respectively. As the inadequacy of Precept’s and Pactiv’s GRAS notifications demonstrate, these favorable suitability determinations, as well as those determinations that followed them, should be rescinded because they permit the use of carbon monoxide in a manner that has the potential to mislead consumers in violation of the FMIA.

F. The Precept Studies, and their Subsequent Conclusions, are Methodologically Flawed

All three of Precept’s studies produced by Kalsec’s FOIA request¹²¹ are methodologically flawed, not satisfying basic requirements for adequate and well controlled scientific studies. These serious deficiencies preclude relevance and verification of data validity. Further, the data fail to address the consumer deception and safety concerns raised by FSIS in its initial letter to FDA concerning the Precept GRAS notification: that the effect of carbon monoxide on meat color 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”¹²²; that, with respect to odor, any objectionable odor would not be readily apparent until the consumer opened the package at home¹²³; and that “FSIS has never regulated nor considered ‘use or freeze by dates’ as being sufficient for food safety.”¹²⁴

¹²⁰ FSIS April 28, 2004 Letter, *supra* note 93, at 3.

¹²¹ *See supra* note 97.

¹²² FSIS April 28, 2004 Letter, *supra* note 93, at 3.

¹²³ *Id.*

¹²⁴ *Id.*

1. The Private Studies Fail to Show that the Red Color Imparted by Carbon Monoxide Does Not Mask Spoilage

The private studies showed that the bright red color imparted to the meat by carbon monoxide did not appear to fade while the meat remained in packaging containing carbon monoxide. The studies therefore fail to assuage the concerns originally expressed by FSIS that the effect of carbon monoxide on meat color could mislead consumers into believing they are purchasing a product that is fresher or of greater value than it actually is and could potentially mask spoilage. Two of studies, the February 14 Excel Report and the June 6 Hormel Report, did not test samples to the point of spoilage, and therefore cannot demonstrate that carbon monoxide does not mask spoilage. Further, both studies used only carbon monoxide-treated meat samples; no control was used to show how color would deteriorate in the types of packaging to which consumers are accustomed. The May 13 Excel Report actually demonstrated that carbon monoxide-treated meat retained the bright red color imparted by the gas even when the meat had in fact spoiled.

Thus, the data submitted by Precept show that the bright red color of meat treated with carbon monoxide does not deteriorate while the meat is packaged with carbon monoxide, even in response to age or microbial spoilage. Although it has been established that consumers rely heavily upon color when evaluating the freshness of meat, as discussed above, no consumer behavior evidence was submitted to demonstrate that consumers would consider factors other than color where color suggests freshness. This contravenes FSIS precedent requiring data concerning the treatment and use of meat under commercial and retail conditions when a substance has the potential to alter meat color.¹²⁵ The data therefore fail to respond to FSIS's concern that the red color imparted by carbon monoxide could mask spoilage.

2. The Private Studies Fail to Show that Odor Would Sufficiently Signal Spoilage

The May 13 Excel Report appears to have been intended to support Precept's contention that odor is an adequate indicator of spoilage of meat packaged with carbon monoxide. That study was methodologically flawed, however, and produced results inconsistent with those obtained in the June 6 Hormel Report. The May 13 Excel Report fails to provide any experimental details surrounding the sensory (aroma) evaluation of the products. Specifically, the report fails to indicate whether the aroma evaluation was performed by a single person or a panel, whether the evaluation was performed by lab technicians or consumers, whether the evaluators were trained, whether the study accounted for the significant proportion of the vulnerable population whose sense of smell is diminished, and whether the study considered the effect of olfactory fatigue. Because the Precept submissions urge that odor should be used as a leading indicator of freshness in meat packaged with carbon monoxide, the results of aroma testing and the methodology used are of supreme importance.

¹²⁵ See Section IV, *supra*.

The May 13 Excel Report only included mean values, with no indication of the variability of the data, particularly whether any of the samples with high microbial count had low odor scores and vice versa. This is particularly important because in the June 6 Hormel Report (addressing the shelf life of steaks in the Precept packaging system), the microbial data showed large variability relative to the mean values. On a sample-by-sample basis, the microbial data was inversely associated with odor scores. For example, in the data for day 42 samples, packages with high microbial count were associated with low odor scores, while samples with high odor scores were associated with low plate counts. The data were similar for day 34 samples, where high aroma scores were associated with low plate count and low aroma scores were associated with high plate count. These data do not support the claim that that odor is a predictable or reliable indicator of microbial spoilage.

Notably, the study described in the May 13 Excel Report measured odor associated with spoiled carbon monoxide-treated meat after packaging was removed. The data do not show that any odor was detectable through a sealed package, as would be presented to consumers at the retail point of purchase. And again, no consumer behavior data was submitted to indicate how consumers would perceive and respond to any odor detected. Accordingly, these data fail to demonstrate that odor would sufficiently signal spoilage, particularly where the color of the meat suggests freshness.

3. The Private Studies Fail to Show that Date Labeling is Sufficient for Food Safety

Finally, these data fail to demonstrate that “use by” date labeling will ensure the safe handling and consumption of meat treated with carbon monoxide. In the studies purporting to support the shelf life of ground beef (February 14 Excel Report) and steaks (June 6 Hormel Report) in the Precept packaging system, the meat was kept in laboratory conditions with temperature control that is unreflective of real-world conditions. The data therefore have little relevance under actual conditions of distribution, display, and storage, in which, as described in the published literature, such temperature control cannot reliably be maintained. As described above, FSIS has explained that open date labeling is insufficient to safeguard consumers because the usefulness of such labeling is dependent upon strict adherence to temperature control, which cannot be assured as a practical matter. Without addressing the potential for temperature abuse, these Precept studies cannot reliably support open date labeling.

Additionally, the steaks in the June 6 Hormel Report were injected with known antimicrobial agents prior to packaging; because no control of untreated meat was employed, any conclusions about the shelf life of meat packaged with carbon monoxide that are drawn from the data are necessarily limited to meat treated with the same antimicrobial agents that were used on the test samples.

The methodological flaws in these studies are particularly concerning given that they purport to establish a shelf life for meat packaged with carbon monoxide that differs substantially from that found by the European Commission’s Scientific Committee on Food. While Precept’s GRAS notification claimed to support a “use or freeze by” date of 28 days after packaging for ground beef and 35 days after packaging for intact muscle cuts, the Scientific Committee found that such products had a much shorter shelf life – 11 days for ground beef, 14

days for beef loin steaks, and 21 days for pork chops.¹²⁶ This substantial discrepancy warrants further evaluation, absent which carbon monoxide cannot be deemed suitable for this use.

Based on the foregoing, these three studies fail to show that date labeling is sufficient to ensure consumer safety, and therefore fail to establish the suitability of carbon monoxide in retail packages of fresh meat.

G. The Precept GRAS Notification is Incomplete: it Fails to Address Deception and Safety Concerns Raised in Published Literature

The Precept GRAS notification fails to document the genuine controversy surrounding this use of carbon monoxide that exists in scientific literature. This notification, as well as any other GRAS notifications concerning this use that similarly fail to discuss information that appears to be inconsistent with the company's GRAS determination, do not comply with the requirements of FDA's GRAS notification review proposed rule and fail to provide USDA with information relevant to the agency's suitability analysis. Accordingly, suitability determinations that contributed to FDA expressing no objection to notifications made by such GRAS notifiers, along with any suitability determinations premised in any part on such GRAS notifications, should be rescinded until USDA can make a full consideration of the suitability of carbon monoxide in fresh meat packaging through notice and comment rulemaking.

Although FDA's proposed GRAS notification rule requires the notifier to include a "comprehensive discussion of any reports of investigations or other information that may appear to be inconsistent with the GRAS determination,"¹²⁷ the Precept GRAS notification omits any mention of questions raised in scientific literature concerning this use of carbon monoxide. The Precept notification cited only three published studies, and declared that "Precept Foods is unaware of any data that would be inconsistent with a finding that carbon monoxide is GRAS when used at 0.4% as a component of a MAP system for fresh meat."¹²⁸ As an initial matter, the Precept GRAS notification failed to acknowledge that the two Sørheim studies cited therein highlighted the controversy surrounding this use of carbon monoxide:

- Sørheim (1999), cited in Precept's GRAS notification, expressly observed that the "inclusion of CO in MA [modified atmospheres] for meat is controversial," and that "CO may mask spoilage because the stable cherry red colour can last beyond the microbiological shelf life of the meat."¹²⁹ Sørheim emphasized that, because carbon monoxide can mask spoilage of the meat, "[w]hen a MA with CO is applied commercially, it is important to have a proper control of the hygienic

¹²⁶ Opinion of the Scientific Committee on Food, *supra* note 119, at 3.

¹²⁷ 62 Fed. Reg. 18937, 18943 (April 17, 1997) (to be codified at 21 C.F.R. 170.30(b)) (Substances Generally Recognized as Safe; Proposed Rule).

¹²⁸ GRAS Notification of Precept Foods, L.L.C. at 25 (January 6, 2004).

¹²⁹ Sørheim (1999), *supra* note 8, at 157.

condition of the meat raw materials and the chill chain temperatures.”¹³⁰ Thus, Sørheim brought into the assessment of the safe use of carbon monoxide the issue of whether temperature can be adequately controlled throughout distribution and storage of treated meat.

- Sørheim (1997) similarly stated that a “possible negative aspect of using CO in the MAP of retail meat is concern that consumers might misjudge the quality of a product, because its true microbiological status may be masked by its stable, cherry red carboxymyoglobin colour.”¹³¹

Of greater concern is the fact that at least three other studies expressly raising questions about the safety of carbon monoxide in fresh meat packaging were published at the time of Precept’s GRAS notification but were not acknowledged in Precept’s submission:

- Kropf first published the fact that the red color imparted by carbon monoxide can last beyond the microbial shelf life of the meat and thus mask spoilage more than twenty years before the filing of the Precept GRAS notification. Kropf has been cited in a number of the other published studies addressing this use of carbon monoxide, including in the 1999 Sørheim study cited in that notification.¹³²
- Nissen found that *Salmonella* strains in inoculated ground beef stored at 10°C for 5 and 7 days grew to a higher number in a high carbon dioxide/low carbon monoxide (0.4%) gas mixture than in a high oxygen mixture.¹³³ That study recognized that “[t]he reason for adding CO to the gas mixture is that it will produce a long-lasting cherry red colour of the meat.”¹³⁴ Significantly, the researchers acknowledged the wide range of temperatures potentially experienced by chilled foods at retail, and stated that “[t]he observed growth of *Salmonella* in the high CO /low CO mixture . . . does . . . emphasize the importance of temperature control during storage.”¹³⁵

¹³⁰ *Id.* at 163.

¹³¹ Sørheim (1997), *supra* note 54, at 311 (September 1997) (Attachment A at Attachment 14) (citation omitted).

¹³² Donald H. Kropf, *Effect of Retail Display Conditions on Meat Color*, 33 Reciprocal Meat Conf. Proc. 15 (1980) (Attachment A at Attachment 17).

¹³³ H. Nissen *et al.*, *Comparison Between the Growth of Yersinia enterocolitica, Listeria monocytogenes, Escherichia coli O157:H7 and Salmonella spp. in Ground Beef Packed by Three Commercially Used Packaging Techniques*, 59 Int’l J. Food Microbiology 211 (2000) (Attachment A at Attachment 9).

¹³⁴ *Id.* at 212.

¹³⁵ *Id.* at 218.

- The European Commission's Scientific Committee on Food observed that "the inclusion of CO in MAP is controversial because the stable cherry-colour can last beyond the microbial shelf life of the meat and thus mask spoilage."¹³⁶ The extended shelf life attained by including carbon monoxide in packaging "may, therefore, under certain conditions imply increased risk of growth of pathogens."¹³⁷ The Committee concluded that carbon monoxide at levels of 0.3%-0.5% would be safe only if the temperature during storage and transport never exceeds 4°C (39°F), and observed in particular that some strains of *Salmonella* would grow at 10°C.¹³⁸ The Committee "wishes to point out that, should products be stored under inappropriate conditions, the presence of carbon monoxide may mask visual evidence of spoilage."¹³⁹

Scientific controversy surrounding the use of carbon monoxide in fresh meat packaging is thus well documented in the published literature. Questions raised in the published literature about the use of carbon monoxide in fresh meat packaging further demonstrate the unsuitability of this use of carbon monoxide. These questions warrant examination by FSIS through notice and comment rulemaking prior to permitting use of this gas in fresh meat packaging under any conditions of use.

H. The Pactiv GRAS Notification Fails to Show that Use of Carbon Monoxide is Suitable

The data included in Pactiv's GRAS notification also fail to demonstrate that Pactiv's proposed use of carbon monoxide is nondeceptive and are inadequate to establish the suitability of this use of carbon monoxide. USDA should accordingly rescind Pactiv's favorable suitability determination, and any favorable suitability determinations given to companies that have also failed to establish the suitability of this use for similar packaging systems.

The data presented by Pactiv do not demonstrate that carbon monoxide's color-altering effect is eliminated before meat products are displayed for sale. Thus, even if FSIS deemed the use of carbon monoxide in gas permeable packages as suitable, FSIS could not lawfully permit its use absent FDA's approval of carbon monoxide as a color additive. As detailed in Section II(C) above, carbon monoxide does not satisfy the definition of a processing aid, and therefore is not exempt from color additive approval and labeling requirements applicable to such ingredients.

It is noteworthy that neither Pactiv's nor Precept's submissions presented, nor does FSIS appear to have considered, evidence concerning consumer behavior. Neither GRAS

¹³⁶ Opinion of the Scientific Committee on Food, *supra* note 119, at 4.

¹³⁷ *Id.*

¹³⁸ *Id.* at 7.

¹³⁹ *Id.*

notification addresses whether this use of carbon monoxide is suitable under actual retail and consumer conditions of use. As described above, this omission deviates from FSIS precedent of examining consumer behavior evidence prior to issuing a suitability determination.¹⁴⁰ Unlike FSIS's previous suitability determinations concerning substances that alter meat color, evidence has not been presented to relieve consumer deception and safety concerns and to justify allowing carbon monoxide in fresh meat packaging.

VI. Failure to Declare Carbon Monoxide on the Product Label Misbrands Meat in Violation of the FMIA, FSIS Regulations, and FSIS Policy

Fresh meat packaging containing carbon monoxide adulterates meat by making it appear to be of greater value than it is and misbrands meat because the package is "filled as to be misleading."¹⁴¹ Assuming *arguendo*, however, that carbon monoxide were allowed in fresh meat packaging, declaration of its presence would be required on the label to comply with the FMIA, FSIS regulations, and settled FSIS policy, for four independent reasons. First, absent declaration of carbon monoxide on the label, this use of the gas has the potential to mislead consumers in violation of the FMIA's misbranding prohibition. Second, carbon monoxide is an ingredient under these circumstances and therefore must be disclosed in the product ingredient listing. Third, failure to identify carbon monoxide on the label contravenes firm FSIS policy to alert consumers when natural meat color has been altered. Fourth, the presence and purpose of carbon monoxide in fresh meat packaging is a material fact that must be declared on the meat label.

A. Due to its Potential to Mislead, Carbon Monoxide Must be Declared under the FMIA

Under the FMIA, meat is misbranded if its labeling is "false or misleading in any particular"¹⁴² or if its container is "filled as to be misleading."¹⁴³ Without identifying the

¹⁴⁰ See, e.g., 53 Fed. Reg. at 49849 (final rule concerning ascorbic acid, erythroic acid, citric acid, sodium ascorbate, and sodium citrate in fresh pork cuts, stating that "[t]he petitioner provided further data on consumer tests to determine the habits of consumers when purchasing fresh pork, as well as methods used by consumers to evaluate freshness and wholesomeness."); 51 Fed. Reg. at 30052 (August 22, 1986) (interim final rule concerning ascorbic acid, erythroic acid, citric acid, sodium ascorbate, and sodium citrate in fresh pork cuts, stating that "due to the potential significance of color maintenance through the use of added substances, this rule is being published as an interim final rule with request for comments so that commercial experience and public comment can be obtained and considered prior to confirmation of the rule as final.").

¹⁴¹ 21 U.S.C. 601(n)(4); 9 C.F.R. 301.2 (defining "misbranded," subsection (4)), 317.8(a).

¹⁴² 21 U.S.C. 601(n)(1); 9 C.F.R. 301.2 (defining "misbranded," subsection (1)). See also 9 C.F.R. 317.8(b)(3) ("The requirement that the label shall contain the name and place of business of the manufacturer, packer, or distributor shall not relieve any establishment from the requirement that its label shall not be misleading in any particular.").

¹⁴³ 21 U.S.C. 601(n)(4); 9 C.F.R. 301.2 (defining "misbranded," subsection (4)), 317.8(a).

presence of carbon monoxide, a fresh meat package containing the gas could mislead consumers as to the product's quality and safety. The normal color cues upon which consumers make decisions are, unknown to the consumer, not reliable. Accordingly, consumers must be notified that carbon monoxide is present in a product through identification of the gas on the product label.

B. Carbon Monoxide is an Ingredient that Must be Declared under the FMIA and FSIS Regulations

Carbon monoxide is a meat ingredient when used in fresh meat packaging. As such, it must be disclosed on the meat product label under statutory and regulatory requirements.

FSIS defines substances as ingredients if they "remain in the food product and have a lasting effect on the product."¹⁴⁴ As acknowledged in Precept's GRAS notification and in FDA's Agency Response Letters to Precept and Tyson,¹⁴⁵ carbon monoxide in retail packaging system remains in the meat at a detectable level and has a lasting technical and functional effect on the color of the meat. Further, FSIS has repeatedly recognized carbon monoxide's status as an ingredient by listing the substance eight times in its Directive listing "safe and suitable ingredients used in the production of meat and poultry products."¹⁴⁶

FSIS affirms that substances that "appear in the finished meat food product at a detectable level, and [] exhibit a continuing technical effect in or on the meat food product" must be "declared on the label of the meat food product."¹⁴⁷ The FMIA as well as FSIS regulation require ingredients to be identified in a product's ingredient listing.¹⁴⁸ In addition, FSIS has

¹⁴⁴ FSIS Guidance on Ingredients, *supra* note 3 (emphasis added).

¹⁴⁵ Agency Response Letter to GRAS Notice No. GRN 000143, *supra* note 55, and Letter from Laura M. Tarantino, Director, CFSAN Office of Food Additive Safety, to Mark L. Itzkoff, Olsson, Frank and Weeda, P.C. (September 29, 2005) ("Agency Response Letter to GRAS Notice No. 000167"), available at <http://www.cfsan.fda.gov/~rdb/opa-g167.html> (both acknowledging the lasting functional coloring effect of carbon monoxide in the retail package).

¹⁴⁶ FSIS Directive 7120.1, *supra* note 2.

¹⁴⁷ FSIS Guidance on Ingredients, *supra* note 3. See also *infra* note 148.

¹⁴⁸ FSIS Directive 7120.1, *supra* note 2, indicates that suitability determinations have been made concerning the use of carbon monoxide on fresh meat, pork, and poultry cuts, as well as ground beef, ground pork, and ground poultry.

Meat without a standard of identity must identify the common or usual name of all ingredients, except when otherwise authorized by the Secretary of USDA. 21 U.S.C. 601(n)(9); 9 C.F.R. 301.1 (definition of "misbranded," subsection (11)).

Similarly, even meat that has a prescribed standard of identity, such as chopped beef, ground beef, and hamburger patties, must identify on the label all optional ingredients required by regulation. 21 U.S.C. 601(n)(7) (requiring for meat with a standard of identity that "its label bears the name of the food specified in the definition and standard and, insofar as *may be* (continued...)

authority to require a substance to be declared on the meat label even absent existing statutory or regulatory requirement that it be declared.¹⁴⁹

Carbon monoxide fails to qualify for any exemption from the ingredient labeling requirement. The fact that carbon monoxide is a packaging gas does not excuse it from the ingredient definition. Carbon monoxide reacts with the meat, remains in the meat, and has a coloring effect in the meat.

The conditions of use in the Tyson system, as described in FDA's Agency Response Letter, make clear the interaction between the carbon monoxide and meat in that system as well as others using carbon monoxide. The Tyson conditions of use include a level of carbon monoxide at 2.2 mg per pound of meat. FDA explains that, "[a]s compared to Pactiv's and Precept's packaging system, Tyson's packaging system is a reduced head space system, and therefore to achieve the same ratio of CO to meat, they use a higher concentration of CO per unit volume. To achieve this end, Tyson states that they will use the concentration of CO necessary to achieve the same ratio of CO to meat (2.2 mg CO per lb of meat) as is used in the Precept and Pactiv systems."¹⁵⁰ This characterization of the three packaging systems for which the use of carbon monoxide has been accepted as GRAS documents that the "dose" of the gas in each system is calibrated by its interaction with and effect on the meat. As this example illustrates, carbon monoxide in fresh meat packaging is intended to have a functional effect on the color of

required by such regulations, the common names of optional ingredients (other than spices, flavoring, and coloring) present in such food.) (emphasis added); 9 C.F.R. 319.1(a) ("Labels for products for which standards of identity or composition are prescribed in this part shall show the appropriate product name, an ingredient statement, and other label information in accordance with the special provisions, if any, in this part, *and otherwise in accordance with the general labeling provisions in part 317 of this subchapter* Any product for which there is a common or usual name must consist of ingredients and be prepared by the use of procedures common or usual to such products insofar as specific ingredients or procedures are not prescribed or prohibited by the provisions of this subchapter.") (emphasis added). FSIS requires by regulation that meat composed of two or more ingredients bear the common or usual name of ingredients in the ingredient statement. 9 C.F.R. 317.2(c)(2), (f). *See also* 59 Fed. Reg. at 12538 ("[A]ll substances used in the preparation of a product are required to be listed in the ingredients statement (9 C.F.R. 317.2(f)(1)).").

¹⁴⁹ 21 U.S.C. 601(n)(12) (stating that the term "misbranded" applies to meat that "fails to bear, directly thereon or on its container, as the Secretary may by regulations prescribe, the inspection legend and, unrestricted by any of the foregoing, such other information as the Secretary may require in such regulations to assure that it will not have false or misleading labeling . . ."); 9 C.F.R. 301.2 (defining "misbranded," subsection (12), as a product that "fails to bear, directly thereon or on its containers . . . such other information as the Administrator may require in such regulations to assure that it will not have false or misleading labeling . . ."); 9 C.F.R. 500.8(a) ("FSIS may rescind or refuse approval of false or misleading marks, labels, or sizes or forms of any container for use with any meat or poultry product under section 7 of the FMIA or under section 8 of the PPIA.").

¹⁵⁰ Agency Response Letter to GRAS Notice No. GRN 000167, *supra* note 145.

the meat. This use of carbon monoxide therefore qualifies for no exemption from ingredient labeling requirements.

In addition, FSIS made clear that carbon monoxide in fresh meat packaging is an ingredient, unless otherwise exempt, in the course of its evaluation of the Pactiv packaging system. As described above, for a substance to meet the definition of a processing aid and therefore be excluded from the ingredient labeling requirement, the data must show that the substance “is not having a continuing effect on the meat food product. Specifically, the supporting data must show that the fresh color of the meat is not preserved. The product will exhibit normal spoilage indicators (e.g., discoloration); and that there is no extension of shelf life as compared to products” to which the substance is not applied.¹⁵¹ Further, the “data must address the sensory characteristics (i.e., color and odor) of the product and show that the characteristics are not altered as compared to untreated” meat.¹⁵²

The data related to carbon monoxide in fresh meat packaging shows the opposite of what FSIS requires to qualify for the processing aid exclusion from ingredient labeling. As previously described, carbon monoxide is added directly to food and is present at levels that are significant and have continuing technical and functional effects in the meat. For carbon monoxide in retail packages, the functional effect continues indefinitely. For carbon monoxide in gas permeable packaging, the functional effect continues during storage, distribution, and for a time after it is initially placed on store shelves. Indeed, FDA’s letter responding to the Precept GRAS notification notes that the purpose of the carbon monoxide in the retail package is to “help maintain the characteristic color of fresh meat.”¹⁵³ Carbon monoxide thus fails to qualify as a processing aid that is exempt from the ingredient labeling requirement.

Further, treating this use of carbon monoxide as an ingredient is consistent with FSIS policy and precedent. All color-altering substances that FSIS has allowed for use in fresh meat as “color preservers,” “color fixatives,” “color maintainers” and the like are required to be identified in the ingredient declaration on the meat package.¹⁵⁴ For example, FSIS regulation requires declaration on the label of organic acids that act as “color preservatives” (i.e., that

¹⁵¹ FSIS Guidance on Ingredients, *supra* note 3.

¹⁵² *Id.*

¹⁵³ Agency Response Letter to GRAS Notice No. GRN 000143, *supra* note 55.

¹⁵⁴ *See, e.g.*, 59 Fed. Reg. at 12536 (March 17, 1994) (allowing the use of ascorbic acid, erythorbic acid, citric acid, sodium ascorbate, and sodium citrate on beef, lamb, and pork cuts in fresh meat “to delay discoloration,” and requiring that the presence of these substances be identified in the ingredient statement on product labels); FSIS Guidance on Ingredients, *supra* note 3 (organic acids permitted for use as “color preservatives” are “considered to be ingredients of the product since they are in the finished meat food product at a detectable level, and they exhibit a continuing technical effect in or on the meat food product. Therefore, the organic acids must be declared on the label of the meat food product.”).

“accelerate color fixing or preserve color during storage,” as does carbon monoxide in meat packaging) because they are ingredients.¹⁵⁵

The record reflects no basis for treating carbon monoxide in fresh meat packaging differently. Notably, the purpose behind the use of organic acids is nearly identical to that of the use of carbon monoxide in fresh meat packaging. The proponent of using organic acids such as ascorbic acid intended for the substances to preserve the fresh color and appearance of meat. The proponent stated that the loss of the fresh color and marketability of untreated fresh meat occurs before the product becomes microbiologically unsafe, yet “[s]ome consumers are reluctant to purchase fresh beef or lamb cuts because of the change to a darker color of the product before spoilage.”¹⁵⁶ The proponent asserted that these substances would delay undesirable discoloration of the product for a period of time not exceeding the product’s microbiological shelf life, and therefore losses to manufacturers due to color deterioration will be reduced.¹⁵⁷ FSIS required that these substances be identified on the label.¹⁵⁸

Governing agency precedent and general principles of administrative law¹⁵⁹ thus require FSIS to treat carbon monoxide in the same manner as other ingredients by requiring the gas to be identified in the ingredient declaration on the product label.

C. Failure to Identify Carbon Monoxide on the Label Contravenes FSIS Policy for Color-Altering Substances

Failure to declare the presence of carbon monoxide on the meat label violates FSIS’s policy of alerting consumers when natural meat color has been altered, as demonstrated in agency regulations and guidance.

FSIS regulations reflect the fundamental principle that consumers be notified when the color of a meat product is altered. For example, concerns about substances that inhibit the oxidation of meat (similar to carbon monoxide which displaces oxygen) prompted FSIS to promulgate a regulation that expressly requires antioxidants added to a product be declared prominently on the label. When antioxidants are added to a product, there must “appear on the label in prominent letters and contiguous to the name of the product, a statement identifying the

¹⁵⁵ 9 C.F.R. 424.21(c). See also FSIS Guidance on Ingredients, *supra* note 3.

¹⁵⁶ 59 Fed. Reg. at 12537.

¹⁵⁷ *Id.* at 12536-7.

¹⁵⁸ *Id.*

¹⁵⁹ See, e.g., *Independent Petroleum Ass’n v. Babbitt*, 92 F.3d 1248, 1258 (D.C. Cir. 1996) (“An agency must treat similar cases in a similar manner unless it can provide a legitimate reason for failing to do so.”); *Department of the Navy v. FLRA*, 962 F.2d 48, 56 (D.C. Cir. 1992); *Hall v. McLaughlin*, 864 F.2d 868, 872 (D.C. Cir. 1989) (“[d]ivergence from agency precedent demands an explanation.”).

officially approved specific antioxidant by its common name or abbreviation thereof and the purpose for which it is added.”¹⁶⁰

When color is added to edible fats, whether by artificial or natural means, the name and purpose of substance must be declared on the label.¹⁶¹ Products that bear artificial coloring, or that are placed in artificially colored casings, must disclose those facts on the label.¹⁶² FSIS permitted the use of color-altering substances in pork products only after requiring the ingredient listing declare the presence of the substances.¹⁶³ Recognizing the importance of meat color to consumer decisionmaking, FSIS regulation mandates that meat “[c]overings shall not be of such color, design, or kind as to be misleading with respect to color, quality, or kind of product to which they are applied.”¹⁶⁴ The principal display panel must provide “at least 20 percent unobstructed clear space, consolidated in one area *so that the true nature and color of the product is visible to the consumer.*”¹⁶⁵

FSIS has explained the rationale for its policy requiring the identification of substances that “artificially color” meat on labels by stating that “the presence of coloring that misleads or deceives the purchaser into believing that a product is of a different color, quality, or kind *than expected* must be indicated by a statement.”¹⁶⁶ Similarly, FSIS’s rationale for the

¹⁶⁰ 9 C.F.R. 317.2(j)(10).

¹⁶¹ 9 C.F.R. 317.2(j)(5).

¹⁶² 9 C.F.R. 317.2(j)(6),(9).

¹⁶³ 53 Fed. Reg. at 49850 (noting that “[c]onsumers can readily avoid buying these products.”). *See also* 59 Fed. Reg. at 12538 (“In addition, on November 4, 1992, the Agency published in the Federal Register a proposed rule (57 FR 52596) to eliminate those prominent disclosure requirements for product name qualifiers where the inclusion of a substance does not significantly alter the basic identity of the finished product or where the prominently disclosed information can be found in the ingredients statement. . . . FSIS believes that such action would not deprive consumers of informative labeling because *all substances used in the preparation of a product are required to be listed in the ingredients statement* (9 C.F.R. 317.2(f)(1)).”) (emphasis added); 58 Fed. Reg. at 45238 (“This rule will permit the use of citric acid as a color preserver on cured pork cuts during storage. . . . Manufacturers opting to use citric acid in this manner will be required to revise the ingredients statements on product labels to show the presence of citric acid.”).

¹⁶⁴ 9 C.F.R. 317.8(b)(5)(i).

¹⁶⁵ *Id.*

¹⁶⁶ Memorandum from Ashland L. Clemons, Acting Director, Standards and Labeling Division, Technical Services, to Branch Chiefs, SLD (Policy Memo 113: Labeling of Products Which Are Artificially Colored) (June 24, 1988), *available at* http://www.fsis.usda.gov/OPPDE/larc/Policies/Policy_Memos_082005.pdf (“This policy memo is issued to clarify when it is necessary that the product name be qualified and to make it clear that in all cases the presence of the coloring must be declared in the ingredients statement.”), and cited in FSIS, Food Standards and Labeling Policy Book 11-12 (August 2005) (“artificially (continued...)”).

declaration requirements for colored meat casings is that “the coloring should not mislead the consumer into believing that the product is leaner, different, or of better quality *than similar products*.”¹⁶⁷

These precedents and the reasoning behind them apply equally to carbon monoxide which alters the color of meat. Carbon monoxide must accordingly be identified on the label, if allowed in meat at all.

D. The Presence and Purpose of Carbon Monoxide in Fresh Meat Packaging is a Material Fact that Must be Declared in Labeling under the FMIA

As discussed in detail in Kalsec’s previous submissions to FDA,¹⁶⁸ the presence and purpose of carbon monoxide in fresh meat packaging is a material fact that must be declared in labeling pursuant to section 601(n)(1) of the FMIA and sections 201(n) and 403(a) of the Federal Food, Drug, and Cosmetic Act (“FDCA”). As FSIS has explained, “[w]hether information is material under section 201(n) of the act depends not on the abstract worth of the information, but on whether consumers view such information as important and whether the omission of label information may mislead the consumer.”¹⁶⁹ FSIS has further stated that “[i]n determining whether labeling is misleading, the agency must take into account the extent to which the labeling fails to reveal material facts in light of representations made about the food or consequences that may result from the use of such food.”¹⁷⁰

This use of carbon monoxide is material because it affects consumer decisions about product quality and safety. It has the potential to mislead consumers by altering the color cues that consumers expect to demonstrate meat freshness, deterioration, and spoilage. Failure to identify carbon monoxide on the label is material in light of the implied representation to consumers that the meat is unprocessed and untreated and that its color is a reliable indicator of its freshness, as well as in light of the serious consumer deception and food safety risks attendant to such representation. The presence of carbon monoxide is also particularly material where meat packages containing carbon monoxide are labeled “All Natural,” as were some of the

colored products”), *available at*

http://www.fsis.usda.gov/OPPDE/larc/Policies/Labeling_Policy_Book_082005_1.pdf (emphasis added).

¹⁶⁷ Memorandum from Margaret O’K. Glavin, Director, Standards and Labeling Division, MPITS, FSIS, to Branch Chiefs (Policy Memo 095: Colored Casings-Labeling of Meat and Poultry Products) (February 27, 1986), *available at* http://www.fsis.usda.gov/OPPDE/larc/Policies/Policy_Memos_082005.pdf, and cited in FSIS, Food Standards and Labeling Policy Book, *supra* note 166, at 11-12 (“artificially colored products”) (emphasis added).

¹⁶⁸ See Kalsec Citizen Petition, *supra* note 6, at 27-29; Kalsec February 1, 2006 Comments, *supra* note 6, at 10.

¹⁶⁹ 64 Fed. Reg. 9089, 9090 (February 24, 1999) (proposed rule).

¹⁷⁰ *Id.*

samples examined in the June 2006 Scientific Reports. Consumers purchasing meat labeled "All Natural" may reasonably expect that no substances are included that would affect the color of the meat, and that its color is a fair representation of its freshness.

Consumer research reveals that color is a key factor to consumers when choosing fresh meat for purchase and consumption.¹⁷¹ Consumer polls conducted by independent news outlets regarding the use of carbon monoxide in fresh meat packaging attest to the significance placed on the labeling of meat treated with carbon monoxide; the polls demonstrate that, while the majority of consumers surveyed want this use of the gas to be banned, most of the remaining respondents want the carbon monoxide to be identified on the product label.¹⁷² Reasonable consumers would likely expect that the color of fresh meat would give them the most important information relative to the freshness of the product. Because carbon monoxide alters the color of meat, use of carbon monoxide in fresh meat packaging is a material fact that must be declared on the product label.

FSIS's policy of requiring the disclosure of facts important to consumer expectations is consistent with well established antideception standards applied by FDA¹⁷³ and the Federal Trade Commission.¹⁷⁴

¹⁷¹ See *supra* notes 74-77.

¹⁷² See survey results accompanying WKMG Local 6, Central Florida, Problem Solvers Report, local6.com, Case-Ready Beef Appears Fresh Weeks After Sell-by Date, <http://www.local6.com/money/9050207/detail.html> (last visited June 9, 2006, as of which date 60% of respondents (2307 votes) said that beef packaged with carbon monoxide should be banned, while another 33% (1250 votes) stated that it should be labeled). See also FDA Urged to Act on Carbon Monoxide in Packaging, Just-Food.com (June 1, 2006) ("US consumer group Food & Water Watch has again urged the US Food and Drug Administration (FDA) to reverse its tacit approval of the practice of using carbon monoxide in case-ready meat packaging after a survey revealed strong consumer disapproval. The survey, conducted by Supermarketguru.com, revealed that nine of every ten respondents believe the practice is deceptive to consumers. The results of the survey, reported in industry newsletter 'Facts, Figures & the Future', showed that 93% of respondents believe that the use of carbon monoxide as a pigment fixative [in fresh meat] was an attempt to fool consumers. The survey also indicated that 68% of consumers were unaware that some meat is packaged with carbon monoxide, which, says Food & Water Watch, keeps meat a fresh-looking red colour even after it may have begun to spoil.") (Attachment N).

¹⁷³ FDA has explained that a fact is material when consumers would expect that fact to be on the product label in light of representations made. See, e.g., FDA, CFSAN, Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering (Draft Guidance) (January 2001), available at <http://www.fda.gov/OHRMS/DOCKETS/98fr/001598gd.pdf> (explaining that consumer interest in whether a food has been produced through bioengineering alone does not make the fact of the method of its production material. That fact could be material, however, where bioengineering produces an unexpected and meaningful trait in the food product that would not be apparent without labeling).

(continued...)

Thus, given the documented consumer reliance upon and expectations based on meat color, carbon monoxide's color-altering effect in meat is a material fact that must be identified on the label, if carbon monoxide is to be permitted in fresh meat packaging at all.

VII. FSIS is Obligated to Prescribe a Substance's Conditions of Use in Meat Under the FMIA

The FMIA charges FSIS with the authority – and responsibility – to make decisions concerning the suitability of a substance's use in meat.¹⁷⁵ USDA serves as the final gatekeeper before a substance may be used in meat. As FSIS has explained, this gatekeeping function is entrusted to FSIS due to the agency's expertise concerning “the unique characteristics of meat . . . products.”¹⁷⁶ USDA's decisions are thus made independently of decisions made by FDA concerning the safety of a substance in food.¹⁷⁷ The roles of USDA and FDA in evaluating new substances are by law distinct.

For example, in the preamble to FDA's *trans* fat labeling final rule, FDA examined consumer behavior research demonstrating that consumers rely on the Nutrition Facts label as a guide to choosing foods that meet their dietary objectives. From that data, FDA determined that “the reasonable consumer would expect that the information on the label would give them the most important nutrition information relative to the healthfulness of the product. Yet the omission of *trans* fat runs counter to that expectation, impeding rational consumer choice.” 68 Fed. Reg. 41434, 41439 (July 11, 2003). Accordingly, FDA concluded that *trans* fat is a material fact that cannot be omitted from the label. 68 Fed. Reg. at 41450.

¹⁷⁴ The Federal Trade Commission (“FTC”) explains that the question of whether a representation or omission is “material” is “whether the act or practice is likely to affect the consumer's conduct or decision with regard to a product or service.” Letter from James C. Miller III, Chairman, FTC, to the Honorable John D. Dingell, Chairman, House Comm. on Energy and Commerce (October 14, 1983) (“FTC Policy Statement on Deception”), available at <http://library.findlaw.com/1983/Oct/14/131419.pdf>, at 2. FTC emphasizes that “[w]here the seller knew, or should have known, that an ordinary consumer would need omitted information to evaluate the product or service . . . materiality will be presumed because the manufacturer intended the information or omission to have an effect.” *Id.* at 6. Given that consumer reliance on color in assessing the freshness of has been well documented in the published literature, processors using carbon monoxide in fresh meat packaging know or should know that consumers would need information alerting them to the fact that the color of such meat is not a reliable indicator of freshness.

¹⁷⁵ See *supra* note 12.

¹⁷⁶ FSIS, Consumer Education and Information, Additives in Meat and Poultry Products (November 2001), <http://www.fsis.usda.gov/oa/pubs/additive.htm> (“Although FDA has overriding authority regarding additive safety, FSIS may apply even stricter standards that take into account the unique characteristics of meat, poultry, and egg products.”).

¹⁷⁷ See, e.g., FSIS Guidance on Ingredients, *supra* note 3 (“The USDA mark of inspection for meat and poultry products reflects a determination by FSIS that the food product is not adulterated, and thus that all ingredients used to make the product must be safe and suitable for the product to receive the mark.”).

Under the FMIA and the Act's implementing regulations, USDA determines the suitability of a substance's use in meat. FSIS's suitability analysis entails the scrutiny of consumer behavior and a substance's potential to mislead or deceive the consumer.¹⁷⁸ As FSIS affirms, "it is incumbent upon FSIS to consider suitability, as well as the safety, of ingredients for use in the production of meat and poultry products in order to prevent these products from being adulterated or misbranded."¹⁷⁹

The FMIA obligates USDA to impose, where it determines appropriate, restrictions on the use of substances in meat products that are more stringent than those imposed by FDA under the FDCA.¹⁸⁰ In its petition and subsequent submissions to FDA, Kalsec has detailed why carbon monoxide is not GRAS in fresh meat packaging under the FDCA and FDA's own requirements for GRAS status.¹⁸¹ Even if FDA decides to not object at this time to the use of a substance, such would nevertheless be prohibited under FMIA standards where the use, "even if safe, may promote deception when used in a meat or poultry product . . ."¹⁸² For example, even though paprika is considered GRAS by FDA and is listed for use as a color additive, FSIS regulations prohibit its use on fresh meat products "because such use adds color that may make the meat appear fresher than it actually is."¹⁸³

Since entering into a Memorandum of Understanding in 2000 to streamline the process for reviewing the use of substances in meat, FSIS and FDA have shared information and consulted as they conducted separate suitability and safety analyses. The Memorandum of

¹⁷⁸ See *supra* text accompanying notes 80-85.

¹⁷⁹ 70 Fed. Reg. 33803, 33810-11 (June 10, 2000).

¹⁸⁰ See generally *Chip Steak Co. v. Clifford Hardin*, 332 F. Supp. 1084 (N.D. Cal. 1971). See also 60 Fed. Reg. 67459, 67461 (Dec. 29, 1995) ("The Secretary of Agriculture's authority under the FMIA to prohibit the use of substances in meat products that are otherwise permitted in foods by FDA was tested in *Chip Steak Co. v. Clifford Hardin* The court held that the legislative history of the FMIA showed that it was the intent of Congress to vest the Secretary of Agriculture with the authority to prohibit the use of substances in meat food products notwithstanding their designation as GRAS. The court noted that under the FMIA, the Secretary had the power to prohibit a substance for use in meat and meat products even if the substance is not adulterative under the food additive provisions of the FDCA. Thus, the Secretary of Agriculture could impose restrictions for food ingredients in meat and meat food products that exceeded restrictions imposed by the Secretary of HHS.").

¹⁸¹ See Kalsec Citizen Petition, *supra* note 6, at 7-10, Kalsec February 1, 2006 Comments, *supra* note 6, at 2-4.

¹⁸² 70 Fed. Reg. at 33810.

¹⁸³ *Id.*

Understanding recognizes the importance and vitality of FSIS's singular expertise and authority to determine suitability of substances in meat.¹⁸⁴

FSIS's congressional mandate to protect consumers against the adulteration and misbranding of meat, and to not affirmatively endorse such meat by marking meat with the mark of inspection, requires FSIS to re-evaluate the suitability of substances it has permitted in meat as needed. FSIS has underscored the importance of its authority to re-evaluate the suitability of "any substance used to provide a technical effect in foods": "Additives are never given permanent approval. FDA and FSIS *continually review* the safety of approved additives, based on the best scientific knowledge, *to determine if approvals should be modified or withdrawn.*"¹⁸⁵

Kalsec therefore urges FSIS to rescind any favorable suitability determinations allowing the use of carbon monoxide in fresh meat packaging because such use violates the FMIA, FSIS regulations, and longstanding FSIS policy.

VIII. Rulemaking is Required Under the FMIA and the APA

USDA must engage in rulemaking to lawfully permit the use of a color additive in meat under the FMIA¹⁸⁶ and to lift the ban on carbon monoxide's use in fresh meat packaging currently imposed by regulation.¹⁸⁷ In addition, FSIS's favorable suitability determinations for uses of carbon monoxide in fresh meat packaging represent a marked departure from established agency precedent that is lawful under principles of administrative law only if USDA has demonstrated that it has considered all relevant factors and has justified the departure.

Under settled principles of administrative law, an agency must offer a reasoned explanation for its change in view when it departs from its prior positions.¹⁸⁸ Agency action may

¹⁸⁴ 65 Fed. Reg. 33330, 33331-33334 (May 23, 2000), *available at* <http://www.fda.gov/ohrms/dockets/98fr/052300c.pdf> (stating at 3332, 3334: "The FMIA and the PPIA [Poultry Products Inspection Act] grant FSIS the authority to regulate the use of GRAS substances, FDA-listed food and color additives, and sources of radiation to ensure that their use does not adulterate meat or poultry products. . . . The provisions of this MOU are not intended to add to or detract from any of the authorities provided to either FDA or FSIS by the FFDC, FMIA, or PPIA, or the regulations promulgated by each agency under such authorities. Each agency reserves the authority to review, independently of the other, matters of concern to their respective authorities."). *See also* 60 Fed. Reg. 67459, 67461 (December 29, 1995) ("Nothing in the current proposal would diminish that authority [of USDA to control the use of substances in meat products].").

¹⁸⁵ FSIS, Consumer Education and Information, Additives in Meat and Poultry Products, *supra* note 176 (emphasis added).

¹⁸⁶ *See supra* note 1.

¹⁸⁷ *Id.*

¹⁸⁸ *See, e.g., Independent Petroleum Ass'n v. Babbitt*, 92 F.3d 1248, 1258 (D.C. Cir. 1996) ("An agency must treat similar cases in a similar manner unless it can provide a legitimate reason for (continued...)")

be deemed arbitrary and capricious “if its rationale does not appear in the administrative record so that its decisionmaking path may reasonably be discerned.”¹⁸⁹ That record must demonstrate that the agency has considered all relevant factors.¹⁹⁰ FSIS drastically changed course after reviewing GRAS notifications and requests for acceptability determinations of companies advocating the use of carbon monoxide in fresh meat packaging, yet FSIS cannot demonstrate that it has met its burden of considering all relevant factors.

FSIS can only comply with applicable legal requirements by promulgating a new policy through notice and comment rulemaking on the public record. Only through rulemaking can the agency demonstrate that it has considered all relevant factors, including consumer behavior data under real-world conditions of use and the perspective of stakeholders. Notice and comment rulemaking enables FSIS to explain its rationale in the administrative record. In particular, rulemaking enables FSIS to explain the agency’s rationale concerning whether carbon monoxide is a processing aid and the agency’s reliance on “use or freeze by” dates to guard consumers against deception and safety risks.

Indeed, although FSIS policy generally prohibits the addition of substances in meat that may affect meat color, in those exceptional cases in which FSIS has authorized such uses, the agency has traditionally been careful to establish enforceable limitations on conditions of use to protect against consumer deception by issuing regulations through notice and comment rulemaking.¹⁹¹ FSIS has recognized that, because it must consider actual conditions of use in determining the suitability of a substance affecting the color of meat, public comment regarding commercial and consumer experience is needed when making decisions about the suitability of color-altering substances.¹⁹² Given the documented controversy about the use of carbon monoxide in fresh meat packaging among scientific experts, governments, consumers, and other

failing to do so.”); *Department of the Navy v. FLRA*, 962 F.2d 48, 56 (D.C. Cir. 1992); *Hall v. McLaughlin*, 864 F.2d 868, 872 (D.C. Cir. 1989) (“[d]ivergence from agency precedent demands an explanation.”).

¹⁸⁹ *Chamber of Argentine-Paraguayan Producers of Quebracho Extract, et al. v. Holder*, 332 F. Supp. 2d 43, 49 (D.D.C. 2004).

¹⁹⁰ *Id.* at 48.

¹⁹¹ See, e.g., 59 Fed. Reg. 12536 (March 17, 1994) (final rule on ascorbic acid, erythorbic acid, citric acid, sodium ascorbate, and sodium citrate on beef, lamb, and pork cuts to delay meat discoloration); 58 Fed. Reg. 45238 (August 27, 1993) (final rule regarding citric acid as a color preserver on cured pork products); 53 Fed. Reg. at 49849 (final rule regarding ascorbic acid, erythorbic acid, citric acid, sodium ascorbate, and sodium citrate as color maintainers on fresh pork cuts to extend color and appearance).

¹⁹² See, e.g., 51 Fed. Reg. at 30052 (interim final rule concerning ascorbic acid, erythorbic acid, citric acid, sodium ascorbate, and sodium citrate, explaining that “due to the potential significance of color maintenance through the use of added substances, this rule is being published as an interim final rule with request for comments so that commercial experience and public comment can be obtained and considered prior to confirmation of the rule as final.”).

stakeholders, rulemaking will also ensure a complete record on safety and suitability and establish enforceable conditions of use to ensure such safe and suitable use of the gas.

In conclusion, allowing carbon monoxide in fresh meat packaging is inconsistent with the FMIA, the Act's implementing regulations, and FSIS's longstanding, principled approach to the regulation of color-altering substances in meat. Evidence shows that consumers rely heavily upon meat color as a critical indicator of freshness, organoleptic indicators of spoilage are inhibited in modified atmosphere packaging, and temperature abuse is extensive throughout the distribution and handling of fresh meat. Because carbon monoxide alters the color of meat in a way that has the potential to mislead consumers, it both adulterates and misbrands meat. Accordingly, carbon monoxide gas is not suitable for use in fresh meat packaging.

For the foregoing reasons, Kalsec requests that USDA take immediate action to enforce the existing ban on such use of carbon monoxide, including by rescinding suitability determinations permitting the use of carbon monoxide, withholding the mark of inspection from meat in packaging containing carbon monoxide, and refusing to allow the processing of meat packaged in atmospheres containing carbon monoxide.

Respectfully Submitted,

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