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June 14, 2006

BY FEDERAL EXPRESS

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Re: Citizen Petition Requesting FDA to Enforce Ban on Carbon Monoxide in Case-Ready Fresh Meat Packaging; Docket No. 2005P-0459

Dear Dr. Tarantino:

This submission responds to comments by Precept Foods, L.L.C. ("Precept") submitted on April 11, 2006, to the docket for the citizen petition filed by Kalsec, Inc. ("Kalsec"), and describes additional new data appended hereto for submission to the petition docket.[1] The Kalsec petition urges FDA to take immediate action to enforce a ban on carbon

[1] Appended hereto as Attachment A are scientific reports from limited unpublished studies that were sponsored by Kalsec and conducted by S&J Laboratories of Portage, Michigan ("June 2006 Scientific Reports").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 before the agency raising food safety and consumer deception concerns relating to the use of carbon monoxide in fresh meat packaging. Several key findings merit close evaluation by FDA and 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, and 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

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monoxide in fresh meat packaging, including by terminating the agency's unlawful acceptance of the Generally Recognized As Safe ("GRAS") notification submitted by Precept ("GRAS Notice No. GRN 000143").[2] As the Precept comments are unsupported by the relevant law and scientific evidence, Kalsec makes this further submission to the record to highlight for FDA's consideration relevant information, data, and analyses concerning the use of carbon monoxide in fresh meat packaging.

A review of Precept's original GRAS notification to FDA reveals that only a limited portion of the published literature relating to this use of carbon monoxide was presented to the agency, that the privately-generated data submitted in support of Precept's GRAS notification was nonresponsive to concerns raised about carbon monoxide in fresh meat packaging, and was methodologically flawed, failing to satisfy basic requirements for adequate and well controlled scientific studies. Moreover, Precept's GRAS notification failed to characterize sufficiently either the conditions of use of carbon monoxide, or the safety and consumer deception issues presented by such use, precluding an adequate assessment by FDA.[3]

These comments address in detail both Precept's GRAS notification and its most recent submission to the Kalsec petition docket, and review the unlawful nature of the use of carbon monoxide in fresh meat more generally. Key points are highlighted as follows:

- Carbon monoxide in fresh meat packaging is a color additive because it reacts with the myoglobin in the meat to form carboxymyoglobin, which imparts a new red color to the meat. It is irrelevant, under the Federal Food, Drug, and Cosmetic Act ("FDCA") and FDA regulations, whether that new color is similar to the color of oxygenated meat.

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

[2] While Kalsec's submissions have focused upon the Pactiv and Precept GRAS notifications (the first two GRAS notifications for the use of carbon monoxide in fresh meat packaging) the Kalsec Citizen Petition and this submission are directed at all uses of carbon monoxide in fresh meat packaging. *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] Similarly, the narrow construction of the conditions of use and attendant safety and consumer deception issues in the Precept submissions also precluded adequate FSIS review of the suitability of carbon monoxide in fresh meat.

- The color imparted by carbon monoxide in fresh meat packaging can mask spoilage. The published scientific literature conclusively documents this fact, as well as the inadequacy of other signs of spoilage to compensate for the loss of this key visual cue. Because of this deceptive coloring effect, carbon monoxide is unsafe for use in fresh meat packaging.

- 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.

- No consumer research has been referenced in the record to establish that odor may sufficiently alert consumers to spoilage or that consumers will consult and follow "use or freeze by" date labeling when color – consumers' customary indicator of wholesomeness – suggests freshness. The absence of such consumer data precludes a finding, as suggested in the Precept submissions, that potential spoilage indicators other than color are adequate to ensure the safe and nondeceptive use of carbon monoxide in fresh meat packaging.

- Carbon monoxide in fresh meat packaging is not GRAS because the published scientific literature documents the controversy among experts as to the safety of this use of the gas, and because Precept's privately-generated data is nonresponsive to documented safety concerns and does not meet applicable standards of quality, independence, and general acceptance.

- The Precept GRAS notification failed to address material distinctions between the intended use of carbon monoxide in retail packaging systems and the use of the gas in systems previously accepted, precluding adequate agency consideration of the appropriate regulatory scheme for this use of carbon monoxide. Namely, carbon monoxide used in a retail meat package is

ineligible for processing aid status, and its function in the meat is that of a color additive.

- The failure to require labeling for the use of carbon monoxide in fresh meat packaging is unlawful because the gas has a functional effect in the finished food and qualifies for no exception from statutorily-mandated ingredient labeling, and because its use in meat is a material fact that must be disclosed in product labeling.

- If carbon monoxide in fresh meat packaging is to be permitted at all, the only lawful avenues are through notice-and-comment rulemaking. Rulemaking is required 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 FDA regulation; and to comply with tenets of administrative law requiring agencies to justify the significant deviation from agency precedent that allowing this use of carbon monoxide entails. Rulemaking will allow public participation of stakeholders to ensure that all material data and information (including data related to consumer behavior under real-world conditions of use) can be considered, and enables the establishment of readily enforceable conditions of safe use of the additive, including labeling.

Rather than responding to the serious legal and scientific deficiencies in the Precept GRAS notification, as exposed through Kalsec's citizen petition, the April 11, 2006 comments filed on behalf of Precept continue to urge FDA to deny the Kalsec petition, dismissing the legal arguments and scientific evidence, and trivializing the issues as representing nothing more than a competitive business dispute. Kalsec has made plain its commercial interest in seeing carbon monoxide in fresh meat evaluated under appropriate legal and scientific standards. 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,[4] and should be embraced by retailers and consumers alike.

The Kalsec Citizen 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

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[4] As detailed in Kalsec's February 1, 2006, comments to the citizen petition docket (Docket No. 2005P-0459/RC1) ("Kalsec's February 1, 2006 Comments"), at 9-10, the safety and consumer benefits Precept attributes to its carbon monoxide-containing case-ready meats are attributable to all case-ready meats generally.

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. To the extent that business motivations should be evaluated in the context of regulatory submissions, it bears mention that proponents of the use of carbon monoxide in fresh meat stand to gain a substantial financial benefit.[5]

Since filing its petition, Kalsec has been supported in its position by several organizations representing the interests of consumers.[6] Additionally several supermarket chains have reportedly said they would not carry carbon monoxide-treated meat, and some have suggested in media reports that the practice is deceptive.[7] Reports from consumer polls taken by independent news outlets regarding the use of carbon monoxide in fresh meat packaging indicate there is substantial concern among consumers regarding the use of carbon monoxide in fresh meat under the current conditions of use.[8] The serious concern expressed by these organizations and consumers about the use of carbon monoxide in fresh meat packaging makes clear that this issue is not a matter of Kalsec's private business interests, and highlights the need for FDA to take immediate action to enforce a ban on this use of carbon monoxide.

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[5] *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 4 (July 2003), *available at* http://www.beef.org/uDocs/ACF13DD.pdf (estimating that "U.S. retailers fail to capture at least one billion dollars of revenue annually from fresh beef sales, due to product discoloration," and suggesting that "CO MAP could contribute to longer shelf life for T-bone steaks, sirloin steaks and ground beef patties," because "sensory panelists found the cuts packaged in CO more acceptable" than those packaged in other systems.).

[6] *See, e.g.,* Letter from Carol Tucker Foreman, Director, Food Policy Institute, Consumer Federation of America, & Barbara Kowalcyk, President, Safe Tables Our Priority, to Division of Dockets Management, FDA (January 17, 2006) and Letter from Wenonah Hauter, Director, Food & Water Watch, to Division of Dockets Management, FDA (February 21, 2006) (Attachment C).

[7] *See* Press Release, Consumer Federation of America, Leading Supermarket Chains Refuse To Sell Carbon Monoxide-Treated Meat (April 5, 2006) (Attachment D).

[8] *See, e.g.,* 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); FDA Urged to Act on Carbon Monoxide in Packaging, Just-Food.com (June 1, 2006) (Attachment E).

I. Carbon Monoxide in Fresh Meat Packaging is a Color Additive

In its prior submissions to FDA, Kalsec has comprehensively demonstrated that carbon monoxide in fresh meat packaging is a color additive under the statutory definition of the term, consistent with the agency's regulation of numerous substances that impart color through chemical reaction with a substance in the food to which it is applied.[9] Kalsec incorporates those submissions by reference, and confines its discussion here to Precept's erroneous assertions that the use of carbon monoxide at 0.4% in a modified atmosphere package is not enough to impart color within the meaning of the color additive definition.

Neither the FDCA nor FDA regulations exempt a substance from the color additive definition because only a small amount is used. To the contrary, the plain language of the statutory "color additive" definition includes substances "capable (alone or through reaction with other substance) of imparting color" to a food.[10] The published scientific literature establishes that carbon monoxide is capable of imparting color to meat, and in fact does impart color at a range of concentrations.[11] The gas therefore satisfies the statutory definition of a "color additive," and is no less a color additive when used at 0.4%, where its coloring effect may be less striking. Precept's assertions are tantamount to saying that FD&C Red No. 3 is not a color additive when only a little is used, or when it is used on a food that is already a shade of red.

Once again, the 1980 FDA determination on nitrites, from which the Precept submission selectively quotes, actually provides further support for the fact that carbon monoxide is a color additive in fresh meat. In its nitrite rulemaking, a significant factor in FDA's ultimate determination to distinguish nitrites from substances that "impart" color to meat was the fact that the intensity of the red color in nitrite-treated meat was not related to the amount of nitrites added to the meat. Partly because "the addition of more nitrites does not increase the intensity of the red color," FDA concluded that nitrites merely "fix" the color in meat.[12] In contrast, adding more carbon monoxide to fresh meat packaging does increase the

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[9] *See* Kalsec Citizen Petition, at 7-10; Kalsec's February 1, 2006 Comments, at 2-4.

[10] 21 U.S.C. 201(t)(1)(B) (emphasis added).

[11] *See, e.g.,* 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 Sci. 157, 162-163 (1999) ("Sørheim (1999)") (Kalsec Citizen Petition at Attachment 18). ("CO binds to myoglobin and forms cherry red carboxymyoglobin. . . . CO in concentrations of 0.5-2.0% enhances and stabilizes a bright red colour of meat. . . . [I]n a study of beef stored in a MA of 2%CO/78% CO_2/20% N_2, the colour of the meat was characterized as "too artificial" by a sensory panel.") (citations omitted).

[12] 45 Fed. Reg. 77043, 77045 (November 21, 1980) (emphasis added).

intensity of the red color of the meat,[13] and therefore the gas does not simply "fix" the color of the meat.

Further, even 0.4% carbon monoxide produces a new, visibly different, color in meat exposed to this level of the gas. Carbon monoxide reacts with myoglobin in the meat to form "cherry red carboxymyoglobin,"[14] which, in contrast to oxymyoglobin, is a new pigment not found naturally in meat. Carbon monoxide at this concentration does not merely "stabilize" the natural pigments in fresh meat, but rather, "0.4% CO seems sufficient to produce a stable, attractive, bright red colour of meat."[15] While the color of carboxymyoglobin is meant to approximate the color of oxymyoglobin in fresh meat, the published scientific literature documents that it is not the same red color, and its functional effects are persistent and distinct in the finished meat.[16]

The fact that this new pigment created by carbon monoxide may be similar to the color of oxygenated meat has no bearing on its color additive status. FDA regulates as color additives numerous substances that impart a color similar to that which consumers would expect to find in a food. For example, FDA regulates astaxanthin meal in farmed salmon feed as a color additive even though, upon ingestion, its effect is simply to enhance the color of the fish flesh in a way that mimics the color of wild salmon flesh.[17] The arguments expressed in Precept's April 11 comments would allow for the use of any red pigment in the coloration of fresh meat, as long as the color successfully mimicked the color of fresh red meat stored in air.

In sum, carbon monoxide at 0.4% of the modified atmosphere for fresh meat is an unlawful color additive under the FDCA definition and regulatory precedent.[18] Because carbon

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[13] *See* Sørheim (1999), *supra* note 11, at 162.

[14] *Id.*

[15] *Id.* at 163 (emphasis added).

[16] *See, e.g., id.* 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).

[17] 21 C.F.R. 73.35. *See also, e.g.*, 21 C.F.R. 73.185 (regulating haematococcus algae meal in salmon feed as a color additive to enhance the pink to orange-red color of the fish flesh); 21 C.F.R. 73.275 (regulating dried algae meal in chicken feed as color additive to enhance the yellow color of chicken skin and egg yolks); 21 C.F.R. 73.295 (regulating tagetes/Aztec marigold meal and extract in chicken feed as color additive to enhance the yellow color of chicken skin and egg yolks).

[18] Similarly, under the FMIA, FSIS prohibits the use of even substances that simulate the natural color of fresh meat. The legislative history of the 1967 Wholesome Meat Act amendments to the (continued...)

monoxide fails to meet the statutory criteria of safety and nondeceptiveness established for color additives under FDCA section 721, as detailed in the Kalsec Citizen Petition, the gas cannot be authorized for use in fresh meat packaging.

II. The Scientific Controversy Documented in the Published Literature Precludes GRAS Status

Aside from the fact that carbon monoxide in fresh meat packaging is a color additive and therefore cannot be GRAS under the same conditions of use,[19] the gas is not GRAS for this use under the FDCA and FDA's own requirements for GRAS status.

As a threshold matter, carbon monoxide's ability to mask spoilage in fresh meat is a major safety concern, as emphasized in the published scientific literature, which is directly relevant to a determination of GRAS status under the applicable FDCA standards.[20] Precept's GRAS notification narrowly focused the safety analysis on the toxicology of residual carbon monoxide in the meat. By portraying the coloring effect of carbon monoxide as unrelated to the safety of the meat,[21] the Precept GRAS notification and April 11 comments omit to address the substantial body of scientific evidence documenting the controversy among experts as to whether carbon monoxide is safe for use in fresh meat packaging. As discussed in detail in Section IV,

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FMIA documents serious expressions of concern about additives in meat that were "potentially deceptive" because they masked spoilage by making meat "appear to have a normal color" or "cancel[led] out the ... appearance of decaying or unhealthy meat." *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), *reprinted in* H.R. REP. NO. 90-653, at 15 (1967); *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. 39 (1967) (statement of Rep. Neal Smith); 113 CONG. REC. 33842 (1967) (statement of Sen. Mondale, speaking on behalf of the Senate Committee on Agriculture). Consequently, FSIS banned the use of paprika in fresh meat as deceptive not because it imparts a new color, but rather because it "preserve[es] the red color characteristic of fresh meat even after the articles have begun to spoil." 33 Fed. Reg. 15027 (October 8, 1968) (Proposed Rule); 9 C.F.R. 424.23(a) & (b).

[19] See Kalsec Citizen Petition, at 11.

[20] 62 Fed. Reg. 18937, 18942-3 (April 17, 1997) (Substances Generally Recognized as Safe; Proposed Rule).

[21] For example, in its April 11, 2006 comments on the Kalsec Citizen Petition, at footnote 10, Precept states that the European Union's ban on carbon monoxide in fresh meat packaging "appears to have been driven by concerns other than safety – namely, the issue of whether CO misleads the consumer with respect to product freshness."

below, Precept's GRAS notification characterizes the intended conditions of use of carbon monoxide as encompassing only ideal conditions of use, by relying primarily upon evidence generated under laboratory conditions of temperature control and lighting, and omitting substantive analysis of actual distribution and retail conditions and consumer behavior. By failing to consider actual conditions of use, as required under governing law,[22] Precept's GRAS notification further excluded from agency consideration significant scientific evidence bearing on the safety of carbon monoxide in fresh meat packaging. As detailed below, the heavy reliance upon the Pactiv GRAS notification and inadequate privately-generated data in the Precept GRAS notification does not resolve the documented controversy among experts about the safety of this use of carbon monoxide. The use of carbon monoxide in fresh meat packaging is therefore not GRAS.

For a substance to be deemed GRAS through scientific procedures, FDA requires that there exist "a basis to conclude that there is consensus among qualified experts about the safety of the substance for its intended use."[23] The agency specifies further that the "common knowledge" element of the GRAS standard generally requires that such consensus be documented through scientific data and information in the published literature.[24] FDA advises that "an ongoing scientific discussion or controversy about safety concerns raised by available data would make it difficult to provide a basis for expert consensus about the safety of a substance for its intended use."[25] Given the controversy documented in the published scientific literature, the use of carbon monoxide in fresh meat packaging cannot be deemed GRAS.

A. The Published Scientific Literature Specifically Raises Questions about the Safety of Carbon Monoxide in Fresh Meat Packaging

While 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,"[26] the Precept GRAS notification failed to include any references to or discussion of the key body of published literature raising questions about the safety of the use of carbon monoxide in fresh meat packaging, and reflected no review of the body of relevant scientific literature by an authoritative GRAS review panel. The Precept

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[22] *See* Kalsec Citizen Petition, at 15-23.

[23] 62 Fed. Reg. 18937, 18942.

[24] 62 Fed. Reg. 18937, 18943 (to be codified at 21 C.F.R. 170.30(b)).

[25] 62 Fed. Reg. 18937, 18942.

[26] 62 Fed. Reg. 18937, 18961 (to be codified at 21 C.F.R. 170.36(c)(4)(i)(A)).

notification cited only three published studies,[27] 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."[28] 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) 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."[29] 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 condition of the meat raw materials and the chill chain temperatures."[30] 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."[31]

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

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[27] Sørheim (1999), *supra* note 11; 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 (September 1997) ("Sørheim (1997)") (Kalsec Citizen Petition at Attachment 14); Watts, D.A. *et al.*, *Fate of [^{14}C] Carbon Monoxide in Cooked or Stored Ground Beef Samples*, 6 J. Agric. Food Chem. 210-214 (1978).

[28] GRAS Notification of Precept Foods, L.L.C. 25 (January 6, 2004) ("GRAS Notice No. GRN 000143").

[29] Sørheim (1999), *supra* note 11, at 157, citing Donald H. Kropf, *Effect of Retail Display Conditions on Meat Color*, 33 Reciprocal Meat Conf. Proc. 15 (1980) (Kalsec Citizen Petition at Attachment 17).

[30] *Id.* at 163.

[31] Sørheim (1997)), *supra* note 27, at 311 (citation omitted).

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.[32] Notably, the Pactiv GRAS notification, upon which the Precept notification heavily relied, cited the Kropf study as the source for the Sørheim citation, quoted above, regarding the potential of carbon monoxide to mask spoilage. The failure to acknowledge the Kropf study in the Precept GRAS notification is unexplained.

- 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.[33] 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."[34] 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 . . . emphasise the importance of temperature control during storage."[35]

- 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."[36] The extended shelf life attained by including carbon monoxide in packaging "may, therefore, under certain conditions imply increased risk of growth of pathogens."[37] 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.[38] The Committee "wishes to point out that, should products be stored under

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[32] Kropf, *supra* note 29.

[33] 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) (Kalsec Citizen Petition at Attachment 9).

[34] *Id.* at 212.

[35] *Id.* at 218.

[36] 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 4 (December 18, 2001) ("Opinion of the Scientific Committee on Food"), (Kalsec Citizen Petition at Attachment 16).

[37] *Id.*

[38] *Id.* at 7.

inappropriate conditions, the presence of carbon monoxide may mask visual evidence of spoilage."[39]

The contention in Precept's April 11 comments that the European Union's ban on carbon monoxide in fresh meat packaging should be disregarded as a "political" maneuver is inapt, and discounts not only the ban, but the scientific evaluation of the Scientific Committee on Food, as well as the substantial body of published scientific evidence supporting the Committee's conclusions. The safety concerns raised in the Committee report show that there is no general agreement among qualified experts that the use of carbon monoxide in fresh meat is safe or does not deceive consumers under the real world conditions in which meat is sold and consumed. Precept's attempt to dismiss the European Union's ban as having "been driven by concerns other than safety – namely, the issue of whether CO misleads the consumer with respect to product freshness"[40] once again disregards the fact that deception in fresh meat packaging is a safety risk. Notably, this safety risk is expressly acknowledged in the document appended to Precept's April 11 comments purportedly in support of this argument. In the letter from the European Commission to the European Parliament on this matter, the Commission explained that the use of carbon monoxide may "present a hazard to the health of consumers if the treated meat product is not stored under appropriate conditions (below 4°C) as it may mask spoilage."[41]

Significantly, the European Union ban was made on grounds readily analogous to U.S. law and experience. Like the FDCA, the governing European Directive mandates that the use of an additive shall not mislead the consumer, a criterion that this use of carbon monoxide could not fulfill.[42] Further, the European officials considered the actual, rather than ideal, conditions of use, as is also required under governing U.S. law. They acknowledged the reality that the requisite temperature control could not be maintained,[43] as has been documented in the literature addressing the American experience, discussed in Subsection II.C., below. They also took into consideration a fact that is equally true in the United States – that many "consumers base their decisions on the general appearance of a meat product rather than on the written information given on the label."[44] 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

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[39] *Id.*

[40] Precept April 11 comments, at n.10.

[41] Letter from Robert J. Coleman, European Commission, to Caroline F. Jackson, European Parliament, at 2 (June 20, 2003) (Attachment F) (emphasis added).

[42] *Id.*

[43] *Id.*

[44] *Id.*

necessarily reflect its freshness, finding that even such extensive labeling would not solve the problem.[45]

There are no grounds upon which to distinguish the basis for the European ban on carbon monoxide in fresh meat packaging from American law and experience. That ban is evidence of the documented controversy surrounding the safety of the use of carbon monoxide in fresh meat packaging. This use of carbon monoxide therefore cannot be GRAS. The limited unpublished studies Precept has submitted in support of its GRAS notification are unsubstantial and cannot overcome the weight of the evidence supporting the food safety and consumer deception concerns that have been raised concerning the use of carbon monoxide in fresh meat internationally.

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

Precept's April 11 comments suggest that the masking of color change indicating spoilage does not present a safety risk because other signs of spoilage would be present, such as odor, slime, or a bulging package.[46] In making such assertions, however, those Precept submissions ignore key facts documented in the published literature that bear significantly on this safety assessment: that the spoilage organisms that might be expected to produce such signals 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); and that a significant portion of the population at greatest risk for foodborne illness has a compromised sense of smell.

The scientific 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.[47] Notably, even the data submitted by

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[45] *Id.* ("In the ENVI Committee the oral proposal was made to inform the consumer by labeling that the colour of the meat does not necessarily reflect its freshness. It is our opinion that even such extensive labeling would not solve the problem, as part of the consumers base their decisions on the general appearance of a meat product rather than on the written information given on the label.")

[46] Precept April 11 comments, at 2, 9.

[47] *See* Kalsec Citizen Petition, at 20-21; J.M. Farber, *Microbiological Aspects of Modified-Atmosphere Packaging Technology – A Review*, 54 J. Food Protection 58, 64 (January 1991) (Kalsec Citizen Petition at Attachment 6) (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* (continued...)

Precept in support of its GRAS notification found lower odor scores with higher microbial counts, as discussed in Section IV below, indicating 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.[48]

Significantly, 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. If consumers detected an 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.

Controlled-Atmosphere Storage of Meats, 34 Food Tech. 59, 59 (March 1980) (Kalsec Citizen Petition 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 Atmosphere Packaging: A Review – Do Modified Atmospheres Enhance Pathogenesis But Delay Signs of Spoilage?* 40 Food Tech. 70, 75 (December 1986) (Kalsec Citizen Petition 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, 205 (1995) (Kalsec Citizen Petition 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) ("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.").

[48] Of course, odor can only be detected once the meat has been purchased and opened by the consumer. Damage or inferiority has therefore been concealed at the point of purchase, rendering the meat adulterated. 21 U.S.C. 402(b)(3), 601(m)(8).

Of even greater concern, however, is the significant portion of the population most vulnerable to foodborne illness that 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 foodborne illness,[49] they are also more likely to experience a diminished sense of smell.[50] The large-scale National Geographic Smell Survey found that about 12% of octogenarians have completely lost their sense of smell.[51] Most troubling is the fact that about half of the elderly population suffers a severely compromised ability to detect mercaptans,[52] for the main odorants produced during the spoilage of carbon

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[49] *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 G) (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 H) (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 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).

[50] *See, e.g.,* Avery N. Gilbert & Charles J. Wysocki, *The Smell Survey*, 122 Nat'l Geographic, 514, 514 (1987) (Attachment I) (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); 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) (Attachment J) (it has "become generally accepted that olfactory function declines with increasing age"); Charles. J. Wysocki & Avery N. Gilbert, *National Geographic Smell Survey: Effects of Age Are Heterogenous*, 561 Ann. N. Y. Acad. Sci. 12 (1989) (Attachment K) (describing age-related loss of smell, and particularly, losses in the ability to detect individual compounds and classes of compounds).

[51] Wysocki & Gilbert, *supra* note 50, at 26, Fig. 17.

[52] *See id.* at 17 ("For mercaptans, a steep decline in detection began more abruptly in the fifth decade."); Wysocki & Pelchat, *supra* note 50, 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.").

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.[53]

The need to consider the effect of the use of a substance on vulnerable populations is well documented in FDA's guidance regarding food and color additive petitions, and as Precept's April 11 comments acknowledge, the same safety standards apply to GRAS substances, food additives, and color additives. FDA guidance documents on estimating exposure to direct food additives highlight the "inherent conservatisms" that are part of the safety assessment of such substances, including exposure estimates to the "high" consumer at the 90th percentile of estimated daily intake.[54] The proponent of the use of a substance cannot consider its impact on only the "average" or "ideal" consumer, or tailor its "intended use" to only such consumers. Similarly, for a substance to be GRAS, it must be safe for even sensitive consumers.[55]

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 of meat packaged with carbon monoxide, particularly for the populations most vulnerable to foodborne illness, this use of the gas cannot be GRAS.

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[53] *See, e.g.*, Gerba, *et al.*, *supra* note 49, 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.").

[54] *See* FDA, Center for Food Safety and Applied Nutrition ("CFSAN"), Estimating Exposure to Direct Food Additives and Chemical Contaminants in the Diet: Examples and Summary, (September 1995), *available at* http://www.cfsan.fda.gov/~dms/opa-cg8e.html (citing examples to "highlight inherent conservatisms" in the agency's exposure estimates); FDA, CFSAN, Office of Food Additive Safety, Guidance for Industry: Recommendations for Submission of Chemical and Technological Data for Direct Food Additive Petitions (March 2006), *available at* http://www.cfsan.fda.gov/~dms/opa2cg4.html.

[55] Of course, even healthy individuals also experience loss of smell on occasion, compromising their ability to experience odor as a warning signal that meat has spoiled. Over 62% of respondents to the National Geographic Smell Survey reported at least one temporary episode of smell loss, in most cases due to the common cold, flu, or sinus infection. Gilbert & Wysocki, *supra* note 50, at 520.

C. The Published Scientific Literature Documents the Significant Incidence of Temperature Abuse

Precept's April 11 comments do not dispute that meat packaged in its carbon monoxide-containing packaging system will not change from its bright red color even when temperature-abused. Rather, those comments merely allege, without any cited support, that the risk of temperature abuse "is speculative and certainly not relevant to the intended or likely conditions of use for CO in fresh meat packaging."[56] This position is untenable in the face of extensive published literature documenting the realities of temperature abuse in the storage, distribution, and retail and consumer handling of fresh meat.[57] Moreover, FDA has already determined that the certainty of such temperature abuse must be acknowledged in a safety assessment, 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.[58]

The attempted analogies in Precept's April 11 comments to other foods that spoil without noticeable change in product color ignores the fact, well documented in the published scientific and industry literature, that when it comes to meat, consumers determine freshness primarily based upon color.[59] This is not the case for products like milk and eggs. Precept's

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[56] Precept April 11 comments, at 6.

[57] *See, e.g.*, FDA, Food Code (2005), at 547, 550 (acknowledging 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)."); Labuza, *supra* note 47, at 202 ("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) (Kalsec Citizen Petition 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, at 16-18, and citations therein.

[58] FDA, Food Code, *supra* note 57, at 547.

[59] *See, e.g.*, National Pork Board/American Meat Science Association Facts: Modified Atmosphere Packaging (MAP): Microbial Control and Quality (1998) (Attachment L), at 3 (continued...)

comments cite no support for the proposition that consumers rely upon open date codes, along with odor and slime, in determining meat's fitness for consumption. To the contrary, FSIS has made clear that date labeling is not sufficient to ensure the safe handling and consumption of meat,[60] particularly because the usefulness of such labeling is dependent upon strict adherence to temperature control,[61] which cannot be assured as a practical matter.

The foregoing reflects the body of published literature relevant to an assessment of the GRAS status of carbon monoxide in fresh meat packaging, which includes studies specifically addressing this use of carbon monoxide as well as the inadequacy of non-color

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("Meat color is the single greatest appearance factor that determines whether or not a meat cut will be purchased") (citation omitted) (emphasis added); M.C. Hunt *et al.*, American Meat Science Ass'n Comm. on Guidelines for Meat Color Evaluation, Guidelines for Meat Color Evaluation, 44 Proc. Reciprocal Meat Conference 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."); 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) (Kalsec Citizen Petition 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) (Kalsec Citizen Petition at Attachment 12) ("Meat color is the main factor affecting beef product acceptability at retail points of purchase.") (citation omitted); *see also* fn. 83 of the Kalsec Citizen Petition, and accompanying text.

[60] Letter from Robert C. Post, Ph.D., Director, FSIS Labeling and Consumer Protection Staff, to Lane Highbarger, Ph.D., CFSAN Office of Premarket Approval, at 3 (April 28, 2004) ("FSIS April 28, 2004 Letter") (Attachment M) ("FSIS has never regulated nor considered 'use or freeze by dates' as being sufficient for food safety.").

[61] FSIS, Food Safety Focus: Focus on Ground Beef (July 2002), http://www.fsis.usda.gov/Frame/FrameRedirect.asp?main=http://www.fsis.usda.gov/oa/pubs/focusgb.htm ("Although 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.").

spoilage indicators in anaerobic carbon monoxide-containing packaging systems and the realities of temperature abuse in the distribution, handling and storage of fresh meat. This literature documents the substantial controversy among experts about the safety of carbon monoxide in fresh meat packaging. FDA explained in its proposed GRAS notification rule that where the published primary literature raises safety questions about a particular use of a substance, the "general recognition" standard has historically required a demonstration of expert consensus in published secondary sources, through convening an expert panel, or by relying upon an opinion or recommendation of an authoritative body.[62] In this case, the secondary literature further documents the controversy surrounding the use of carbon monoxide in fresh meat,[63] Precept did not convene an expert GRAS panel, and no statements of authoritative bodies support this use of carbon monoxide. Accordingly, the controversy remains unresolved, and the use of carbon monoxide in fresh meat packaging cannot be deemed GRAS.

III. The Pactiv GRAS Notification Does Not Support GRAS Status of Carbon Monoxide in the Retail Meat Package

In asserting the GRAS status of carbon monoxide in fresh meat, the Precept notification relied heavily upon the data submitted in the Pactiv GRAS notification,[64]and shaped the focus of agency review by associating the Precept packaging system with the Pactiv system that FDA had previously accepted as GRAS.[65] The Precept notification was narrowly tailored to focus the safety assessment on the toxicology of the carbon monoxide used in its packaging

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[62] *See* 62 Fed. Reg. 18937, 18943.

[63] *See* Michel Renerre, *Oxidative Processes and Myoglobin, in* Antioxidants in Muscle Foods: Nutritional Strategies to Improve Quality 113, 126-127 (Eric Decker *et al.*, eds., 2000) (Attachment N) ("in modified atmosphere packaging (MAP), there is a need to ensure that bacterial contamination is not masked by color-enhancement processes. This problem is paramount with carbon monoxide packaging") (citing M. Renerre & J. Labadie, *Fresh Meat Packaging and Meat Quality*, 39 Proc. Int'l. Cong. Meat Sci. Tech. 361 (1993)).

[64] *See, e.g.,* GRAS Notice No. GRN 000143, *supra* note 28, at 12 ("Detailed information establishing the GRAS status of CO intended for use in MAP systems for fresh meat is set forth in GRAS Notice No. GRN 000083, the Pactiv notification, which is incorporated by reference herein.").

[65] *See, e.g., id.* at 8 ("The Precept Foods MAP system is a variation of, and would substitute for, comparable systems that have similarly been determined to be GRAS.") and at 11 ("Like Pactiv and Cryovac, Precept Foods has developed a MAP system that employs low levels . . . of CO in a mixture of N2 and CO2. The planned MAP system is similarly designed to deliver high quality case-ready meat products, and to do so in a form that is convenient for both retailers and consumers. In each system, CO serves the same intended purpose -- to stabilize the color of the meat cuts and ground meat packaged therein.").

system. The Precept notification argued that its carbon monoxide packaging system presented no toxicological differences from the Pactiv system, all the while skirting the critical legal and scientific distinctions between Precept's conditions of carbon monoxide use, and thus, also the food safety and consumer deception issues presented.[66]

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 intended to dissipate through the gas permeable packaging before retail sale, thus allegedly having no technical or functional effect in the finished food product sold to consumers.[67] By contrast, in the Precept system, carbon monoxide gas is added directly to the retail meat package where it stays, functioning to impart a red color to the aging meat indefinitely while it remains in the unopened package.[68] This distinction in the carbon monoxide conditions of use is critical for purposes of both GRAS status and labeling requirements.[69]

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[66] *See, e.g.,* GRAS Notice No. GRN 000143, *id.* at 11 ("Although there are differences between the three systems, these differences are not of toxicological significance, as described below.") and at 8 ("This GRAS determination is based upon the same approach used to assess the safety of other MAP systems containing CO -- namely, a comparison of CO intake estimated to result from the specific modified atmosphere of interest to national health-based standards for acceptable exposure to CO in ambient air.").

[67] 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.

[68] *See* Letter from Laura M. Tarantino, Director, CFSAN, to Gary J. Kushner and Anne M. Boekman, Hogan and Hartson (July 29, 2004) ("Agency Response Letter to GRAS Notice No. 000143"), *available at* http://www.cfsan.fda.gov/~rdb/opa-g143.html ("Precept states that the CO is included in the modified atmosphere to help maintain the characteristic color of fresh meat."). Carbon monoxide serves the same function in the Tyson system. *See* 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 ("Tyson states that the CO is included in the modified atmosphere to help maintain the characteristic color of fresh meat.")

[69] This section addresses implications for GRAS status. The implications for labeling are discussed in Section VII, below.

Notably, in the case that a substance that is added to meat qualifies as a "processing aid" under FDA regulations, because it is present at insignificant levels and has no technical or functional effect in the finished food, then such a substance is not required to be listed in the ingredient statement on the food label. While the argument Pactiv advances in its GRAS notification ultimately is unsuccessful, Pactiv attempts to establish that its proposed use of carbon monoxide qualifies as a "processing aid," emphasizing the opportunity for carbon monoxide to dissipate through the gas permeable package before retail sale. Were it the case that the evidence, in fact, had shown that carbon monoxide constituted a processing aid, and had no technical or functional coloring effects in the finished food, then it would qualify as a "secondary direct food additive" that could reasonably be the subject of a GRAS notification, but this is not the case in the Pactiv system. Moreover, since the Precept packaging system involves the direct addition of carbon monoxide to the fresh meat sold to consumers, specifically for coloring purposes, carbon monoxide constitutes neither a processing aid nor secondary direct food additive, and plainly constitutes a color additive and ingredient which must be disclosed in product labeling. The conditions of carbon monoxide use are markedly different in the Pactiv and Precept packaging systems.

To elaborate upon the distinctions between the two systems, in the Pactiv 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. During distribution and storage of meat in the outer bag, the carbon monoxide reacts with the meat to produce cherry-red carboxymyoglobin. At retail, the individual packages are removed from the outer bag and placed on store shelves. The Pactiv GRAS notification included data purporting to show that color is retained only during storage and that color begins to deteriorate after removal of the outer bag and placement of the meat in retail display, although the Pactiv GRAS notification contains conflicting information about the rate at which carboxymyoglobin converts to other pigment forms, thereby allowing color deterioration to occur.[70] The Pactiv notification

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[70] 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 Notification of Pactiv Corporation at 28 (August 29, 2001) ("GRAS Notice No. GRN 000083"). This conclusion appears to have been drawn from the expert report submitted in support of that notification, 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) ("Kansas State study"). 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 (continued...)

also included data that purported to demonstrate that the color of treated meat would deteriorate if exposed to temperature abuse. Based on these data, Pactiv's GRAS notification asserted that the intended use of carbon monoxide in this packaging system was that of a processing aid, because the carbon monoxide had no technical or functional effect in the finished food presented to consumers. Upon categorizing the intended use of carbon monoxide as a processing aid, the Pactiv GRAS notification did not address the applicability of the statutory color additive definition to this use of the gas.

As a threshold matter, the data included in Pactiv's GRAS notification fail to support processing aid status. The contradictory data concerning the rate of conversion of carboxymyoglobin to oxymyoglobin once the meat packages are removed from the outer bag fail to establish that the carbon monoxide has no functional effect in the finished meat package presented to the retail consumer at the point of purchase. Additionally, the Kansas State study submitted in support of the Pactiv GRAS notification acknowledges that carbon monoxide in the Pactiv system does have some effect on color life extension for certain cuts of meat.[71]

Further, the carbon monoxide in the Pactiv system does not satisfy the relevant definition of a processing aid, which means "[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."[72] The carbon monoxide in

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report does not contain any information as to the identity of the pigments on the meat surface or description of experiments to make such 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* Sørheim (1997), *supra* note 27, at 310 ("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*, 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 O) (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).

[71] The Kansas State study, *supra* note 70, 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."

[72] 21 C.F.R. 101.100(a)(3)(ii)(*c*). FSIS acknowledged that this is the relevant definition in this context. *See* Letter from Robert C. Post, Ph.D., Director, FSIS Labeling and Consumer (continued...)

the Pactiv system cannot be a processing aid because it is not added during processing but rather after processing (as well as packaging) has been completed, and because the gas is plainly intended to have a functional effect on the meat, even if this effect is intended to occur only during distribution and storage of the meat in the outer bag. Because carbon monoxide in the Pactiv system does not satisfy the processing aid definition, it is not exempt from ingredient labeling, and its coloring effect in the meat must be considered that of a color additive, which cannot be accepted as GRAS. Thus, even on its own terms, the Pactiv GRAS notification cannot be deemed to have established the GRAS status of carbon monoxide in fresh meat and thereby serve as a springboard for subsequent carbon monoxide GRAS notifications.

Even assuming, *arguendo*, that the Pactiv GRAS notification established GRAS status for the use of carbon monoxide in an outer bag containing retail-ready meat packages, that notification has no relevance to GRAS notifications in which the carbon monoxide is intended for use in the ultimate retail package. Significantly, the Pactiv GRAS notification raised questions about the safety of a packaging system such as Precept's, where the carbon monoxide is retained in the retail package. The Pactiv notification addressed the published literature expressing concerns that the coloring effect of carbon monoxide could mask spoilage, and asserted that such concerns were not present in the Pactiv system because it "does not mask spoilage of the meat" because it "does not involve use of a modified atmosphere including CO in the retail package."[73] Pactiv also recognized that color is the key cue used by consumers to judge fresh meat, and therefore conducted testing to address the question, "did the carboxymyoglobin deteriorate in a predictable way that consumers could continue to use visual color to judge freshness or potential spoilage?"[74] The Pactiv notification also stated that "[o]ne goal of this research was to see if the color of CO-treated meat might mask spoilage."[75] The notification concluded that the carbon monoxide in the Pactiv packaging system did not cause meat color to hide spoilage.[76]

Protection Staff, to Lane Highbarger, Ph.D., CFSAN Office of Premarket Approval, at 2 (February 13, 2002) ("FSIS 2002 Letter") (Attachment P). FSIS has no definition of "processing aid" in its labeling regulations, but rather applies FDA's definition. USDA/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/IngredGuid.htm (last visited June 9, 2006).

[73] GRAS Notice No. GRN 000083, *supra* note 70, at 22.

[74] *Id.* at 31.

[75] *Id.* at 35.

[76] *Id.* at 36.

While extensively referencing the Pactiv GRAS notification, the Precept notification makes no mention of the concerns expressed by Pactiv that carbon monoxide in a retail package could mask spoilage, and fails to address the key distinction that carbon monoxide in the Precept system is intended to remain functional in the retail package. The Precept notification contains no assertion that the proposed use of carbon monoxide is that of a processing aid. Carbon monoxide in that system is not a processing aid because it is intended to have a coloring effect on the finished meat product.

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*), upon facts comparable to those surrounding the use of carbon monoxide in fresh meat packaging. 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.'"[77] 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.[78] 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.[79] The court found that FDA acted within its discretion in reaching this conclusion.[80]

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.[81] 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.[82] While

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[77] 80 F.3d 623, 632 (1st Cir. 1996).

[78] *Id.* at 627, 633.

[79] [1988-1989 Transfer Binder] Food Drug Cosm. L. Rep. (CCH) ¶ 38,062 at 37,901 (D.D.C. 1987).

[80] *Id.* at 38,902.

[81] [1980-1981 Transfer Binder] Food Drug Cosm. L. Rep. (CCH) ¶ 38,065 at 38,304-38,305 (C.D. Cal. 1980).

[82] *Id.*

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*).[83] 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 FDA's definition of a processing aid.

FSIS guidance amplifies FDA's definition of a processing aid in the context of substances for use in fresh meat, and makes clear that substances affecting meat color are not processing aids. FSIS guidance states that, for a substance to meet the definition of a processing aid, 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.[84] 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.[85]

In retail packaging systems such as the Precept system, the carbon monoxide is used precisely to have a continuing effect on the color of treated meat, so that the color is different from that of untreated meat. 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.[86] Where carbon monoxide is intended or permitted to remain functional for its coloring effect in the retail package, the gas cannot be deemed a processing aid.

Because the Precept GRAS notification failed to address this critical distinction between its proposed use of carbon monoxide and that accepted as a processing aid in the Pactiv system, the important question of color additive status was never brought to the fore. However, upon clarification that processing aid status is not available to carbon monoxide in the Precept and other retail packaging systems, it is clear that this use of the gas is not carved out of the color additive definition that would otherwise apply. Because carbon monoxide in a retail meat package functions to color the meat, it is a color additive. As such, it cannot be evaluated through the GRAS notification process, but may be authorized only after notice and comment

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[83] *Id.* at 38,305-38,306.

[84] FSIS Guidance on Ingredients, *supra* note 72.

[85] *Id.*

[86] *See, e.g.*, Precept's April 11 comments, at 9.

rulemaking resulting in an FDA regulation listing the color additive and establishing conditions to ensure the safe and nondeceptive use of the additive.

IV. Precept's Privately-Generated Data Does Not Support GRAS Status

In addition to its heavy reliance upon the previously-accepted Pactiv GRAS notification, the Precept notification also includes reports of three privately-generated internal studies, according to the materials provided to Kalsec in response to a FOIA request to FDA 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.[87] Unlike the Pactiv notification, the Precept GRAS notification contains no report of an independent expert GRAS review panel examining the safety and suitability of the proposed use of carbon monoxide in fresh meat. As a matter of law, the internal unpublished studies cannot support GRAS status of carbon monoxide in fresh meat packaging because the general recognition requirement for eligibility for GRAS status permits unpublished studies to be used only to corroborate published studies already establishing GRAS status, [88] which the literature relating to this use of carbon monoxide fails to do. Substantively, these privately-generated studies fail to establish GRAS status of the use of carbon monoxide in fresh meat packaging because they fail to demonstrate that this use of carbon monoxide will not mask spoilage.

The studies document that the red color of meat packaged with carbon monoxide does not deteriorate even when the meat has spoiled, and fail to show that odor or "use by" date labeling overcomes the loss of this important consumer cue to freshness. These were the key concerns expressed by FSIS in its April 28, 2004 letter to FDA regarding the Precept GRAS notification. First, FSIS observed that the data demonstrated 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."[89] It noted that the data in the Precept GRAS notification show that carbon monoxide "minimizes the degradation of product color that can occur prior to microbial spoilage. Thus, a

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[87] Nancy Rathje & Graciel 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") (collectively referred to as "Precept Reports"). Studies were provided to Kalsec in response to its FOIA request, and are marked "Confidential information."

[88] 21 C.F.R. 170.30(b); 62 Fed. Reg. 18937, 18943.

[89] FSIS April 28, 2004 Letter, at 3.

product that may have microbial levels sufficient to cause spoilage may appear to be acceptable to the consumer."[90] Second, with respect to odor, FSIS observed that any objectionable odor would not be readily apparent until the consumer opened the package at home.[91] Third, FSIS addressed the inadequacy of date labeling, stating that "FSIS has never regulated nor considered 'use or freeze by dates' as being sufficient for food safety."[92]

FSIS sent a subsequent letter to FDA after reviewing additional data submitted by Precept to address the concerns expressed in its April 28 letter.[93] This subsequent letter cites data provided by Precept concerning the shelf life of fresh meat stored in packaging containing carbon monoxide. FSIS stated in that letter that the data indicated that meat remained wholesome before the "use or freeze by" dates proposed by Precept expired. While the three privately-generated studies appear to be the data discussed in this subsequent letter, the reports of these studies do not resolve the three key concerns FSIS posed in its original letter to FDA,[94] and each suffers from serious methodological flaws.

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

The private studies show that the bright red color imparted to the meat by carbon monoxide did not appear to fade while the meat remained in the carbon monoxide-containing package. The studies therefore fail to assuage the concerns originally expressed by FSIS that the

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[90] *Id.* at 2.

[91] *Id* 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 objectionable odor.").

[92] *Id.*

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

[94] 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. Further, to the extent additional data was submitted that has not been provided to Kalsec in response to its FOIA request, such data fails to satisfy the common knowledge element of the GRAS standard. *See* 62 Fed. Reg. 18937, 18943 ("In FDA's view, the common knowledge element of the GRAS standard precludes a GRAS determination if the data and information evaluated by [even] an expert panel are only available in files that are not publicly accessible, such as in confidential industry files.").

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 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 was packaged with carbon monoxide, even in response to age or microbial spoilage. Although it has been established that consumers rely primarily 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.[95] The data therefore fail to respond to FSIS's concern that the red color imparted by carbon monoxide could mask spoilage.

B. 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. However, that study was methodologically flawed 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 product. Specifically, the report fails to indicate whether the aroma evaluation was done by a single person or a panel, by lab technicians or consumers, whether the evaluators were trained, whether it accounted for the

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[95] Notably, FSIS has historically emphasized the need for such consumer behavior data, particularly regarding the use of substances affecting meat color. For example, FSIS deliberately examined consumer behavior evidence when evaluating the use of antioxidants that maintain the color of fresh pork cuts. In that case, the petitioner submitted data reporting on consumer research to determine the habits of consumers when purchasing fresh pork, as well as methods used by consumers to evaluate freshness and wholesomeness. It also evaluated data regarding the typical duration of refrigerated and frozen storage by consumers. These data indicated that consumers use product color as the first test for wholesomeness. FSIS also engaged an independent firm to conduct a study to corroborate data provided by the petitioner. Significantly, that study evaluated the treatment under commercial and retail conditions rather than laboratory conditions, to simulate the consumer's experience. 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).

significant proportion of the vulnerable population whose sense of smell has diminished, and whether the study considered the effect of olfactory fatigue. Since 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.

The May 13 Excel Report also 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, and on a sample-by-sample basis, some of the highest microbial counts were associated with low 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 odor is a predictable or reliable indicator of microbial spoilage. Certainly, these inconsistencies within the notifier's own data preclude GRAS status.

Notably, the study described in the May 13 Excel Report measured odor associated with spoiled carbon monoxide-treated meat <u>after</u> the packaging was opened. 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.

C. 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. 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. 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."[96] 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, described above, 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.[97] This discrepancy precludes GRAS status for carbon monoxide under the conditions of use proposed by Precept, as a documented scientific controversy exists as to the shelf life of meat packaged with the gas.

Further, especially given that date labeling is a cornerstone of the argument in Precept's submissions that the use of carbon monoxide in fresh meat packaging is safe and does not mask spoilage, the failure to provide any evidence that consumers will consult such labeling is fatal to a claim of GRAS status.

Based on the foregoing, it is plain that carbon monoxide in the Precept packaging system is not GRAS. The published scientific literature documents substantial controversy as to the safe use of this gas in fresh meat packaging, and the Precept GRAS notification fails to include any other data or information that would resolve this controversy, as required under FDA's GRAS notification proposed rule.

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

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

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[96] FSIS, "Food Safety Focus: Focus on Ground Beef" (July 2002), at http://www.fsis.usda.gov/Frame/FrameRedirect.asp?main=http://www.fsis.usda.gov/oa/pubs/focusgb.htm.

[97] Opinion of the Scientific Committee on Food, *supra* note 36, at 3.

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.[98] 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.

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 $1x10^5$ to $1x10^6$ 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, while 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.

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[98] June 2006 Scientific Reports, *supra* note 1.

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."[99] 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. 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.

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.[100]

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,[101] 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, as discussed in Section IV.C, above, these data suggest that the accuracy of the asserted 28-day shelf life merits

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[99] FSIS April 28, 2004 Letter, at 2.

[100] Scientific literature suggesting the potential for growth of pathogens in the types of packaging systems at issue was discussed in the Kalsec Citizen Petition at 17.

[101] As noted in n. 1, *supra*, Consumer Reports reported similar findings in its limited study of carbon monoxide-packaged meat.

careful review. Notably, the potential consumer deception and food safety harms presented by an erroneous shelf life estimate would 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.

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 FDA 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 FDA-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.

VI. FDA's Combustion Product Gas Food Additive Regulation Prohibits Carbon Monoxide in Fresh Meat Packaging

As detailed in the Kalsec Citizen Petition and in Kalsec's February 1, 2006 Comments,[102] FDA's food additive regulation at 21 C.F.R. 173.350 prohibits the use of carbon monoxide in fresh meat packaging. Precept's April 11 comments assert that "the plain language of that regulation does not" prohibit the use of carbon monoxide in fresh meat packaging,[103] and selectively reference an FDA press conference without mentioning that Dr. Tarantino expressly stated in that conference that "[t]here is no plain reading of that regulation."[104]

FSIS has made clear to FDA, however, that 173.350 applies to the use of carbon monoxide in fresh meat packaging, and that combustion product gas is prohibited for use in fresh meat because of its deceptive coloring effect. In its February 13, 2002 letter to FDA regarding the Pactiv GRAS notification, FSIS observed that carbon monoxide is considered in the allowance for combustion product gas as a food additive in the packaging of certain foods, and explained that this rule prohibits the use of combustion product gas in fresh meat packaging precisely "because of concerns that the treatment of meat with combustion product gases may

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[102] *See* Kalsec Citizen Petition, at 23-25; Kalsec's February 1, 2006 Comments, at 6-8.

[103] Precept April 11 comments, at 5.

[104] Transcription of the Tuesday, February 21, 2006 teleconference, hosted by FDA/CFSAN (Dr. Linda Tarantino, Mike Herndon, Susan Bro, *et al.*), produced by Powell Tate|Weber Shandwick from a publicly available voice recording on Wednesday, February 22, 2006 (Attachment R), at 5.

cause the meat to retain its fresh red color longer than meat not so treated, thereby misleading the customer and increasing the potential for masking spoilage."[105] More specifically, these well-established concerns about the coloring effects of combustion product gas plainly relate to carbon monoxide, since carbon monoxide is the only combustion product gas that affects meat color in the manner of concern.

FSIS proceeded to analyze the Pactiv system within the applicable regulatory framework, including 21 C.F.R. 173.350. In light of data submitted by Pactiv purporting to show that its system did not result in color life extension once the packages were displayed at retail and that product in packages exposed to mild temperature abuse exhibited color deterioration,[106] FSIS concluded that the use of carbon monoxide in the Pactiv system would not mask color change in a manner that could mislead the consumer and increase the potential for masking spoilage. For these reasons, and significantly, because FSIS accepted the carbon monoxide in the Pactiv system as a processing aid, it determined that 21 C.F.R. 173.350 did not operate to ban the use of carbon monoxide in the Pactiv system.

The significant differences between the Pactiv and Precept packaging systems detailed in Section III, above, preclude the same finding with respect to the Precept system. Precept's submissions do not dispute that the red color attributed by the carbon monoxide in its system does not deteriorate at retail or when the package is temperature abused. The carbon monoxide in Precept's system does not meet the definition of a processing aid in FDA's regulations at 21 C.F.R. 101.100(a)(3)(ii)(*c*), nor did Precept's GRAS notification attempt to characterize it as such. Accordingly, there are no grounds to excuse the carbon monoxide in the Precept system from the prohibition for use in fresh meat packaging codified at 21 C.F.R. 173.350.

As documented in Kalsec's prior submissions,[107] established principles of administrative law prohibit FDA from reversing the codified prohibition on the use of carbon monoxide in fresh meat packaging through the acceptance of a GRAS notification. Such a change can only be accomplished through notice-and-comment rulemaking to amend 21 C.F.R. 173.350.

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[105] FSIS 2002 Letter, *supra* note 72, at 1-2.

[106] As detailed in Section III, above, contradictions within the Pactiv GRAS notification belie the processing aid status of carbon monoxide in that packaging system.

[107] *See* Kalsec Citizen Petition, at 4-5, 24-5; Kalsec's February 1, 2006 Comments, at 7-8.

VII. Carbon Monoxide in Fresh Meat Packaging Must Be Declared on the Label

Carbon monoxide in fresh meat packaging must be declared on the meat label, for three reasons. First, carbon monoxide in fresh meat packaging is a color additive, which is required by statute to be declared in labeling.[108] Second, the carbon monoxide is an ingredient in the meat, and qualifies for no exemption from ingredient labeling requirements. Third, as detailed in Kalsec's prior submissions,[109] the presence and purpose of carbon monoxide in fresh meat packaging is a material fact that must be declared on the label. Because the status of carbon monoxide as a color additive has been detailed in Section I, above, this section addresses only the second and third reasons for label declaration of carbon monoxide in fresh meat packaging.

A. Carbon Monoxide is an Ingredient in Meat, and Qualifies for No Exemption From Ingredient Declaration

Carbon monoxide is an ingredient when used in fresh meat packaging, and as such, it must be disclosed on the meat product label. FSIS defines substances as ingredients "if they remain in the food product and have a lasting effect on the product,"[110] and requires such substances to be identified in ingredient labeling of the meat product.[111] As acknowledged in Precept's GRAS notification and in FDA's Agency Response Letters to Precept and Tyson Foods, Inc. ("Tyson"),[112] carbon monoxide in retail packaging systems remains in the meat at a detectable level and has a lasting technical and functional effect on the color of the meat.[113]

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[108] 21 U.S.C. 343(k); 21 U.S.C. 601(n)(11).

[109] *See* Kalsec Citizen Petition, at 27-29; Kalsec's February 1, 2006 Comments, at 10.

[110] FSIS Guidance on Ingredients, *supra* note 72.

[111] *Id.*; 21 U.S.C. 601(n)(9); 9 C.F.R. 301.1 (definition of "misbranded," subsection (11)). Similarly, the FDCA and FDA regulations require declaration of ingredients in a food fabricated from two or more ingredients, unless an exemption applies. 21 U.S.C. 343(i)(2); 21 C.F.R. 101.4.

[112] Agency Response Letter to GRAS Notice No. GRN 000143, *supra* note 68, and Agency Response Letter to GRAS Notice No. GRN 000167, *supra* note 68 (both acknowledging the lasting functional coloring effect of carbon monoxide in the retail package).

[113] The contentions in Precept's April 11 comments that the carbon monoxide in its packaging system remains at "only residual levels" and "has no effect on meat products as consumed" have no bearing on this analysis. The ingredient definition and exemptions thereto relate only to whether the substance is present in the finished food at "detectable levels" and has an effect on the meat food product to which it is applied, not whether the substance has any effect on the consumer. *See* FSIS Guidance on Ingredients, *supra* note 72.

Accordingly, carbon monoxide is an ingredient in the meat that must be declared in ingredient labeling on the package.

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.[114] While FSIS accepted the use of carbon monoxide in that system as a processing aid,[115] carbon monoxide-containing retail packaging systems are ineligible for any exemption from the ingredient labeling requirement. As discussed in Section III, above, the evidence in the record demonstrates that the processing aid exemption cannot apply to carbon monoxide in such packaging systems, because the stated purpose of this use of the gas is to have a coloring effect in the finished meat product. Indeed, the Precept GRAS notification and related agency documents in the public record do not appear to address the applicability of the processing aid exemption to this use of carbon monoxide.

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 lasting coloring effect on 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."[116] 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 color of the meat. The carbon monoxide accordingly is intended to have a functional effect on the meat, and therefore qualifies for no exemption from ingredient labeling requirements.

Further, while Precept's submissions assert that the carbon monoxide in its system is not a color additive but rather a "color stabilizer" or "color fixative" in fresh meat, such designation does not excuse the gas from identification in the ingredient declaration, as these

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[114] *See* FSIS 2002 Letter, *supra* note 72, at 2-3.

[115] As discussed in Section III, above, the data submitted in support of the Pactiv GRAS notification do not establish the status of carbon monoxide in that system as a processing aid, and therefore the gas must also be labeled where used in the Pactiv system.

[116] Agency Response Letter to GRAS Notice No. GRN 000167, *supra* note 68.

substances remain "ingredients." Indeed, all of the substances that FSIS has allowed for use in fresh meat as "color stabilizers," "color fixatives," "color maintainers" and the like are required to be identified in the ingredient declaration on the meat package.[117] Additionally, FDA's Agency Response Letter to GRAS Notice No. GRN 000015 for the use of carbon monoxide as a component of tasteless smoke for use to protect the taste, aroma, and color of seafood – which is cited in Precept's GRAS notification as evidence of the GRAS status of carbon monoxide – classifies the substance as a chemical preservative that must be declared in the ingredient declaration,[118] consistent with FDA requirements for label declaration of chemical preservatives.[119]

The record reflects no basis for treating carbon monoxide in fresh meat packaging differently. Notably, the purpose and motivation behind the use of ascorbic acid, erythorbic acid, citric acid, sodium ascorbate, and sodium citrate is nearly identical to those advanced in the Precept and Tyson GRAS notifications. Those substances are used in modified atmosphere packaging for fresh meat to preserve the fresh color and appearance of the meats. The proponent of this use of these substances stated that the loss of the fresh color and marketability of untreated fresh meat occurs before the product becomes microbiologically unsafe, and some consumers are reluctant to purchase such meats because of the change to a darker color of the product before spoilage. 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.[120]

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[117] *See, e.g.*, 59 Fed. Reg. 12536 (March 17, 1994) (Final Rule regarding Ascorbic Acid, Erythorbic Acid, Citric Acid, Sodium Ascorbate, and Sodium Citrate on Beef, Lamb, and Pork Cuts) (allowing the use of these substances 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 72 (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."); 21 C.F.R. 172.160, 172.170 & 172.175 (potassium nitrate, sodium nitrate and sodium nitrite codified as "food preservatives," which must be declared in ingredient labeling).

[118] *See* Letter from Janice F. Oliver, CFSAN Deputy Director, to Martin J. Hahn, Hogan & Hartson, L.L.P. (March 10, 2000) ("Agency Response Letter to GRAS Notice No. GRN 000015"), *available at* http://www.cfsan.fda.gov/~rdb/opa-g015.html.

[119] 21 U.S.C. 343(k); 21 C.F.R. 101.22.

[120] 59 Fed. Reg. 12536-7.

This governing agency precedent, as well as general principles of administrative law, [121] require FDA and FSIS to treat carbon monoxide in the same manner as these substances, and to require the gas to be identified in the ingredient declaration on the product label.

In sum, there is no basis in the record to support FDA acceptance of the use of carbon monoxide in meat under conditions of use that do not include ingredient labeling to disclose the use of the gas to affect meat color.

B. The Presence and Purpose of Carbon Monoxide in Fresh Meat Packaging is a Material Fact that Must Be Declared in Labeling

As discussed in detail in the Kalsec Citizen Petition and February 1 Comments, [122] the presence and purpose of carbon monoxide in fresh meat packaging is a material fact that must be declared in labeling, under sections 201(n) and 403(a) of the FDCA, and section 601(n)(1) of the FMIA. This use of carbon monoxide is material in light of the implied representation that the meat is unprocessed and untreated and that its color is a reliable indicator of its freshness, [123] and because of the serious food safety risks attendant to such representation.

FDA has made clear that consumer expectations are relevant to the determination of whether a fact is material and must be declared on the label.[124] For example, in the preamble

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[121] *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."); *see also* Kalsec Citizen Petition, at 4-5, and citations therein.

[122] See Kalsec Citizen Petition, at 27-29; Kalsec's February 1, 2006 Comments, at 10.

[123] Additionally, because carbon monoxide-treated meat packages currently bear no indication of the presence and function of the gas, the assertion in Precept's April 11 comments that the company has no evidence of complaints about such products has no relevance. Consumers having negative experiences with such meat have no way of knowing that the meat has been so treated and that their adverse experiences are attributable to the use of the gas, and thus would not be likely to complain. Further, the record contains no evidence of any systems in place that would capture and classify consumer complaints relating to carbon monoxide-treated meat.

[124] Similarly, 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 (continued...)

to FDA's *trans* fat labeling final rule, the agency 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."[125] Accordingly, FDA concluded that *trans* fat is a material fact which cannot be omitted from the label.[126]

The issues surrounding the use of carbon monoxide in fresh meat packaging are highly analogous. The meat industry and independent consumer research reveals that consumers rely heavily upon meat color in choosing fresh meat for purchase and consumption.[127] The reasonable consumer would likely expect that the color of fresh meat would give them important information relative to the freshness of the product. Yet the omission of the fact that carbon monoxide has been added to make the meat red runs counter to that expectation, impeding rational consumer choice.[128] FSIS has affirmed these principles in requiring label declaration of colorants in meat, explaining 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."[129] The use of carbon monoxide in fresh meat packaging is similarly

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on color in assessing the freshness of has been well documented in the published scientific and meat industry 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.

[125] 68 Fed. Reg. 41434, 41439 (July 11, 2003).

[126] 68 Fed. Reg. 41434, 41450.

[127] See note 59 *supra*.

[128] Consumer interest alone does not make a fact material. Rather, 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 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.)

[129] 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, and cited in Food (continued...)

a material fact required to be declared on the product label. As discussed in Section V, above, this is particularly the case where carbon monoxide is used in packages labeled, "All Natural," which a consumer may reasonably expect to include no substances that would affect the color of the meat. Pursuant to section 201(n), label declaration of the presence and purpose of carbon monoxide such meat packages is required in light of the representations made on the label.

Given the documented consumer reliance upon meat color, which has been well recognized by FSIS, Precept's claim that consumers have other "important product information," such as date labeling, has no bearing on the fact that carbon monoxide's coloring effect in meat is material and must be identified on the label.

VIII. Rulemaking is Required to Ensure a Complete Record on Safety and to Establish Enforceable Conditions of Safe Use of Carbon Monoxide in Fresh Meat Packaging[130]

FDA's acceptance, in coordination with FSIS, of GRAS notifications for the use of carbon monoxide in fresh meat represents a marked departure from established agency precedent. While agency policy generally prohibits the addition of substances to meat that may affect meat color, in those exceptional cases in which FDA or FSIS has authorized such uses, the agencies have traditionally been careful to establish enforceable limitations on conditions of use to protect against consumer deception by issuing regulations through notice and comment rulemaking.[131] FSIS has recognized that, because it must consider actual conditions of use in

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Standards and Labeling Policy Book 11-12 (August 2005) ("artificially colored products"), *available at* http://www.fsis.usda.gov/OPPDE/larc/Policies/Labeling_Policy_Book_082005_1.pdf.

[130] As documented in Section VI, above, rulemaking is also required because current FDA regulations prohibit the use of carbon monoxide in fresh meat packaging, and this ban cannot be lifted except through notice-and-comment rulemaking. *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").

[131] *See, e.g.*, 21 C.F.R. 172.170 (sodium nitrate), 172.175 (sodium nitrite), and 181.34 (sodium nitrite and potassium nitrite); 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); 59 Fed. Reg. 12536 (Mar. 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) and 58 Fed. Reg. 45238 (Aug. 27, 1993) (final rule regarding citric acid as a color preserver on cured pork products).

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-affecting substances.[132]

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.[133] Agency action may be deemed arbitrary and capricious "if its rationale does not appear in the administrative record so that its decisionmaking path may reasonably be discerned."[134] That record must demonstrate that the agency has considered all relevant factors.[135] Because FDA and FSIS have drastically changed course upon reviewing GRAS notifications and requests for acceptability determinations of companies advocating the use of carbon monoxide in fresh meat packaging, the agencies presently cannot demonstrate that they have met their burden of considering all relevant factors.

FDA can only comply with applicable legal requirements by promulgating its new policy through notice and comment rulemaking on the public record. Moreover, if FDA continues to deem the use of carbon monoxide in fresh meat packaging to be safe, rulemaking offers the benefit of lending authority and enforceability to such an agency determination. Given the documented controversy concerning this use of carbon monoxide, rulemaking would afford the agency the opportunity to assure the public and other stakeholders that it has considered all relevant facts, including the European ban and FDA's food additive regulation prohibiting this use of the gas, and explain its conclusion that carbon monoxide is safe and nondeceptive when used in fresh meat. Rulemaking would also enable FDA to more easily and efficiently undertake an enforcement action for violation of the conditions of use specified for this use of carbon monoxide, where those conditions are specified by regulation rather than in a "No Objection"

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[132] *See, e.g.*, 51 Fed. Reg. 30052, 30052 (August 22, 1986) (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.")

[133] *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.")

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

[135] *Id.* at 48.

letter responding to a GRAS notification. Under the Administrative Procedure Act, conditions of use specified in a regulation constitute legally binding requirements, thereby allowing an agency to readily establish that statutory requirements have been violated by showing that the agency's regulation has been violated.

In light of the established controversy about the use of carbon monoxide in fresh meat among scientific experts, governments, consumers, and other stakeholders, rulemaking is required to ensure a complete record on safety and suitability, and to establish enforceable conditions of use to ensure the safe and nondeceptive use of the gas.

Respectfully submitted,

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