

ATTACHMENT 1

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| I. Carbon monoxide in fresh meat packaging is a color additive [p. 6] | CO is <u>not</u> a color additive as used in fresh meat packaging: the gas does not “impart” color to meat because it does not add or change natural meat color in the ordinary sense of the term (i.e., to a degree apparent to the naked eye). In all instances, meat color is a function of myoglobin, which is responsible for the range of colors that occur naturally in meat. |
| In its prior submissions, Kalsec has “comprehensively demonstrated” that CO is a color additive, consistent with FDA’s regulation of substances that “impart” color [p. 6] | Kalsec cites previous submissions that relied heavily on outdated agency precedent, as described in our January 23, 2006 comments, p. 2-4. Continued reliance on these submissions, particularly those citing a tentative FDA position that was later reversed, is misplaced. |
| Precept erroneously asserted that use of 0.4% CO in a MAP system is not enough to impart color: a substance is not exempt from the color additive definition because only a small amount is used [p. 6] | Precept never asserted that a substance is exempt from the color additive definition simply because a small amount is used. The key issue is whether a substance is capable of “imparting” color.(1) Though the use of CO at high concentrations (e.g., 2%) is not relevant to an intended use that is five times lower, CO does not “impart” color to meat at any concentration, as described below. |
| CO is capable of imparting color to meat, and in fact does impart color at a range of concentrations [p. 6] | CO does not add a new or different color to meat at any concentration. The color in meat is a function of myoglobin, which CO stabilizes in the form of carboxymyoglobin. The appearance attributed to CO at higher concentrations results simply from a more extensive conversion of myoglobin to carboxymyoglobin. This is no different from oxygen, which also achieves a different depth of penetration at differing usage concentrations—the appearance of meat in an atmosphere with 21% oxygen is not precisely the same as one with 80%, but oxygen is not regulated as a color additive. |
| Partly because higher usage levels of nitrites do not increase the intensity of the red color of meat, FDA concluded that nitrites merely fix color; the same is not true for CO [p. 6] Because increasing amounts of CO increase the intensity of the red | FDA described the issue of whether nitrites “impart” or merely “fix” color as “turn[ing] on how the chemical reactions [between nitrites and myoglobin] are characterized.” (2) In deciding that nitrites do not “impart” color, FDA decided not to focus too narrowly on such chemical reactions, but to take a practical approach.(1) FDA |

¹ Except as otherwise noted, page references are to the Kalsec comments to FDA, dated June 14, 2006.

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| <p>color of meat, the gas does not simply “fix” color [p. 6-7]</p> | <p>concluded that “nitrites do not add a new color to bacon, but instead react with the naturally occurring pigment in meat (myoglobin) to produce during the curing process a form of the pigment that is more stable.”(3) FDA further stated that the “color of the nitrite-cured bacon is not readily distinguishable . . .from the color of the uncured pork belly at or shortly after slaughter.”(3) This is precisely the case with CO: CO interacts with myoglobin to form carboxymyoglobin, a form of the pigment that is more stable and indistinguishable from the color of fresh meat packed in traditional overwrap packaging.</p> <p>The only observation related to the “intensity” of color in the nitrite decision comes as FDA describes the comments it received:</p> <p>“On technical grounds, the comments argue that the true color-imparting pigment is myoglobin, which can be various shades of purple, red, pink, or brown depending on the compounds with which it interacts. They argue that the effect of nitrites is to maintain the myoglobin in a stable form that is red in color, noting correctly that the intensity of the red color in nitrite-treated meat is related directly to the concentration of the pigment, not the amount of nitrites added to the meat—once the pigment is stabilized by nitrites, the addition of more nitrites does not increase the intensity of the red color. Thus, these comments seem to argue, the color is ‘imparted’ to meat by a naturally occurring pigment; nitrites merely ‘fix’ the pigment in a form that produces a stable, red, color.”(2)</p> <p>These arguments actually support the current status of CO. The color of any meat—nitrite-cured or otherwise—is directly related to the concentration of the pigment myoglobin. Once the pigment has been stabilized, whether in the form of nitric acid myoglobin, oxymyoglobin, or carboxymyoglobin, addition of more nitrites, oxygen, or CO, respectively, does not change the pigment’s color. Use of CO at higher concentrations (e.g., 2%) will simply convert more myoglobin than lower concentrations. Most importantly, however, CO is not used to change the color naturally present in meat.</p> |
| <p>Even 0.4% CO produces a new, visibly different, color in meat, as</p> | <p>This is a misinterpretation of the quoted source. The article states</p> |

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| documented in the scientific literature [p. 7, citing Sørheim (1999)] | that carboxymyoglobin is “spectrally similar” to oxymyoglobin. From the perspective of the color scientist, substances that are “spectrally similar” are often indistinguishable in color when viewed by the naked eye. This is the case for oxymyoglobin and carboxymyoglobin, which have extremely similar absorbance properties. Indeed, the absorbance spectra of the two feature points of maximum absorbance differing no more than 1-4 nanometers, which would not allow meaningful differentiation of these pigments.(4) |
| The fact that the “new pigment” (i.e., carboxymyoglobin) created by CO may be similar to the color of oxygenated meat has no bearing on its color additive status [p. 7] | <p>Carboxymyoglobin is not merely <u>similar</u> to oxymyoglobin; the two pigments are <u>indistinguishable</u> to the naked eye. Whether a substance adds color apparent to the naked eye is central to any “color additive” determination.</p> <p>Carboxymyoglobin is not a “new” pigment but a more stable form of myoglobin; the same is true of nitric oxide myoglobin.</p> |
| <p>The arguments detailed 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” [p. 7]</p> <p>FSIS prohibits the use of even substances that simulate the natural color of fresh meat, such as paprika, which FSIS found to “preserve the red color characteristic of fresh meat even after the articles have begun to spoil” [p. 7-8, fn 18]</p> | <p>Substances such as added oxygen, nitrites, and CO are actually quite unique because they bind with meat myoglobin to form more stable forms of the pigment. Each substance is therefore a color fixative, with varying degrees of stability, but not a color additive. In contrast, a red pigment added to meat would <u>not</u> be merely fixing myoglobin in a stable form, but would be capable of imparting a truly new color to meat (i.e., a color not directly attributed to myoglobin).</p> <p>The color imparted to meat by substances like paprika is not attributed in any way to myoglobin. Further, upon inspection, the presence of such added color would be apparent to the naked eye, even though it may be similar to that of fresh meat. Thus, paprika precedent is not relevant to packaging gases like CO and oxygen. The basic nature of paprika as a solid matter that cannot be removed, once added, no doubt contributed to existing FSIS policy for this color additive.</p> |
| The legislative history for the Wholesome Meat Act amendments “documents serious expressions of concern about additives in meat that were ‘potentially deceptive’ because they masked spoilage by making meat ‘appear to have normal color’ or ‘cancel[led] out the . . . appearance of decaying or unhealthy meat” [p. 7-8, fn 18] | The quoted material reflects only a portion of the actual statements and does not represent the overall context in which the statements were made. As the full statements demonstrate, a major focus at the time of the amendments was concern that state regulation of meat facilities did not provide the same level of protection as Federal |

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| | <p>oversight. The statements also expressly recognize the role of odor as an indicator of spoilage.</p> <p>More specifically, Representative Neal Smith actually said that “This bill would also require imported meat to be handled under the same minimum requirements as domestically slaughtered meat and it would encourage the States to establish or strengthen met inspection services. In many cases, a housewife is not even warned of spoilage by the usual detection of <u>discoloration or odors</u> because chemicals have now been discovered which are used to make the meat <u>appear to have a normal color, odor, and flavor.</u>”(5)</p> <p>Similarly, Senator Mondale, expressing concern about State regulation that did not live up to Federal standards, said that: “We learned during the Senate hearings that the normal rules of consumer self-help are of no value whatsoever in the absence of the Federal stamp of approval. First, modern chemicals and drugs completely nullify the usual tests of <u>sight and smell</u> with respect to meat. Injections of antibiotics, sulfites, and nitrites, and ascorbate—which I call a sort of healthy formaldehyde—<u>cancel out the smell and appearance</u> of decaying or unhealthy meat.”(6) Though Senator Mondale’s views are outdated with respect to concerns about substances like nitrites and ascorbic acid, his point about the important role of Federal oversight remains valid.</p> <p>Mr. Leonard’s statement also recognized the value of regulation, stating that “with the high-speed equipment . . . have come chemical and other ‘fast’ curing processes, artificial tenderizing, artificial smoking, coloring agents, and other additives that are potentially deceptive or dangerous to one’s health <u>when their use is not regulated.</u>” (7) The use of CO as a safe packaging gas is carefully regulated at the Federal level.</p> |

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| <p>II. CO is not GRAS for its intended use in meat packaging</p> | <p>The GRAS status of CO used in fresh meat packaging is well established. The intended use of CO is GRAS because, among other reasons:</p> <ul style="list-style-type: none"> •CO presents no toxicological concerns at the trace concentrations used. •Low oxygen atmospheres, such as vacuum packaging, have a long history of safe use—indeed, most bulk meat is transported to retailers in low oxygen vacuum packaging, where it is then held until placed in consumer packaging. •Nothing about CO changes this established safety profile (most significantly, CO is not reasonably expected to promote pathogen growth). •Use of CO in retail packages has an established safety record in Norway. It is unreasonable to suggest that a system widely and safely used in a country such as Norway for nearly twenty years fails to meet the “reasonable certainty of no harm” standard. •All of the above factors are recognized in the literature; there is no meaningful scientific dispute about these basic facts. |
| <p>“[C]arbon monoxide’s ability to mask spoilage is a major safety concern” [p. 8]</p> | <p>CO does not mask spoilage: it does not prevent spoilage from occurring, nor does it mask tell-tale signs of spoilage such as odor, gas or slime. If spoilage is apparent in any way, it is not masked.</p> <p>Moreover, fresh meat safety is a function of pathogens: for meat to be unsafe, one must assume that pathogens are present, are allowed to grow uninhibited by spoilage organisms, and are not killed by cooking. These conditions, if they exist at all, are independent of color. Thus, red meat can be unsafe; brown meat can be wholesome.</p> <p>Kalsec’s logic also characteristically focuses solely on risk and not on protective factors. For example, spoilage is itself a protective factor, in that pathogens are often poor competitors for resources, as explained in our January 2006 comments. In addition, new research confirms other reports of the beneficial effect of MAP systems, including those with CO, on pathogen growth. Research conducted by Texas Tech University and presented in part at the 2006</p> |

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| | <p>Reciprocal Meat Conference showed that beef inoculated with pathogenic bacteria (<i>Salmonella</i> and <i>E. coli</i> O157) and then packaged in a low oxygen environment with CO had less pathogenic bacteria after 14 days than similarly inoculated beef wrapped in traditional packaging.(8) Publication of this research is in process.</p> |
| <p>Precept's GRAS notice narrowly focused the safety analysis on the toxicology of residual CO in the meat [p. 8]</p> | <p>The toxicology of residual CO was just one part of Precept's safety assessment in GRAS Notification No. 143 (GRN 143). Precept considered all of the factors detailed above, particularly similarities to other systems long accepted as safe.(9) From a safety and suitability perspective, CO environments are no different than other low oxygen systems, such as vacuum packaged meats. Further, Precept incorporated GRN 83 into its GRAS notice by reference, so all of the safety analysis and data submitted as part of that submission are properly considered to be part of GRN 143.</p> <p>It is actually Kalsec that seems to have the narrow focus – it advances arguments suggesting that meat cannot be safely distributed unless it discolors in the package before the end of its shelf life, yet ignores the many years of experience with systems that demonstrate the opposite. Meat does not discolor in vacuum packaging or when cured with nitrites, but these systems and technologies are safe. Deli meats in MAP systems do not discolor, but these systems are safe.</p> |
| <p>Precept's GRAS notice characterizes the intended conditions of use as including only ideal conditions, and relies primarily on evidence generated under "laboratory conditions" of temperature control and lighting, and omitting substantive analysis of actual distribution and retail conditions and consumer behavior [p. 9]</p> | <p>Precept Foods has approximately 185 years of combined experience in the meat industry and carefully designs all studies to reflect realistic conditions of distribution and use. To address the potential for temperature fluctuations, Precept Foods tested performance of the system under abusive conditions and confirmed that the system would not mask spoilage. Precept Foods also takes actual conditions into account as it sets shelf life for individual products, and to date has used a shelf life less than those specified in GRN 143. In other words, the 28/35 day shelf life conditions in GRN 143 are guidelines; Precept Foods selects the time period (not to exceed 28 or 35 days, as applicable) most achievable for any particular product in light of the specific conditions.</p> <p>Moreover, GRN 143 points to practical experience with systems that</p> |

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| | present nearly identical issues, as well as almost twenty years of experience in Norway. This information is direct evidence of actual distribution, retail conditions, and consumer behavior. |
| 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” [p. 9] | As the quote demonstrates, consensus is potentially compromised by an ongoing <u>scientific</u> discussion or controversy about <u>safety</u> . There is no meaningful dispute among qualified scientists as to the safety of CO for its intended use in fresh meat packaging. |
| A. The published literature raises questions about the safety of CO in fresh meat packaging [p. 9] | Kalsec attempts to generate controversy by taking isolated statements in the published literature, some of which are not even safety related, out of context. In fact, the published literature supports the safety of CO, raises no material questions about safety, and reflects no severe conflict of expert opinion regarding the key safety factors detailed above. |
| The Precept GRAS notice failed to include any references to or discussion of the key body of published literature raising questions about the safety of CO in fresh meat packaging [p. 9] | <p>This is a serious mischaracterization of the scientific literature. Kalsec cites five references as evidence of controversy (two by the same lead author), but each of these references actually supports CO safety, as discussed below.</p> <p>Kalsec also mischaracterizes GRN 143. GRN 143 noted that literature addressing CO references objections that color stability may exceed microbiological shelf life, potentially masking spoilage.(10) Though this is not a safety issue, it was noted and resolved.</p> |
| The Precept GRAS notice reflected no review of the scientific literature by an authoritative GRAS panel [p. 9] | A GRAS panel is not a requirement—the requirement is expert consensus regarding safety. Moreover, at least two expert panels on CO safety have been convened, both of which support the use of CO described in GRN 143. The GRAS panel described in GRN 83 notice featured Dr. Sørheim, Dr. Hunt, and Dr. Cornforth, all of whom support the safety of CO in retail packages.(11) A GRAS panel was also convened in the development of GRN 188, currently under FDA consideration, which addressed the use of CO in a retail package.(12) |
| The GRAS notice failed to acknowledge that the two cited Sørheim studies highlighted the controversy surrounding this use of CO [p. 10] | As noted above, GRN 143 did acknowledge and address the suitability objections that have been raised by critics of CO. |

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| | <p>The evidence of “controversy” that Kalsec attributes to Dr. Sørheim actually was a reference to an observation noted in the Kropf paper. In 1997 and again in 1999, Sørheim et al. repeated Kropf’s observation about possible masking of spoilage (discussed more fully below), and responded by stating that any spoilage will be evident based on odor. Specifically, in 1997, Sørheim et al. responded to the Kropf observation by stating that “However, consumers will be able to detect spoilage by the presence of off-odours” (13); in 1999, Sørheim et al. stated that “the consumer must evaluate the microbiological condition of meat in a CO mixture by off-odours.”(14) That these potential concerns did not affect the authors’ judgments regarding safety is apparent when the articles are read in their entirety. For example, in the 1999 paper, the authors noted that “CO used in concentrations below 1% does not present any hazard to the consumer” and “there appears at present to be no fully satisfactory alternative to the CO mixture used in packaging of retail-ready red meats in Norway.”(14)</p> <p>It is especially ironic that Kalsec offers Dr. Sørheim’s work as evidence of controversy, since Dr. Sørheim was a member of the GRAS panel for GRN 83 and has characterized CO as safe for use in retail packages.</p> |
| <p>The GRAS notice failed to acknowledge the Kropf study from 1980, which “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” [p. 10-11]</p> | <p>The Kropf study was cited in GRN 83 and the Sørheim references (which were attached to GRN 83). GRN 143 incorporated these materials by reference.</p> <p>More importantly, the statement does not accurately represent the Kropf reference. After noting that CO was not authorized (in 1980) for commercial use and briefly discussing safety issues, that reference states the following:</p> <p>“However, the regulatory agencies may be more concerned about misrepresentation of the condition of meat products and the <u>possible</u> masking of the microbial condition by the bright red carboxymyoglobin. A combination of CO with other gases, such as CO₂, which control microbial growth, should have better prospects for</p> |

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| | <p>approval.” (15)</p> <p>This reference addresses the potential for consumer deception, not safety. Kropf was correct: each time the agencies have reviewed CO, they have considered the <u>possible</u> masking of spoilage. FSIS considered data and other information relevant to this issue and concluded that spoilage was not masked, a conclusion supported by the literature. In 1997, Sørheim et al. cited the Kropf observation and noted in the very next sentence that “However, consumers will be able to detect spoilage by the presence of off-odours.” The 1980 observation by Kropf—which anticipated that CO could be useful under appropriate circumstances—must be read in this context.</p> |
| <p>The GRAS notice failed to acknowledge the Nissen study from 2000, which found that <i>Salmonella</i> 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 CO mixture than in a high oxygen mixture [p. 11]</p> | <p>The 2000 Nissen study was cited in and attached to (in pre-publication form) GRN 83. GRN 143 incorporated this study by reference.</p> <p>Nissen et al. evaluated the microbiological safety of ground beef packed in three atmospheres: (1) high carbon dioxide/low CO; (2) high oxygen, and (3) “chub” packs, which consist of ground beef packaged in airtight plastic casings. For the high carbon dioxide/low CO mixture, the authors found no or very limited growth of <i>Yersinia enterocolitica</i> or <i>Listeria monocytogenes</i> at normal refrigeration temperatures (4°C or about 39°F). At abusive temperatures (10°C or about 50°F), the authors reported that <i>Y. enterocolitica</i> and <i>Escherichia coli</i> O157:H7 were nearly or totally inhibited. In contrast, growth of <i>Salmonella</i> spp. at abusive temperatures was described as “not inhibited,” a result the authors characterized as “contrary to what is found in many other studies.” (16) The authors also noted that the competitive flora on the samples was initially very low.</p> <p>Not surprisingly, Kalsec focuses only on the <i>Salmonella</i> results, not the broader picture. Indeed, the authors also found that that <i>Y. enterocolitica</i> grew better at both normal and abusive temperatures in high O₂ mixtures and chub packs than in high carbon dioxide/low CO. Does this mean that high oxygen mixtures or chub packs are unsafe? Of course not. The example demonstrates why this type of research,</p> |

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| | though very useful and important, cannot be used in a simplistic manner to assess the fundamental safety of any packaging gas. |
| Nissen et al. recognized that the reason for using CO is to “produce a long-lasting cherry red colour of the meat,” stated that the observed growth of <i>Salmonella</i> does “emphasize the importance of temperature control during storage,” and referenced the range of temperatures experienced by chilled foods at retail [p. 11] | These observations do not suggest any evidence of controversy about CO safety. As stated in GRN 143, CO is used for the purpose of stabilizing meat color. Temperature control is important for all perishable foods. |
| The European Commission’s Scientific Committee on Food decision stated that CO-MAP is “controversial because the stable cherry-colour can last beyond the microbial shelf life of the meat and thus mask spoilage”; the decision found that “the extended shelf life attained by including carbon monoxide in packaging ‘may,’ therefore, under certain conditions imply increased risk of growth of pathogens” and advised that CO “would be safe only if the temperature never exceeds 4° C” [p. 11] | <p>It was unnecessary to specifically address the Scientific Committee on Food opinion in GRN 143 because this opinion views the intended use of CO in a favorable light. The Committee reviewed toxicological and microbial aspects of CO, and concluded as follows:</p> <p>“[T]here is no health concern associated with the use of 0.3%-0.5% CO in a gas mixture with CO₂ and N₂ as a modified atmosphere packaging gas for fresh meat provided the temperature during storage and transport does not exceed 4°C.”(17)</p> <p>Cold chain management is important for any perishable food, not simply fresh meats marketed in MAP systems.</p> <p>As described in our April 11 comments, the Committee also found that CO “may mask visual evidence of spoilage” if meat is stored under inappropriate conditions. The use of CO stabilizes product color, but does not mask off-odors or visual signs of spoilage such as slime or bulging packages.</p> |
| The European Union’s “ban” on CO in fresh meat packaging should not be disregarded as a political “maneuver” [p. 12] | <p>At the outset, it is highly inappropriate to refer to the EU status of CO in fresh meat packaging as a “ban.” There is no Community legislation of which we are aware that affirmatively prohibits the use of CO. Rather, CO is not a permitted packaging gas in the EU because it has not (yet) been approved. This is an important distinction.</p> <p>The vote of the European Parliament committee to not approve CO was not a “maneuver” in any way. Rather, it was a vote by a political body. Of interest, it reportedly was a very close vote, as we</p> |

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| | <p>understand 23 members voted to allow the proposed use of CO, 27 voted against the proposed use, and 4 abstained. The primary point, however, is this: only scientific materials warrant consideration in a GRAS decision.</p> |
| <p>The EU policy on CO was made on grounds analogous to U.S. law and experience, particularly since both EU and U.S. law prohibit additives that may mislead the consumer; further, the European Commission letter attached to Precept's April 11 comments reflected a judgment that CO presents a health risk [p. 12-13]</p> | <p>The proper use of CO does not mislead the consumer. Moreover, regulators in the EU and the United States frequently reach different decisions on questions of both safety and consumer deception. Different regulatory schemes—including dramatically different labeling requirements—for products of modern biotechnology offer just one example.</p> <p>The letter from the European Commission Health & Consumer Protection Directorate-General provides additional insight into the distinctive policy approaches taken in the United States and Europe. In addressing whether to recommend changes to the existing authorizations for nisin, a GRAS antimicrobial in the United States, the letter stated that the “Commission agrees with the principle that antimicrobial agents should not be used in the food production chain.”(18) Though the Commission was actually contemplating an exception for nisin, the fact remains that such a principle is obviously at odds with U.S. law and policy. U.S. agencies are no more bound to accept EU policy on CO than on antimicrobials, biotechnology, or any other matters in which different points of view are evident.</p> <p>As for the Commission statement regarding CO safety, as addressed in our April 11 comments (footnote 10), any perishable food product that is not handled properly may present a health risk to consumers.</p> |
| <p>B. The published literature “documents the inadequacy” of spoilage indicators other than color in anaerobic packaging systems [p. 13]</p> | <p>References to the spoilage literature are selective and ignore practical experience with both CO-containing atmospheres and MAP systems generally. In the past four years, well over 100 million pounds of fresh meat products packaged in low levels of CO have been sold in the United States. Not only has Precept Foods observed no noteworthy trend of consumer complaints regarding these products—sales are strong and increasing, reflecting excellent consumer acceptance and high quality.</p> |

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| | <p>Kalsec's remark that consumers would not know to report negative experiences is nonsense: consumers are the most important judge of product quality and routinely advise when a product is unacceptable or questionable. Across all product lines, Precept Foods, Cargill, and Hormel annually receive thousands of consumer communications, including inquiries, comments, complaints, and compliments. To suggest that consumer feedback is irrelevant or that consumers are unqualified to assess negative experiences defies this practical experience as well as common sense. Moreover, like many other products, all Precept Foods packages using the CO technology bear a toll-free number to ensure that consumers can easily convey any issues or concerns.</p> |
| <p>Other signs of spoilage (e.g., odor, slime, bulging packages) don't assure safety because spoilage organisms that produce such signals are suppressed or altered in anaerobic packaging systems that contain carbon dioxide [p. 13]</p> | <p>Safety is a function of the factors addressed previously, so the presence of a spoilage-indicating odor is not necessary to "assure safety" for purposes of the GRAS standard. Nonetheless, indicators of spoilage are important to suitability. If spoiled, meat packaged in anaerobic atmospheres with carbon dioxide will evidence signs of spoilage such as odor, gas formation, and slime.</p> <p>In an anaerobic environment, lactic acid bacteria will predominate, displacing pseudomonads and other aerobic bacteria.(19) Although lactic acid bacteria typically produce fewer malodorous compounds than the more aerobic bacteria, this does not mean that spoilage is "masked"; it simply means that good quality shelf life is extended because off-odors may not develop as rapidly (though low oxygen systems with CO are not used to extend shelf life beyond similar low oxygen systems). In addition to lactic acid bacteria, low oxygen environments with CO may contain facultative anaerobes such as <i>Hafnia alvei</i> and <i>Serratia liquefaciens</i>. These microorganisms produce putrescine and cadaverine, which are very malodorous compounds. Heterofermentative lactics and enterics can also produce copious amounts of gas, causing swelled packages.(20) Thus, at the end of shelf life, or after extended temperature abuse, spoilage odors and gassy packages will develop.</p> <p>That meat packaged in low oxygen systems with CO can spoil and</p> |

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| | <p>emanate off-odors is reported in the literature and confirmed in the Precept Foods abuse study submitted in conjunction with GRN 143. Indeed, even Kalsec's own research has confirmed the ability of meat packaged in low oxygen environments to spoil and emanate off odors.</p> <p>More recently, this conclusion was yet again confirmed by research conducted by Texas Tech University and presented at the 2006 Reciprocal Meat Conference.(21) In this research, which will be submitted for publication, a majority of panelists detected off odors in ground beef packaged in a low oxygen atmosphere with CO after approximately 14 days of storage in a retail case. Though such products are not actually "spoiled" unless the off odors are sufficient to cause product rejection, the results do confirm that anaerobic packaging systems with carbon dioxide will not suppress the formation of off-odors. It should be noted that the conditions of this test kept the product in a display case for the duration of the shelf life, conditions not reflective of normal fresh meat distribution.</p> |
| <p>Signs of spoilage such as odor aren't sufficient because "a significant portion" of the population at greatest risk for foodborne illness has a compromised sense of smell, as well as individuals with colds or the flu [p. 13, 15-16]</p> | <p>Once again, Kalsec ignores common sense and real-life experience with CO-containing atmospheres and MAP systems generally. Following this line of logic, for example, would lead to the faulty assumption that products such as milk, for which odor is an important sign of spoilage, or MAP-packaged deli meats, for which odor may be the only organoleptic sign of spoilage (other than an off-flavor), are somehow unsafe for consumption by those with a compromised sense of smell. Along the same lines, since Kalsec considers color deterioration to be central to safety, would the company suggest that fresh meat is not safe for consumption by individuals who are color blind or otherwise sight-impaired?</p> |
| <p>Because odor can be detected only after purchase, damage or inferiority would be concealed at the point of purchase, rendering meat adulterated [p. 14]</p> | <p>Odor is not the only signal that may occur with product spoilage; slime and bulging packages are additional examples, both of which would be visible at the point of purchase. The broader problem with this sort of accusation, however, is the continued focus on the most extreme of hypotheticals, while ignoring the millions of high quality products that have been and continue to be sold. Moreover, to the extent that Kalsec intends to imply that the meat industry is somehow trying to "conceal" poor quality products, the accusation is not only incorrect—it</p> |

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| | is highly offensive. |
| Studies submitted by Precept found lower (i.e., more acceptable) odor scores with higher microbial counts, suggesting that odor is a questionable indicator for detecting spoilage [p. 14] | It is inappropriate to attempt to infer that the relationship between microbial growth and odor will be linear. In fact, the type of microorganisms present will substantially affect odor formation. Depending on the microflora, offensive odors may be apparent at 10 ⁴ (indicating spoilage) or may not be detectable even at 10 ⁸ . Total plate count values are suggestive of spoilage, but cannot serve as absolute indicators. |
| Any odor that could be detected when meat spoils in a CO atmosphere would be a unique smell to which consumers are unaccustomed; there is “no evidence in the record establishing that consumers would reliably interpret this odor as a sign that the meat is spoiled and unsafe to eat” [p. 14] | Kalsec approaches CO-containing MAP systems as if they are novel technologies. In fact, nearly twenty years of successful marketing in Norway and four years of experience in this country provide ample evidence for the record that such systems are safe and suitable. Further, any type of low oxygen system, including low oxygen vacuum packaging, retail chub packs, and low oxygen packaging with CO, would be expected to emanate the same sorts of odors upon spoilage, since the microbiology of these products will be similar. In short, odor-specific data of the type suggested are unnecessary. |
| C. The published literature “documents the significant incidence” of temperature abuse [p. 17] | <p>Kalsec improperly attempts to elevate the risk of temperature abuse to a central safety consideration in a GRAS determination. The application of appropriate temperature controls is a fundamental good manufacturing practice (GMP) requirement for all perishable foods. The intended conditions of use on which a GRAS assessment is based necessarily assume GMP compliance. Temperature abuse, therefore, is not part of the intended conditions of use of a GRAS substance.</p> <p>Despite the fundamental role of GMP compliance in a GRAS determination, Kalsec highlights the risk of temperature abuse for CO, while simultaneously assuming that such abuse would have no material consequences for other systems that fail to threaten its livelihood. Would the threat of temperature abuse call into question the safety of carbon dioxide—a GRAS-affirmed antimicrobial gas that Kalsec claims to dangerously suppress spoilage organisms in CO-containing systems? Wouldn't apparently widespread temperature abuse harm all low oxygen products, which Kalsec has admitted are</p> |

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| | <p>safe? What consequence would such a viewpoint have on food products such as fresh produce and deli meats, which are generally consumed without cooking? Kalsec apparently seeks to establish a new paradigm for evaluating the safety of packaging systems for refrigerated foods and substances used therein.</p> <p>The actual risk of temperature abuse is also exaggerated. Kalsec cites FDA Food Code statements about temperature abuse, but does not note that the Food Code describes supermarket meat cases as having a relatively good record of temperature control. The bottom line: improvement in this area is always needed, but temperature abuse is not so prevalent or extreme that it calls into question the general safety of perishable foods, as Kalsec appears to suggest.</p> |
| <p>The Precept position that temperature abuse is not relevant to intended or likely conditions of use for CO is “untenable” in the face of published literature documenting the realities of temperature abuse [p. 17]</p> <p>FDA has determined that the potential for temperature abuse must be acknowledged in risk assessments [p. 17]</p> | <p>We stand by our position that Kalsec’s focus on temperature abuse is speculative, excessive, and misplaced, as described above. Moreover, as explained in our January 23, 2006 comments, the Precept Foods abuse study <u>did</u> account for the risk of temperature abuse by examining performance of the Precept Foods systems at 50°F. This study confirmed literature reports that signs of spoilage will be evident if a product in a CO-containing environment is abused.</p> |
| <p>The analogies to other foods that spoil without noticeable change in color (e.g., milk, eggs) ignores the fact that consumers determine meat freshness based on color [p. 17]</p> | <p>Consumers decide whether to purchase and consume fresh meat not only on color, but also on general appearance, open date codes, and, for opened packages, on odor.</p> <p>Consumer experience with spoilage on foods generally is relevant to fresh meat. Kalsec would have the agencies believe that activities that consumers do every day—evaluate whether to consume food based on a use-by date, odor, general appearance, and color—are somehow irrelevant to meat packaged in CO-containing atmospheres.</p> |
| <p>The record contains no support for the proposition that consumers rely on open date codes, along with odor and slime, in determining meat’s fitness for consumption [p. 18]</p> | <p>In Precept’s experience, consumers widely rely on date codes. Consumer reliance on date codes is also documented in the annual report of U.S. Grocery Shopper Trends, published by the Food Marketing Institute.(22) According to the Trends report, virtually all consumers (99%) are aware of date codes, with 83% of consumers participating in that survey reporting use of date codes with respect to</p> |

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| | <p>fresh meat and poultry specifically. When asked about the frequency with which date codes are used, 92% of consumers responded that they checked date codes “every time” or “fairly often”; 77% reported discarding foods past the use-by date “every time” or “fairly often.”</p> <p>Most participating consumers tied date codes to some degree of health risk: 25% felt eating a food past the code date would present a “serious” health risk; 37% felt it would present “some” health risk; 30% felt a “slight” health risk would be presented. Though such views are inappropriate, since date codes are typically quality-based, the apparent view of date codes as relevant to health further suggests that consumers take date codes seriously.</p> <p>It is important to note that, except for questions focusing on use of date codes in specific food categories, survey questions appeared to address date codes generally.</p> |
| <p>FSIS stated that date labeling is not sufficient to ensure safe handling and consumption of meat, especially since FSIS guidance states that product dating is reliable only if the proper temperature has been maintained [p. 18]</p> | <p>The safety of CO does not rest on date labeling. Safety (i.e., GRAS status) is based on the factors described previously. Key factors are the lack of toxicity under the intended conditions of use and the absence of a negative effect (and indeed, the possibility of a beneficial effect) with respect to pathogen growth.</p> <p>Suitability is based on the fact that CO does not change key meat characteristics and does not mask spoilage. Significantly, a single communication in an extended regulatory review process does not reflect the totality of evidence considered in that review.</p> <p>FSIS consumer guidance appropriately educates consumers to consider all relevant factors when evaluating a product’s condition, and not to rely solely on date labeling. This message reflects prudent advice for all meat products, including those packaged in environments with CO.</p> |
| <p>The secondary literature further documents the controversy surrounding the use of CO in fresh meat [p. 19]</p> | <p>The cited reference does not demonstrate controversy about CO safety or even suitability – it merely notes a need to “ensure that bacterial contamination is not masked by color-enhancement processes.”(23) As explained previously, low oxygen systems with</p> |

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| | CO do not mask spoilage. |
| <p>A GRAS panel would be needed to address the controversy raised in the literature and secondary sources regarding CO [p. 19]</p> | <p>As described previously, there is no meaningful scientific controversy regarding CO safety. Further, at least two GRAS panels have been convened. The GRAS panel described in GRN 83 notice featured Dr. Sørheim, Dr. Hunt, and Dr. Cornforth, all of whom support the safety of CO in retail packages. A GRAS panel was also convened in the development of GRN 188, currently under FDA consideration, which addressed the use of CO in a retail package.(12)</p> <p>Several experts have publicly responded to Kalsec’s campaign against low oxygen systems with CO. For example, in a perspective published in <i>Food Technology</i>, Professors Joseph Sebranek, Melvin Hunt, Daren Cornforth, and Susan Brewer stated that—</p> <p>“The claim that CO packaging will result in unsafe products is not scientifically sound. There is no greater risk of pathogenic bacteria associated with CO packaging than with any other packaging system currently used for fresh meat. In fact, a valid argument can be made that CO packaging creates opportunities to increase safety. It is important to realize that the presence or absence of bacteria of public health significance on meat is independent of meat color.”(24)</p> <p>The views of these and other qualified experts support GRAS status and refute Kalsec’s claim of scientific controversy about safety.</p> |
| <p>III. The Pactiv GRAS notice does not support GRAS status in the retail meat package [19]</p> | <p>GRN 83 set out fundamental principles regarding CO toxicity, the lack of an effect of CO on microbial growth, and practical experience in Norway, all of which are equally applicable to the Precept Foods system. The two notifications differed with respect to the evidence used to establish suitability: Pactiv showed that its system did not mask spoilage because color deteriorated in the retail package; Precept Foods showed that its system did not mask spoilage because signs such as odor will convey spoilage, if any.</p> |
| <p>The Precept GRAS notice stated that differences between the Pactiv and Precept systems its CO system were not of toxicological significance, and did not adequately address “critical” legal and</p> | <p>Differences between the Pactiv and Precept Foods systems were clearly described in GRN 143.(25) The fact that these differences were understood and critically assessed is apparent from Dr. Post’s</p> |

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| <p>scientific distinctions between the two conditions of use [p. 19-20]</p> <p>In the Pactiv system, the CO is intended to dissipate through permeable packaging prior to sale; in the Precept system, CO is added directly to the retail meat package, where it stays and maintains a red color while it remains in the unopened package [p. 20]</p> | <p>letter of April 28, 2004.</p> |
| <p>If CO qualifies as a “processing aid” then it is a secondary direct additive that may reasonably be the subject of a GRAS notification, but CO has a technical effect on color, and therefore is a “color additive” and ingredient [p. 20]</p> | <p>The “processing aid” definition is a labeling concept and a separate issue from the scope of the statutory “color additive” definition.</p> |
| <p>The Pactiv GRAS notice has conflicting data regarding the conversion of carboxymyoglobin to other pigment forms and thus fails to establish the lack of a technical or functional effect in the retail container; further, the data suggest there may be some color life extension as compared to systems without CO [p. 20-22]</p> <p>The CO in the Pactiv system does not satisfy the definition of “processing aid” because it is added after processing is complete and has a technical or functional effect in the finished food [p. 22-23]</p> | <p>Labeling is not required for CO or any other packaging gas under longstanding FSIS policy. Even if the “processing aid” definition is applied, however, CO labeling is still not required. CO is used at trace levels that are insignificant and without a permanent technical effect: once the meat is removed from the atmosphere, carboxymyoglobin will convert to metmyoglobin.</p> <p>The labeling status of CO is necessarily the same as that of oxygen, carbon dioxide, or any other gas used to create a particular packaging environment.</p> |
| <p>The Pactiv GRAS notice raised questions about the safety of using CO in the retail package and asserted that such concerns were not presented by its system [p. 23]</p> <p>The Pactiv GRAS notice also investigated whether consumers could continue to use visual color to judge freshness or spoilage, and concluded that its research showed that the system did not cause meat color to hide spoilage [p. 23]</p> | <p>Actually, GRN 83 cited the Norwegian experience of packaging fresh meats in 0.3 to 0.5% for retail as “further important evidence” of safety for the Pactiv system.(11) The notice also observed that “CO has been used to package fresh meats, even at retail, since 1985, with commercially safe and satisfactory results.” Thus, GRN 83 referenced the Norwegian experience with CO in retail packages as supportive evidence of safety.</p> <p>From an FSIS perspective, a key issue in both GRN 83 and GRN 143 was whether the respective systems would mask spoilage. In GRN 83, Pactiv showed that its system did not mask spoilage because the color would deteriorate in the retail package in a manner similar to other packaging systems. In GRN 143, Precept Foods showed that its system would not mask spoilage based on other signs of spoilage, as well as the similarity of the Precept system to other systems long in</p> |

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| | use (e.g., vacuum packaging). Thus, neither the Pactiv system nor the Precept Foods system will mask spoilage. |
| The Precept GRAS notice extensively references the Pactiv notice but makes no mention of the concerns expressed by Pactiv that CO in a retail package could mask spoilage [p. 24] | GRN 143 noted the objections raised by critics of CO regarding the potential for masking spoilage, and addressed these concerns.(10) |
| <p>The Precept GRAS notice fails to address the key distinction that CO is intended to remain functional [p. 24]</p> <p>The Precept GRAS notice contains no assertion that the proposed use is that of a processing aid [p. 24]</p> | GRN 143 clearly described the Precept Foods system; Dr. Post’s letter of April 28, 2004 demonstrates that the system was understood and critically assessed. There is no requirement to address labeling issues in a GRAS notice or a request for a suitability determination, especially where there is ample precedent such as the longstanding approach to packaging gases. |
| Judicial precedent establishes that substances affecting color or otherwise making a product appear to be of greater value than it is are not processing aids as defined in 21 C.F.R. § 101.100(a)(3)(ii)(c) [p. 24-25] | <p>FSIS makes determinations as to whether a substance is an “ingredient” on a case-by-case basis. These determinations are necessarily food and substance-specific. The cases cited by Kalsec address circumstances that are very different from the use of CO in fresh meat packaging.</p> <p><i>United States v. Randazzo</i> (26) addressed the use of sodium hydroxide to change “grayish and black-striped shrimp harvested in China to look like pink shrimp from the Gulf of Mexico,” a use described by FDA as “chemically burning” the shrimp to a pinkish-orange color.(27)</p> <p>The focus in <i>Sea Snack Foods v. United States</i> (28) was the ability of sodium hydroxide to result in water retention, an effect that would result in consumers paying more for less product.</p> <p>Finally, <i>Stauffer Chemical Co. v. Food and Drug Administration</i>(29) addressed the use of STPP in tuna, which resulted in greater retention of liquid, altered taste and texture, and a lighter color suggesting that the tuna was a higher grade than was in fact the case.</p> <p>These cases were not simply about color—they addressed use of chemicals to make a product appear to be of a completely different origin or grade than was in fact the case. Moreover, each case</p> |

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| | <p>involved net weight considerations, which present an entirely unique set of circumstances; a substance that affects net weight in a meaningful way could never be described as “insignificant.”</p> <p>To the extent that these cases do address color, it is in the context of chemical substances and not packaging gases. A packaging gas that stabilizes color, whether oxygen or CO, differs from a chemical substance that accomplishes the same effect. This difference is based on the long history of packaging gases and the unique relationship between atmosphere, myoglobin, and meat color.</p> <p>In contrast to the facts presented in the above cases, the intended use of CO is solely to maintain the natural color of meat during an established shelf life. CO does not affect net weight or grade of meat, nor does it increase price. If anything, the greater efficiencies made possible by CO will help keep prices low.</p> <p>The proper analysis of ingredient labeling from the Precept Foods perspective is described more fully below in Section VII(A) of these comments.</p> |
| <p>FSIS guidance provides that substances affecting color are not processing aids; classification of a substance as a processing aid requires data showing that sensory characteristics, including color and odor, are not altered as compared to untreated meat [p. 25]</p> | <p>The cited guidance deals primarily with chemical substances such as organic acids. FSIS may reasonably treat packaging gases as unique from solid, liquid, or other substances physically added to meat products. Such substances affect color by modes of action unrelated to atmosphere. Further, as guidance, the document is necessarily non-binding and thus cannot create rigid data requirements.</p> |
| <p>The color additive issue was never effectively raised during the GRAS review process; because CO has a functional effect it is not a processing aid and is therefore not carved out of the “color additive” definition that otherwise would apply [p. 25]</p> | <p>It was unnecessary to raise the color additive issue during the GRAS review process because the precedent is well-settled, particularly in light of the longstanding use of high oxygen systems.</p> |
| <p>IV. Precept’s privately-generated data does not support GRAS status [p. 26]</p> | <p>The studies accompanying GRN 143 were designed to corroborate information in the published literature regarding performance of CO-containing systems under abusive conditions, establish the effective concentration of CO in a modified atmosphere, establish a suitable shelf life, and confirm that the systems will not adversely affect meat</p> |

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| | characteristics. All of these objectives were achieved. |
| The internal studies fail to show that odor or “use-by” dates overcome the loss of color as a freshness cue [p. 26] | Once again, Kalsec approaches CO as if it were a novel technology, but that is simply not the case. The safety and suitability of CO are supported not only by the company studies, but also by the published literature, longstanding experience with consumer reliance on open code dating (especially in connection with the numerous products with stable packaged color, such as poultry, deli meats, and bacon, to name just a few) and many years of marketing experience in this country and in Norway. |
| <p>In its April 28, 2004 letter to FDA, FSIS expressed concerns about the potential for masking spoilage, the inability of consumers to detect odor until a package is opened at home, and limitations of date labeling [p. 26-27]</p> <p>In its June 2, 2004 letter, FSIS cited data, presumed to be the same data submitted with the GRAS notice, that did not appear to resolve the concerns raised in the earlier FSIS correspondence [p. 27]</p> | <p>This cited letter shows that FSIS carefully reviewed the Precept Foods system. The central concern cited by FSIS was whether “product that may have microbial levels sufficient to cause spoilage may appear to be acceptable to the consumer.” This concern, among others, was addressed in additional submissions to FSIS, as well as discussions with the agency.</p> <p>As a result of the additional information and discussions, FSIS was ultimately satisfied that the system did not mask spoilage and was as suitable as other systems long in use.</p> |
| Even if additional studies were submitted, such studies fail to meet the common knowledge element of the GRAS standard [p. 27 n. 94] | The common knowledge element of the GRAS standard requires that data and information pivotal to a safety determination be in the public domain. None of the private studies provided pivotal safety data; they merely corroborated reports in the published literature that CO-containing MAP systems do not mask spoilage. |
| A. The private studies fail to show that CO does not mask spoilage [p. 27] | The published literature reports that CO does not mask spoilage. To confirm that such reports are fully applicable to the Precept Foods system, Excel Corporation undertook a study of the system under abusive conditions (the “abuse study”). Contrary to Kalsec’s arguments, this study did confirm that CO will not mask spoilage. |
| The private studies show that the color resulting from CO does not fade while in the retail package; the May 13 Excel report demonstrated that meat retained the red color associated with CO even when the meat had in fact spoiled [p. 26, 27, 28] | Numerous packaging systems, such as vacuum packaging, maintain a stable product color even in the event of spoilage. The key issue is whether spoilage can be detected through means such as odor or appearance (other than color). Experience with vacuum packaging |

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| | demonstrates that spoilage cannot be masked. |
| Two of the 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 CO does not mask spoilage [p. 28] | Indeed, these studies were not designed to demonstrate that CO does not mask spoilage: that was the purpose of the abuse study. |
| The February 14 Excel report and the June 6 Hormel report used only CO packaging formats, with no control to show how color would deteriorate in packaging to which consumers are accustomed [p. 28] | Again, these studies were designed to address performance of the technology (e.g., usage concentrations and effect on meat characteristics) and shelf life. |
| No consumer behavior evidence was submitted to demonstrate that consumers would consider factors other than color in assessing freshness [p. 28] | <p>It is absurd to suggest that nearly twenty years of marketing experience in Norway, not to mention over four years of experience in this country, do not offer appropriate and relevant evidence of consumer behavior. Rarely is there as much direct experience with a technology or approved substance as there is for CO.</p> <p>Further, consumers do rely on factors such as odor in evaluating freshness. Even the 1988 final rule on organic acids that Kalsec cites states that “data indicated that product color was the first test for wholesomeness, but . . . consumers also used odor and flavor as indicators.” (30)</p> |
| FSIS has historically emphasized the need for such consumer behavior data, especially regarding the use of substances affecting meat color [p. 28 n. 95] | The regulatory approach nearly twenty years ago to uses of chemical preservatives almost certainly viewed as novel at the time is not relevant to packaging systems that are already well-understood, rooted in precedent, and the subject of considerable practical experience. Kalsec’s laser-beam focus completely disregards the entire context in which low oxygen systems with CO are used. |
| B. The private studies fail to show that odor would sufficiently signal spoilage [p. 28] | Abuse studies conducted by Precept Foods confirm reports in the literature that product packaged in low oxygen atmospheres with CO will spoil and will emanate off odors. |
| The May 13 Excel report “fails to provide any experimental details” regarding sensory evaluation [p. 28] | Sensory evaluations in all Excel studies are conducted using trained personnel and widely accepted procedures. The procedures are similar to those described in the literature and those employed in Kalsec’s study. Details regarding these procedures are available to the agencies upon request. |

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| <p>The May 13 Excel report included only mean values, with no indication of variability of the data, especially whether any samples with high microbial counts had low odor scores [p. 29]</p> <p>In the June 6 shelf life study, some samples with higher microbial counts were associated with low odor scores and vice versa, calling into question a claim that odor is a predictable or reliable indicator of spoilage [p. 29]</p> | <p>These comments reflect a fundamental misconception regarding the nature of spoilage. Total plate count values are indicative of spoilage, but cannot serve as absolute indicators of spoilage; sensory characteristics must be considered. Significantly, the type of microorganisms present will substantially affect odor formation. Depending on the microflora, odors may be apparent at 10⁴/g or may not be detectable even at 10⁸/g. Thus, it is inappropriate to attempt to infer that the relationship between microbial growth and odor will be direct and progressive.</p> <p>Accordingly, it is not surprising that unspoiled products such as those examined in the June 6 study may differ microbiologically from products in which spoilage is deliberately induced. The key issue is whether any spoilage that may occur will be evident in a low oxygen system containing CO—the answer is yes.</p> <p>Measures of variance were not included in the abuse study, but Precept Foods would be happy to provide such analyses if requested by USDA or FDA.</p> |
| <p>The “inconsistencies” within the Precept Foods data (i.e., differences in the relationship between odor scores and microbial counts in the abuse study and the June 6 shelf life study) preclude GRAS status [p. 29]</p> | <p>That the studies differed is not surprising. Indeed, a meat scientist would expect a study of abusive conditions on ground beef to differ from a study of standard conditions on intact muscle.</p> <p>Moreover, there is nothing inconsistent regarding the formation of off-odors when a product’s shelf life has been compromised (as in the abuse study) and results reflecting higher microbial counts as the end of shelf life approaches (as in the June 6 shelf life study).</p> <p>Regardless of how the studies are characterized, however, GRAS status is unaffected. Shelf life is an FSIS matter that goes to suitability, not a safety concern.</p> |
| <p>Notably, the May 13 Excel report measured odor only after the package was opened [p. 29]</p> | <p>Signs such as bulging packaging and slime may indicate spoilage in a retail setting. Moreover, low oxygen systems with CO are no different from numerous other products in the marketplace, such as vacuum packaged products and deli meats.</p> |

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| C. The private studies fail to show that date labeling is sufficient for food safety [p. 29] | The shelf life studies were designed to document an appropriate time period during which products packaged in a low oxygen atmosphere with CO can reasonably be expected to be fresh. Just as with low oxygen vacuum packaging or similar systems, the safety of CO-containing atmospheres does not rest on date labeling. |
| In the shelf life studies, meat was kept in laboratory conditions with temperature control unreflective of real-life conditions [p. 29] | <p>Precept Foods is a joint venture between Cargill and Hormel, two of the largest and most experienced red meat companies in the United States, with approximately 185 combined years of industry experience. Consistent with this expertise, the shelf life studies were carefully designed to simulate conditions of centralized production, distribution, and display of retail beef and pork.</p> <p>The conditions studied did reflect optimal temperature control. The potential for temperature fluctuations in the cold chain, however, is addressed not in a single shelf life study, but in ongoing monitoring conducted by Precept Foods. As part of this quality control monitoring, including monitoring of temperature control in retail settings, Precept Foods sets shelf life on a case-by-case basis. Precept Foods considers the 28 and 35-day limits specified in GRN 143 to represent only a guideline, not a requirement; to date, product shelf life has been set much more conservatively than these values. For example, a shelf life of about 24 days has been used for most whole muscle cuts of beef and pork.</p> |
| FSIS has explained that open dating is insufficient to protect consumers because the usefulness of such labeling is dependent on strict adherence to temperature control [p. 29] | <p>Again, use-by dates are important features of many perishable foods, but are only one aspect of product quality. Like hot dogs, luncheon meats, retail chub packs, or numerous other products, a use-by date is interpreted in light of other factors, such as signs of spoilage.</p> <p>The consumer guidance that Kalsec references addressed “sell by” dates as follows:</p> <p>“What is the significance of the "Sell-By" date on the package? “Sell-By” dates are a guide for retailers. 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.</p> |

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| | <p>USDA suggests that consumers cook or freeze ground beef within 2 days after purchase for maximum quality.”(31)</p> <p>In contrast to the “sell by” dates referenced in this consumer guidance, the “use or freeze by” dates accompanying Precept Foods’ products <u>do</u> serve as a guide for consumers and <u>are required</u> by FSIS as a condition of using a low oxygen system with CO. The efficacy of such dates is enhanced by the FSIS guidance, which also addresses the importance of good handling practices and signs of spoilage, such as bad odor and a “sticky” feeling on the outside.</p> |
| <p>Without addressing the potential for temperature abuse, the Precept shelf life studies cannot reliably support open date labeling [p. 30]</p> | <p>Precept Foods takes the potential for temperature fluctuations into account when setting the shelf life for individual products. Significantly, the 28 and 35-day limits for ground products and whole muscle cuts serve as guidelines; these values were never intended to apply to all products. Precept Foods is currently using shelf life limits that are more conservative than these targets, to allow for tolerance and temperature variations. Any reputable company will take the same approach, as a brand cannot survive continual sales of products that have undergone spoilage.</p> |
| <p>The steaks in the June 6 Hormel report were injected with known antimicrobial agents, limiting the application of the results to meat treated with the same agents [p. 30]</p> | <p>This concern was raised by FSIS in its April 28, 2004 comments and addressed with additional data and discussions. The pertinent data included studies in which untreated meat was examined, as well as data for untreated ground beef, which represents a worst-case scenario from a spoilage perspective.</p> |
| <p>The Precept Foods studies establish a shelf life for meat packaged in CO that differs substantially from the shelf life noted by the European Commission’s Scientific Committee on Food—this precludes GRAS status by demonstrating a scientific controversy regarding shelf life [p. 30]</p> | <p>Kalsec confuses the GRAS standard by attempting to elevate shelf life to a basic safety issue. The focus of a GRAS determination is necessarily whether a substance can be safely used for any appropriate shelf life. In contrast, the specifics of shelf life are determined on a case-by-case basis, taking into account such factors as raw material quality, the type of meat product, distribution needs, likely temperature variations, and similar conditions.</p> <p>Significantly, the reference to shelf life by the Scientific Committee on Food was simply a recognition of shelf lives obtained in the Sørheim et al. 1999 study. It was not a recommendation on the</p> |

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| | commercial shelf life for all meat products stored in low oxygen atmospheres with CO. |
| V. New data lend support to potential food safety and consumer deception concerns about the use of CO [p. 30] | As the authors admit, the new study is limited, involving “a relatively small number of ground beef samples purchased in a local region.” The panel was neither blinded nor unbiased, relying on an open-label design, with subjective issues such as aroma evaluated by Kalsec employees and laboratory consultants. Also problematic are potentially confounding factors, such as the selection of low oxygen packaging from one store and high oxygen packaging from another, with no attempt to record initial temperatures of the ground beef or the retail display case. This one difference, alone, could render the initial APC and AnPC data meaningless. |
| Limited studies commissioned by Kalsec show that, on average, commercially available ground beef packaged in CO had a statistically significant higher bacterial count than commercially available ground beef packaged in high oxygen MAP [p. 31] | Even if the cold chain temperatures are assumed to be similar for the different packaging formats, the differences in APC and AnPC data are not surprising and attributable to other storage differences. In all studies, the CO-MAP product was approximately <u>two weeks</u> older than the high oxygen samples. Higher AnPC counts in the CO-MAP samples indicates that the population is composed primarily of lactic acid bacteria. |
| Some of the CO-packaged beef products were found to have bacterial counts indicative of spoilage (i.e., greater than 10 ⁷ colony forming units per gram), but none of the high oxygen MAP products did [p. 31] | The authors assume that when microbial counts reach 10 ⁷ /g, the product is automatically spoiled. This is a gross oversimplification of food spoilage. Obvious signs of spoilage can occur at 10 ⁴ if certain types of microorganisms predominate, while ground beef that contains 10 ⁷ /g can be organoleptically acceptable if the predominant flora consists of homofermentative lactic acid bacteria. |
| Carboxymyoglobin is stable following temperature abuse or spoilage, but high oxygen products became “discolored” when bacterial levels reached around 1x10 ⁵ to 1x10 ⁶ per gram [p. 31] | As we have stated repeatedly, color is a poor measure of spoilage because it is a function of oxidation, not microbial growth. Of note, in three separate sensory evaluations of extremely temperature abused product (70°F), the low oxygen product with CO displayed obvious signs of spoilage <u>before</u> the high oxygen product.(32) Specifically, in the first Kalsec study (Table 1B, p.6), the CO-MAP had “noticeable sulfur comp odor” while the high oxygen product had “slight butter/oxidized odor.” In the second study (Table 2C, p. 9), the |

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| | <p>CO-MAP had “off odor, sulfur comp odor,” while the high oxygen system had a “slight oxidized odor.” In the third study (Table 3C, p. 12), CO-MAP had “noticeable sulfur comp odor”; the high oxygen packaging had “slight oxidized odor.”</p> <p>Kalsec has essentially argued that spoilage is masked if any sign of spoilage is not immediately apparent. Precept Foods does not agree with this position, but if Kalsec is indeed correct, is the rosemary extract in these high oxygen packages masking spoilage? Presumably referring to off flavors, which can signal spoilage, Kalsec’s website explains that rosemary extract “is ideally suited for addition to any food product or ingredient that could benefit from the mild masking effect of rosemary flavor.”</p> <p>http://www.kalsec.com/products/herbalox_season_over.cfm (accessed August 2006). If the same degree of scrutiny were applied to rosemary extract as Kalsec suggests should be applied to CO—which would be inappropriate—one might well reach the conclusion that rosemary extract is “masking spoilage,” based on this description. Since it is the total picture of product quality that is controlling (e.g., color, odor, flavor, etc.), neither rosemary extract nor CO is reasonably described as masking spoilage.</p> |
| <p>Ground beef packaged in a CO-containing environment was observed to have a “sulfury odor”; ground beef packaged in high oxygen was observed to have a rancid odor more commonly associated with meat spoilage [p. 31]</p> | <p>The issue is whether the odor is objectionable. Whether “sulfury” or rancid, an off odor is objectionable and a sign of spoilage.</p> |
| <p>The higher microbial levels and color in the products packaged in CO validate concerns that use of CO in fresh meat packaging may make “bacterially contaminated meat” to be fresher or of better quality than it actually is [p. 32]</p> | <p>It is important to note that spoilage organisms are natural constituents of meat and desirable to keep any pathogens that may be present in check. Thus, it is unclear precisely what Kalsec intends to convey in its reference to “bacterially contaminated meat.” Spoilage organisms are expected and not a safety concern, while pathogen contamination can occur without any visible signs. In this regard, CO-containing formats are no different from high oxygen packaging, vacuum packaging, or other types of packaging—that is, meat containing high levels of microorganisms could appear acceptable. Indeed, if the microorganisms are naturally occurring spoilage organisms, it is not the level, but the undesirable effects (e.g., off odors, off flavors, or</p> |

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| | comparable indicators) that render the product “spoiled.” |
| The “high levels of bacteria and significant growth rates” observed for aerobic and anerobic bacteria suggest that CO-containing systems will also support increased growth of pathogens [p. 32] | As discussed previously, this speculation is contrary to the published literature (e.g., Nissen et al. 2000) and more recent data generated by Texas Tech University (in publication). |
| The data also call into question the 28-day shelf life specified in the GRAS notices [p. 32] | One limited study does not call into question a shelf life validated with sound data and experience. Moreover, the shelf life presently in use for ground beef products packaged in CO-containing environments is 21 days, not 28, and is comparable to the shelf life used for similar low oxygen systems (e.g., retail chub packs, with a shelf life of around 20 days). There is no reason why low oxygen environments with CO should be treated any differently from other low oxygen formats widely in use. |
| Though the studies are limited and cannot fully explain the “high levels of bacteria” found in CO-containing systems, they suggest that a careful evaluation of microbial safety issues is merited [p. 33] | It is inappropriate to suggest that one limited study should override the literature and nearly twenty years of experience with CO-containing systems, including four years in this county. |
| VI. FDA’s Combustion Product Gas regulation prohibits CO in fresh meat packaging [p. 33] | <p>The combustion product gas regulation does not apply to CO because it addresses a different product. Kalsec would have the agencies interpret this regulation in a way that would preclude the use of well accepted gases that are also present in combustion product gas, such as carbon dioxide, in fresh meats.</p> <p>Moreover, solely for the sake of argument, even if the regulation did apply, it does not prohibit the use of CO. Thus, it does not preclude a GRAS determination, some 40 years after the regulation issued, for CO.</p> |
| Precept incorrectly asserted that the plain language of the combustion product gas regulation does not prohibit the use of CO in fresh meat [p. 33] | The regulation states that combustion product gas may be used to “displace or remove oxygen in the processing, storage, or packaging of beverage products and other food, except fresh meats.” An exception, which merely carves out a food category from an approval, is not the same as a prohibition. The point, however, is entirely academic because the regulation addresses a specific type of gas mixture and not isolated CO, as explained in our January 23 letter. |
| FSIS has applied the combustion product gas regulation to fresh meat | When combustion product gas was approved in the 1960s, approval |

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| <p>packaging, and has made clear that combustion product gas is prohibited because of its “deceptive” coloring effect [p. 33]</p> | <p>for fresh meats may well have been withheld due to concerns about the potential for masking spoilage, but this is not surprising. This precedent is necessarily specific to combustion product gas and its particular intended conditions of use, as well as the state of the industry at the time. It does not preclude a determination, some 40 years later, that a different system could employ CO without masking spoilage or deceiving the consumer. Notably, at the time combustion product gas was first approved, there was no widespread history of use of low oxygen vacuum packaging.</p> |
| <p>FSIS determined that the combustion product gas “prohibition” did not ban use of CO in the Pactiv system because FSIS concluded that the system did not result in a color life extension and the CO was a processing aid [p. 34]</p> | <p>FSIS did not apply the combustion product gas regulation directly to CO in assessing GRN 83. Rather, FSIS cited the regulation as a way of introducing the relevant suitability issue—whether use of CO may mask spoilage. In other words, in evaluating any CO-containing system, FSIS considers the potential for masking spoilage.</p> <p>There is more than one approach to demonstrating that a system does not mask spoilage. FSIS concluded that the Pactiv system did not mask spoilage because color deteriorated in the retail package, among other considerations. FSIS concluded that the Precept Foods system did not mask spoilage because of other factors, such as odor, as well as the similarity of CO-containing formats to other low oxygen systems. Both approaches are legitimate ways to show that spoilage is not masked.</p> <p>Further, the letter demonstrates the agencies’ interpretation of the combustion product gas regulation. For example, FSIS pointed out that CO is “considered in the allowance for combustion product gas,” distinguishing CO and combustion product gas as different materials. Indeed, if the regulation rigidly applied to CO and imposed a prohibition on CO as such, FDA and FSIS would have simply objected to GRN 83, without considering its conditions of use. The fact that FSIS found CO to be a processing aid does not change the result, since combustion product gas is itself a processing aid, as a secondary direct food additive.</p> <p>In addition, Kalsec’s argument that any system resulting in a color life</p> |

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| | extension is per se unsuitable is not consistent with FSIS precedent. Certainly, high oxygen systems result in a color life extension beyond meat held under normal atmospheric conditions, but such systems do not deceive the consumer. |
| VII. CO in fresh meat packaging must be declared on the label [p. 35] | This allegation seeks to change long-standing FSIS policy regarding the labeling of packaging gases. As described more fully below, CO as used in fresh meat packaging is neither an "ingredient" nor a material fact that must be disclosed. |
| A. CO is an ingredient in meat, and qualifies for no exemption from ingredient labeling [p. 35] | <p>Under section 1(n)(9) of the Federal Meat Inspection Act, ingredient labeling is required for any food that is "fabricated from two or more ingredients." FSIS determines whether a substance is an "ingredient" on a case-by-case basis, an inquiry that is necessarily food and substance-specific. Safe and suitable gases, including carbon dioxide, oxygen, and CO, have long been used to create desirable packaging environments, but such gases are not used to "fabricate" any meat product within the meaning of section 1(n)(9). In other words, meat products packaged in a beneficial environment are not properly considered to be "fabricated from two or more ingredients."</p> <p>For example, carbon dioxide has been known to beneficially affect the shelf life of meat since at least 1882.(19) High oxygen atmospheres are used for their effect on color in the retail package. Despite these well-known benefits, FSIS and FDA have not required packaging gases to be labeled as ingredients. An ingredient labeling requirement for CO used as a packaging gas would represent a dramatic shift from this well-settled precedent.</p> |
| <p>FSIS considers substances to be ingredients if they remain in the food product and have a lasting effect [p. 35]</p> <p>CO as used in fresh meat packaging remains in meat at a detectable level and has a lasting technical and functional effect on color [p. 35]</p> <p>The fact that CO is a packaging gas does not excuse it from the ingredient definition, as it reacts with meat, remains in meat, and has a lasting coloring effect [p. 36]</p> | <p>FSIS judges whether a substance is an "ingredient" or a "processing aid" on a case-by-case basis. FSIS has never classified packaging gases as ingredients.</p> <p>As a matter of policy, FSIS has historically applied FDA's "processing aid" definition in assessing whether ingredient labeling is required, although that definition merely serves as guidance and is not binding. Even if that definition is applied, however, CO labeling is still not required. CO is used at trace levels that are insignificant and without</p> |

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| <p>FSIS made clear that CO in fresh meat packaging is an ingredient, unless otherwise exempt, as it evaluated the Pactiv system [p. 36]</p> | <p>a permanent technical effect: once the meat is removed from the atmosphere, carboxymyoglobin will convert to metmyoglobin.</p> <p>Once again, there is no reasonable basis for distinguishing CO from other packaging gases currently used to create favorable packaging environments, especially oxygen. Significantly, the fact that CO is more effective at color stabilization than oxygen does not change the result—both are used for a technical effect on color in the retail package.</p> |
| <p>The Tyson conditions of use make clear the interaction between CO and meat in that system, reflecting a calibration of the CO “dose” [p. 36]</p> | <p>Again, the same is true of oxygen and any other gas used to create a particular packaging environment. Labeling is not required.</p> |
| <p>Classification of CO as a color stabilizer doesn’t excuse the gas from ingredient labeling [p. 36-37]</p> | <p>Due to the unique effect of packaging gases, it doesn’t matter whether the purpose of the gas is to stabilize color or achieve a different effect: labeling is still not required under longstanding FSIS policy.</p> |
| <p>Tasteless smoke, which is cited in support of the GRAS status of CO, is classified as a chemical preservative and must be declared as such; there is no basis for treating CO in fresh meat packaging differently [p. 37]</p> | <p>Safety and labeling are entirely different issues. In terms of incidental additive labeling, precedent is paramount. The labeling of tasteless smoke follows the well-established practice of labeling liquid and other types of smoke as ingredients.</p> |
| <p>The FSIS labeling precedent for ascorbic acid, erythorbic acid, citric acid, sodium ascorbate, and sodium citrate is applicable to CO, as the purpose and motivations for use of these substances are nearly identical to those for CO [p. 37]</p> | <p>The cited precedent deals with chemical substances such as organic acids. FSIS may reasonably treat packaging gases as unique from solid, liquid, or other substances physically added to meat products, which affect color and other meat characteristics in ways unrelated to atmosphere.</p> <p>In its focus on precedent for substances such as ascorbic acid, which almost certainly were novel when first evaluated in the 1980s, Kalsec ignores the more applicable agency precedent for packaging gases. Gases have been used for many decades to create desirable atmospheres for food product storage and handling, but labeling is not required, even in the package.</p> |
| <p>General principles of administrative law require FDA and FSIS to treat CO in the same manner as ascorbic acid and similar substances [p.</p> | <p>FDA and FSIS are not required to regulate substances in a similar manner if there are meaningful differences between the two, as is the</p> |

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| 38] | case with packaging gases and substances such as ascorbic acid. Indeed, to treat CO differently from oxygen or carbon dioxide would violate the very principles that Kalsec relies upon. |
| There is no basis in the record to support acceptance of CO under conditions of use that do not include ingredient labeling [p. 38] | There is no requirement to address labeling in a GRAS notification or a request for a suitability determination. Moreover, the precedent with other functional packaging environments provides ample precedent for not labeling CO in fresh meat packaging. |
| B. The presence and purpose of CO in fresh meat packaging is a material fact that must be declared in labeling [p. 38] | The presence and purpose of CO in fresh meat packaging is not a material fact for which labeling is required. |
| <p>The use of CO is material in light of the implied representations that the meat is unprocessed and untreated and that color is a reliable indicator of freshness, as well as “serious food safety risks” [p. 38]</p> <p>The fact that industry has received no complaints about products packaged in CO-containing atmospheres has no relevance because consumers would not know to report “negative experiences” with any such products and because the record contains no evidence of any systems that would capture and classify relevant consumer complaints [p. 38 n. 123]</p> <p>Use of CO is material for labeling purposes because consumers need to know that the color of such products is not a reliable indicator of freshness; consumers rely heavily on meat color in choosing fresh meat, and the omission of CO information impedes rational consumer choice [p. 38 n.124, 39]</p> <p>In light of consumer reliance on color, other labeling information, such as date codes, has no effect on materiality [p. 40]</p> | <p>Materiality must be assessed in light of the current commercial and consumer landscape. Commercially available fresh meat products spend a substantial portion of shelf life in atmospheres designed to promote optimal quality and color in a manner similar to low oxygen systems with CO. For instance, high levels of oxygen are used in a carefully calibrated manner to extend color life in the retail package, and traditionally packaged meats are shipped and stored in low oxygen vacuum packaging before being further processed and packed into retail containers. Kalsec’s logic would suggest that such products are inappropriately represented as “unprocessed” and “untreated,” but labeling is not required.</p> <p>The lack of ingredient or other gas-related labeling is especially noteworthy with respect to high oxygen systems, which are prone to off-flavors and premature browning of cooked meat. Though high oxygen packaging remains safe and suitable, the need for good handling practices is paramount. The possibility that cooked color may not be representative of a high internal temperature is addressed adequately through safe handling statements, not ingredient or other labeling. The example demonstrates how Kalsec’s laser beam focus on CO as part of its public relations campaign fails to account for the broader regulatory and consumer perspective.</p> <p>In sum, from a materiality standpoint, the key factors are (1) the ability of meat in any low oxygen atmosphere to spoil and evidence signs of spoilage when severely abused; and (2) existing labeling, including</p> |

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| | <p>safe handling statements and date coding, that provides important product information; and (3) availability of a toll-free number, which Precept Foods provides on every product packed in a low oxygen environment with CO, to call with questions or comments.</p> <p>With specific regard to consumer feedback, longstanding experience with low oxygen and other systems confirms that, regardless of the packaging format, both retailers and consumers report when a product is of unacceptable or questionable quality. Across all product lines, Precept Foods, Cargill, and Hormel annually receive thousands of consumer communications, including inquiries, comments, complaints, and compliments. To suggest that consumer feedback is irrelevant or that consumers are unqualified to assess negative experiences defies this real-life experience as well as common sense.</p> |
| <p>Under FDA policy, such as the precedent for <i>trans</i> fat labeling, consumer expectations are relevant to determining whether a fact is material and should be labeled [p. 38-39]</p> | <p>FDA required <i>trans</i> fat labeling pursuant to the Nutrition Labeling and Education Act (NLEA); labeling of meat and poultry products is governed by FSIS pursuant to the Federal Meat Inspection Act and the Poultry Products Inspection Act. Regardless of the statutory scheme, however, materiality assessments are necessarily made on a case-by-case basis. A materiality assessment that addresses nutrition labeling, which involves a particular regulatory and consumer landscape, is quite different from a materiality assessment made for other purposes, such as packaging composition. Kalsec repeatedly suggests low oxygen packaging with CO to be novel, but in fact, the effects of these systems are consistent with well-accepted and widely used packaging formats for which gas-specific labeling has never been required.</p> |
| <p>Consumer interest alone does not make a fact material [p. 39 n. 128]</p> | <p>This is correct.</p> |
| <p>FSIS has explained that color that may deceive the consumer into believing a product is of a different color, quality, or kind than expected must be indicated by a statement [p. 39]</p> | <p>The use of CO does not deceive the consumer in believing the product is of a different color, quality, or kind of meat than expected. Low oxygen systems with CO maintain the natural appearance of meat products, stabilizing the natural color and reflecting the same quality and kind of meat that would be apparent absent the use of CO. The centrally applied “use or freeze by” date informs the consumer of the period in which the meat will be fresh.</p> |

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| <p>VIII. Rulemaking is required to ensure a complete record on safety</p> | <p>Rulemaking is not required and would be a waste of agency resources.</p> |
| <p>FDA's acceptance of the GRAS notifications for CO represents a departure from agency precedent [p. 40]</p> <p>Agency precedent is either to disallow substances that affect meat color, or to establish enforceable limitations through notice-and-comment rulemaking [p. 40]</p> <p>An agency must offer a reasoned explanation for its change in view when it departs from previous positions [p. 41]</p> | <p>On the contrary, it is Kalsec that proposes a departure from agency precedent, including precedent concerning color additives, combustion product gas, and packaging gases generally.</p> |
| <p>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 [p. 41]</p> | <p>The administrative record is sufficiently detailed, especially in light of the considerable precedent and experience with packaging gases.</p> |
| <p>Rulemaking is necessary to provide an opportunity for public input and assure the public that all relevant facts have been considered [p. 41]</p> | <p>As Kalsec has demonstrated, to excess, the FDA Citizen Petition process allows public input to be provided on any issue at any time.</p> |
| <p>Rulemaking is necessary to establish enforceable conditions of safe use of CO [p. 41]</p> | <p>Rulemaking is unnecessary and would be a waste of agency resources. It is difficult to imagine conditions that could be more enforceable than those imposed in order to receive the mark of federal inspection of meat products.</p> |
| <p>IX. The intended use of CO is not suitable for fresh meat packaging under FSIS requirements [FSIS letter p. 7-38]</p> | <p>The intended use of CO is suitable and consistent with longstanding FSIS policy, as described throughout these comments.</p> |
| <p>Meat is adulterated under the Federal Meat Inspection Act if "damage or inferiority has been concealed in any manner . . . or if any substance has been added thereto or mixed or packed therewith so as to . . . make it appear better or of greater value than it is." [FSIS letter, p. 7]</p> | <p>The use of CO does not conceal damage or inferiority, nor does it make meat appear to be of better or greater value than it is, consistent with section 1(m)(8) of the Federal Meat Inspection Act. CO does not change the natural color or quality of fresh meat products. Low oxygen packaging with CO delivers high quality meat products just as low oxygen vacuum packaging, under substantially the same conditions, including shelf life.</p> |

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| | <p>For instance, where vacuum packaging is used in connection with traditional overwrap packaging, the low oxygen atmosphere is removed just prior to repackaging and retail display, but the basic product nature and total shelf life will be similar, if not identical, to products packaged with CO. In both types of systems, the meat is equally fresh and of a comparable quality. Of note, in a low oxygen system with CO, the natural quality of the meat is maintained without the need for added ingredients, such as rosemary extract, to counter the off-flavors and similar disadvantages of high oxygen systems.</p> |
| <p>The use of CO is inconsistent with FSIS guidance, which provides that substances adulterate or misbrand meat by “making products look better or of greater value than untreated products or masking normal spoilage indicators” [FSIS letter, p. 8-9]</p> <p>FSIS policy prohibits the use of substances in meat that “mask” discoloration, a normal spoilage indicator. [FSIS letter, p. 9]</p> | <p>The cited guidance does not restrict the use of CO. As described immediately above, low oxygen systems with CO do not make meat appear to be “better or of greater value than untreated products.” Meat products packaged in CO will be of equal quality to conventionally packaged meat, which is almost universally held in a low oxygen atmosphere until packaged at the retail level. Additionally, the use of CO does not mask spoilage—if spoilage is apparent, it is not masked.</p> <p>Kalsec improperly reads FSIS guidance to mean that color stabilization of any sort is necessarily prohibited, but that is not the case. As compared to “untreated” products, nitrite-cured meats and vacuum-packaged meats both have stable colors, and high oxygen systems extend color life from 3-4 days to 10 or more days. These technologies, among others, are suitable.</p> |
| <p>CO is an unapproved color additive and produces a “new” pigment not found naturally in meat [FSIS letter, p. 9-16]</p> | <p>As discussed in detail above (Section I) and in our previous comments, CO is not an unapproved color additive and does not create a “new pigment” – it creates a more stable form of myoglobin, like nitric acid myoglobin. As also discussed above, Kalsec misinterprets the cited Sørheim reference to mean that carboxymyoglobin and oxymyoglobin are visually distinct, when that is not the case.</p> |
| <p>CO is not suitable under FSIS’s restrictive policy towards color-altering substances in fresh meat and related precedent [FSIS letter, p. 17-22]</p> | <p>The suitability determinations for CO are not inconsistent with FSIS policy regarding color-altering substances. Significantly, CO does not “alter” color—it stabilizes the natural color of fresh meat and thus results in a color indistinguishable from meat exposed to air. The</p> |

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| <p>FSIS bans sorbic acid and its salts by regulation because these substances inhibit development of select aerobic bacteria that produce visual clues of spoilage, while simultaneously permitting growth of other organisms that present health hazards [FSIS letter, p. 17]</p> <p>Where FSIS has decided to permit a substance that may modify color, it has done so only after requiring labeling disclosure and typically after proceeding by notice-and-comment rulemaking [FSIS letter, p. 19]</p> | <p>suitability of this effect is well-established, based on the natural relationship between meat color and atmosphere and the precedent established by other packaging systems. Both vacuum packaging and high oxygen formats delay discoloration and therefore affect color directly in the retail package, but neither technology (nor oxygen as an added packaging gas) is regulated in the manner Kalsec suggests is required.</p> <p>A comparison to the sorbic acid prohibition is similarly inapt. As described previously, CO is not used for any antimicrobial effect on either spoilage organisms or pathogens. The carbon dioxide present in low oxygen systems with CO does have the potential to have an antimicrobial effect and, of course, any low oxygen system will inhibit aerobic spoilage organisms. The literature and confirmatory studies, however, show that low oxygen systems with CO do not mask spoilage (because anaerobic organisms will remain capable of causing spoilage), and indeed, may have a beneficial inhibitory effect on pathogens. Low oxygen systems with CO, therefore, do not present the same situation as sorbic acid and its salts.</p> <p>Finally, in its focus on precedent for substances such as ascorbic acid, which almost certainly were novel when first evaluated in the 1980s, Kalsec ignores the more applicable agency precedent for packaging gases. Simply put, it is entirely reasonable to distinguish chemical substances such as ascorbic acid from packaging gases, based on the long history of use of the latter.</p> |
| <p>X. If permitted, CO used in meat packaging must be declared on the product label [FSIS letter p. 38-46]</p> | <p>As described in detail previously, CO is not required to be declared on the labels of meat products for which it is a packaging gas.</p> |

References

1. 45 Fed. Reg. 77043, 77045-46 (Nov. 21, 1980).
2. *Id.* at 77045.
3. *Id.* at 77046.
4. E. Antonini and M. Brunori, *Hemoglobin and Myoglobin in their Reactions with Ligands*, in *Frontiers in Biology*, V21:13, (A. Neuberger and E.L. Tatum, Eds. 1971).
5. *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) (emphasis added).
6. 113 Cong. Rec. 33842 (1967) (statement of Sen. Mondale) (emphasis added).
7. *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) (emphasis added).
8. M. Brashears, et al. (in publication); see Texas Tech University System Press Release, *Texas Tech Researchers: Despite Carbon Monoxide, Beef Consumers Still Safe* (June 26, 2006) available at <http://www.texas-tech.edu/stories/0606-beef.php> (accessed August 2006).
9. GRAS Notification No. GRN 000143, Carbon Monoxide Intended for Use in Case-ready Packaging for Fresh Meats 23-24 (Jan. 6, 2004) (GRN 143).
10. *Id.* at 19.
11. GRAS Notification No. GRN 000083, Notification of Claim for General Recognition of Safety of Carbon Monoxide in a Modified Atmosphere system for Packaging Fresh Meat 14, 23, 40-41 (Aug. 29, 2001) (GRN 83).
12. GRAS Notification No. GRN 000188, GRAS Claim for the Use of Carbon Monoxide in Modified Atmosphere Packaging for Red Meat Products 20 (Dec. 22, 2005).
13. O. Sørheim et al., *Technological, hygienic, and toxicological aspects of carbon monoxide used in modified-atmosphere packaging of meat*, 8 *Trends in Food Sc. & Tech.* 307, 311 (1997) (Attachment 14, Kalsec Petition, Nov. 15, 2005, FDA Docket No. 2005P-0459: CP1).
14. O. 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.* 157-164 (1999) (Kalsec Petition Attachment 18).
15. D.H. Kropf, *Effect of Retail Display Conditions on Meat Color*, 33 *Reciprocal Meat Conf. Proceedings* 15, 29 (1980) (emphasis added) (Kalsec Petition Attachment 17).

16. 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. J. Food Micro., 211-220 (2000) (Kalsec Petition Attachment 9).
17. Opinion of the Scientific Committee on Food on the use of carbon monoxide as a component of packaging gases in modified atmosphere packaging for fresh meat, SCF/CS/ADD/MSAd/204 Final (18 Dec. 2001) (Kalsec Petition Attachment 16).
18. Letter from Robert J. Coleman, European Commission, to Mrs. Caroline F. Jackson, European Parliament (Attachment 4, Comments of Precept Foods, LLC, Apr. 11, 2006, FDA Docket No. 2005P-0459: C6).
19. J.M. Jay, *Modern Food Microbiology* 283-84, 286, 288-89 (6th ed. 2000) (Attachment 1, Comments of Precept Foods, LLC, Jan. 23, 2006, FDA Docket No. 2005P-0459: C2).
20. Gamage, S. D., J. B. Luchansky and S. C. Ingham, *Pulsed-field gel electrophoresis typing of Hafnia alvei isolated from chub-packed and retail ground beef*, Letters in Appl. Microbiol. 26 (1998) (Attachment 3).
21. Brooks, C. et al., Reciprocal Meat Conf. Proceedings (2006) (in publication) (Attachment 4).
22. Food Marketing Institute, U.S. Grocery Shopper Trends 68-69, 115, 117, 121 (2006) (Attachment 5).
23. Michel Renner, *Oxidative Processes and Myoglobin*, in *Antioxidants in Muscle Foods: Nutritional Strategies to Improve Quality* 113, 126-27 (Eric Decker et al., eds. 2000)(Attachment N, Comments of Kalsec, Inc., June 14, 2006, FDA Docket No. 2005P-0459: RC 2).
24. J.G. Sebranek, M.C. Hunt, D.P. Cornforth, and M.S. Brewer, *Carbon Monoxide Packaging of Fresh Meat*, 60 J. Food Tech., No. 5, 184 (May 2006) (Attachment 2).
25. GRN 143, *supra* note 9, at 5-6, 8-12.
26. 80 F.3d 623 (1st Cir. 1996).
27. FDA, *Shrimp Processor Goes to Jail*, FDA Consumer (July-Aug. 1995).
28. [1988-1989 Transfer Binder] Food Drug Cosm. L. Rep. (CCH) ¶ 38,062 (D.D.C. 1987).
29. [1980-1981 Transfer Binder] Food Drug Cosm. L. Rep. (CCH) ¶ 38,065 (C.D. Cal. 1980).
30. 53 Fed. Reg. 49848, 49849 (Dec. 12, 1988).
31. FSIS, Focus on Ground Beef, available at http://www.fsis.usda.gov/Fact_Sheets/ground_beef_and_food_safety/index.asp (accessed August 2006).
32. Appendix One, Letter from Donald R. Berdahl, Kalsec to Laura M. Tarantino, FDA (June 13, 2006) (Attachment A, Comments of Kalsec, Inc., June 14, 2006, FDA Docket No. 2005P-0459: RC 2).