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**Re: Use of Carbon Monoxide (CO) in Case-Ready Fresh Meat Packaging;
Docket No. 2005P-0459; Reply to Kalsec Comments Dated June 14, 2006**

Dear Dr. Tarantino and Dr. Post:

On behalf of our client, Precept Foods, LLC (“Precept Foods”), we are responding to the June 14, 2006 letters submitted by Kalsec, Inc. (“Kalsec”) concerning the use of carbon monoxide (CO) in fresh meat packaging. ^{1/} With this most recent submission, Kalsec’s written contributions to the petition docket now exceed 130 pages of text, much of which is repetitive, irrelevant, misleading, or simply incorrect. We once again urge the Food and Drug Administration (FDA) to deny the petition. Similarly, we urge the Food Safety and Inspection Service (FSIS) of the U.S. Department of Agriculture (USDA) to deny Kalsec’s request that FSIS withdraw the existing suitability determinations for CO.

^{1/} A joint venture between Cargill Meat Solutions Corporation and Hormel Foods Corporation, Precept Foods markets case-ready fresh meat products in modified atmosphere packaging (MAP) systems that include low levels of CO (at a target concentration of 0.4%).

Laura M. Tarantino, Ph.D.
Robert C. Post, Ph.D.
August 17, 2006
Page 2

Our previous submissions, dated January 23, 2006 and April 11, 2006, explained in detail why the intended use of CO in fresh meat packaging is safe (and generally recognized as safe (GRAS)), suitable, and a benefit to consumers. We also provided detailed explanations as to why CO is not an unapproved color additive, is not “banned” by the regulation for combustion product gas, and is otherwise lawful. These submissions are incorporated by reference into this additional response.

In the interest of efficiency and brevity, we will not attempt in this letter to repeat the detailed information provided in our previous comments. We do believe it important, however, to address the “big picture” that the Kalsec submissions overlook, as well as the individual details that we find lacking. In short, with this submission, we address both the “forest” and the “trees” of CO regulation.

I. THE BIG PICTURE: PACKAGING SYSTEMS WITH CO ARE SAFE AND SUITABLE

In support of its extensive campaign against low oxygen packaging systems with CO, Kalsec has inundated FDA and FSIS with information and allegations about CO. The company has alleged that CO is an unapproved color additive, unsafe for its intended use, the subject of scientific controversy, and otherwise inconsistent with FDA and FSIS precedent. Citing supposedly widespread temperature abuse, and focusing its arguments on meat color, Kalsec speculates that fresh meat products held in low oxygen systems with CO will spoil in a way that will not be apparent to consumers. Such spoilage, Kalsec contends, will result in deception by leading consumers to purchase products that appear to be of a higher quality than is in fact the case. Moreover, Kalsec argues that CO must be labeled as an ingredient even if it is safe and suitable, based on the effect CO has on color stability in the retail package.

In offering these and other arguments, Kalsec attempts to depict low oxygen packaging systems with CO as novel and worthy of what would amount to unprecedented regulatory scrutiny. Throwing good science and common sense to the wind, Kalsec suggests that the same food industry that delivers safe and suitable food products to consumers daily—including meat products stored in low oxygen packaging—is somehow not capable of doing so with similar formats that include CO. Kalsec similarly suggests that the same consumers who rely on date codes and judge the quality of numerous products daily are somehow unqualified to judge products stored in an atmosphere with CO. Kalsec sharply criticizes the use of CO from almost every angle imaginable, yet seemingly fails to appreciate the broader regulatory, commercial and consumer landscape upon which its use is necessarily based.

Low oxygen systems with CO are firmly rooted in well-accepted packaging formats in which atmosphere is used to promote optimal quality and color, among other benefits. The precedent established by such formats is central to the regulatory status of CO, and therefore addresses the safety, color additive, labeling, and other issues raised by Kalsec. Further, the use of CO as part of a low oxygen system is itself the subject of considerable marketing experience in this country and in Norway. Because such details are disregarded, once again, in Kalsec’s latest submission, below is a brief summary of the key context underlying the regulatory status of

Laura M. Tarantino, Ph.D.

Robert C. Post, Ph.D.

August 17, 2006

Page 3

CO. This important precedent is addressed in greater detail in the attached assessment (Attachment 1) of Kalsec's most recent submission, as well as our previous comments.

- **Atmosphere is a critical factor in all fresh meat packaging.** Virtually all fresh meats distributed commercially in the United States spend a substantial portion of shelf life in a carefully designed atmosphere. Packaging atmospheres are used to protect meat quality, stabilize color, and achieve similar effects, and may be characterized by a specific combination of gases (e.g., low oxygen or high oxygen) or the complete absence of gases (as in vacuum packaging). This functional use of atmosphere in food packaging is not new. Carbon dioxide has been known to have a beneficial effect on the shelf life of fresh meats for well over a century, 2/ and low oxygen vacuum packaging (a format that sets meat color by excluding oxygen) has been successfully used in the meat industry for over thirty years. From a regulatory perspective, therefore, the effects of low oxygen packaging with CO are not novel.
- **Widely used atmospheres are similar to low oxygen systems with CO.** Among the most commonly used packaging atmospheres are low oxygen formats, which are widely recognized as superior in terms of protecting product quality. Whether “low oxygen” or “high oxygen,” commercially available atmospheres are strikingly similar to low oxygen CO packaging in many respects. For example:
 - Most—if not all—fresh meat products delivered for traditional handling in grocery stores are held in low oxygen vacuum packaging prior to final packaging for retail sale. These low oxygen atmospheres are equivalent to low oxygen environments with CO in terms of color stability and microbiology. Notably, while in a low oxygen atmosphere, the color of vacuum-packaged beef is stable (as deoxymyoglobin, a purplish-red color) and does not change in response to temperature.
 - Vacuum packaging is also widely used for fresh and cured meats in retail packages, such as deli meats, bacon, sausage, and hot dogs. Though not packaged using a true vacuum-based process, so-called “chub” packs of ground beef (i.e., beef packaged in tube-shaped containers wrapped in casing) are regarded as a type of vacuum packaging. Again, these systems are equivalent to low oxygen packaging with CO in numerous respects, including color stability and microbiology.
 - In addition to low oxygen vacuum packaging, in which all gases are removed, low oxygen environments are also created with packaging gases. For example, low oxygen systems with gases such as carbon dioxide and nitrogen are widely used to package deli meats and many other foods.

2/ J.M. Jay, *Modern Food Microbiology* 283-84 (6th ed. 2000) (Attachment 1, Comments of Precept Foods, LLC, Jan. 23, 2006, FDA Docket No. 2005P-0459: C2).

Laura M. Tarantino, Ph.D.

Robert C. Post, Ph.D.

August 17, 2006

Page 4

- Case-ready fresh meats (i.e., meats in retail-ready packages) are also distributed in high oxygen systems, primarily 80% oxygen and 20% carbon dioxide. The oxygen in these systems is used to stabilize product color beyond that achievable in traditional overwrap systems (e.g., a 10-11 day color life in contrast to 3-4 for overwrap). The same is true for CO, though like all low oxygen packaging, CO results in a color that remains stable in the container. Though high oxygen systems are safe and suitable, such systems do have quality disadvantages, including promotion of off odors and flavors. ^{3/} Moreover, adequate cooking is important (as with all meats) because meat packaged in high oxygen systems may brown before it has reached an internal temperature sufficient to kill pathogens that may potentially be present. Thus, as with any packaging format, good handling practices are essential. In its zeal to point out theoretical risks posed by low oxygen packaging with CO, Kalsec has disregarded the fact that similar risks might be imagined for other widely used packaging formats, including traditional overwrap containers as well as the high oxygen systems on which its rosemary extract business has thrived.
- **Low oxygen systems with CO are as safe and suitable as long-accepted formats.** Safety and suitability determinations for CO's intended use in fresh meat packaging are substantially based on established packaging formats:
 - Safety is based on three fundamental principles (among others): the lack of toxicological concern under the conditions of CO use (which has not been disputed); the underlying safety of packaging systems with environments similar to low oxygen systems with CO; and the fact that CO does nothing to change this established safety record. Significantly, the safety of any meat product is based on an absence of pathogens and adequate handling, including cooking. Despite Kalsec's arguments to the contrary, and as described more fully in Attachment 1, CO is not reasonably expected to stimulate or otherwise affect pathogen growth. Further, color is not a function of safety—meat discoloration does not occur, for example, in the vacuum packaging used to hold meat products in bulk storage. The use of CO satisfies the reasonable certainty of no harm standard under the intended conditions of use.
 - General recognition of safety is based on, among other things, expert consensus regarding safety. As explained in Attachment 1, there is no meaningful scientific dispute regarding the key safety factors supporting CO use. In an attempt to manufacture controversy, Kalsec has taken information out of context in the scientific literature. For example, Kalsec quoted the

^{3/} As Kalsec's website explains, high levels of oxygen "can induce unwanted off-flavors from oxidation of the meat." See http://www.kalsec.com/products/map_over.cfm (accessed August 2006).

Laura M. Tarantino, Ph.D.

Robert C. Post, Ph.D.

August 17, 2006

Page 5

work of Sørheim et al. (1997 and 1999) as evidence of expert recognition that CO can “mask spoilage.” ^{4/} Though possible masking of spoilage is a suitability issue (and not the proper focus of a GRAS analysis), the authors actually noted that “consumers will be able to detect spoilage by the presence of off-odours.” ^{5/} Indeed, Dr. Sørheim was a member of the GRAS panel convened in the development of GRAS Notice No. 83 and is supportive of CO safety. ^{6/} As two other members of that GRAS panel have observed in response to Kalsec’s efforts to question the safety of CO, “[t]he claim that CO packaging will result in unsafe products is not scientifically sound.” ^{7/}

- Suitability is based on, among other factors, the use of CO to stabilize the natural color of fresh meat products. Significantly, low oxygen systems with CO do not misrepresent the condition of fresh meat. In the unlikely event of temperature abuse, spoilage is no more masked in a low oxygen system with CO than in a retail chub pack or vacuum packaged meat. For example, if abused sufficiently, meat held in a low oxygen vacuum package for retail handling (e.g., primal cuts) would spoil, but when removed from the low oxygen environment for further processing and placement in a retail container, the meat would bloom and be cherry red for a period of time. As with CO-containing systems, signs other than color, such as odor, would be relied upon to signal the condition of the meat.
- The precedent established by low oxygen and high oxygen systems also demonstrates CO to be consistent with FDA and FSIS precedent for color additives and ingredient labeling. For example, oxygen is used in high oxygen systems to convert myoglobin to oxymyoglobin, with the goal of maintaining color for the intended shelf life. Oxygen, however, is not regulated as a “color additive” (because it stabilizes meat color by prolonging the life of its natural cherry red color), nor is it labeled as an ingredient (because it is a packaging gas). The same is true of CO. The fact that CO results in a more stable color than oxygen does not change the outcome—both are used in a retail container to create a particular environment during a specified shelf life.

^{4/} Letter from Donald R. Berdahl, Kalsec, Inc. to Laura M. Tarantino, Ph.D., at 10 (June 14, 2006).

^{5/} O. Sørheim, et al., *Technological, hygienic, and toxicological aspects of carbon monoxide used in modified atmosphere packaging of meat*, 8 Trends in Food Sci. & Tech. 307, 311 (1997) (Attachment 14 of Kalsec Citizen Petition, Nov. 15, 2005, FDA Docket No. 2005P-0459).

^{6/} GRAS Notice No. GRN 000083, 40-41 (Aug. 29, 2001).

^{7/} 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, at 184 (May 2006) (Attachment 2).

- **Low oxygen systems with CO are the subject of extensive and growing experience.** Low oxygen systems with CO are the subject of considerable marketing experience in their own right. The most extensive marketing experience occurred in Norway, where CO was safely and successfully used in MAP systems for fresh meat for nearly twenty years, until Norway was forced to discontinue use of CO as a condition of trade with the European Union. In this country, CO-containing systems have been used for more than four years to package well over 100 million pounds of fresh meat products. Few GRAS and suitability determinations are supported by such extensive practical experience.
- **Low oxygen systems with CO deliver high quality meat products.** Aside from issues of regulatory process and labeling, critics of CO have not questioned that fresh meat packaged in a CO-containing system can be sold in a safe and suitable manner when handled properly for an appropriate shelf life. Instead, the putative issues have focused almost exclusively on the potential for abuse, namely exposure to temperatures that may result in spoilage while the product retains a stable red color. Kalsec argues that Precept Foods does not account for real-life conditions of use, but in fact, it is Kalsec that refuses to acknowledge (or is unaware of) the realities of cold chain management in the fresh meat industry:
 - Most food products are held at appropriate temperatures during production, distribution, and storage. This is not to say that improvement is unnecessary; improvement in cold chain practices is always needed. Widespread abuse of the type Kalsec suggests, however, would not simply affect meat products packaged in low oxygen environments with CO—food products of all kinds would be affected in an obvious way. There is no credible evidence that abuse leading to routine product spoilage or unsafe products is occurring, such that low oxygen packaging should be abandoned. In fact, as FDA points out in the 2005 Food Code, the fresh meat case has a relatively good record of temperature control as compared to other areas, §/ and fresh meat products will always be cooked before consumption. Kalsec’s arguments amount to a charge that low oxygen packaging is unsuitable, but the record certainly does not support this contention.
 - Indeed, sales data for low oxygen systems of all types strongly refute any suggestion of serious flaws in cold chain management. For example, since approximately 1976, Cargill has built ground beef packaged in case-ready chub packages into a business with annual sales of over 50 million pounds. In the case of low oxygen packaging with CO, well over 100 million pounds of product have been sold in the past four years; moreover, sales are increasing, with triple-digit growth in 2005 (as compared to 2004). Such growth in sales is not possible without high quality products that are meeting consumer expectations. Kalsec’s

§/ FDA, 2005 Food Code 547 (Annex 6).

suggestion that retailers and consumers would not know to complain is nonsense—regardless of the packaging format, both retailers and consumers know when a product is of unacceptable quality. In a business highly dependent on repeat sales, it would make no business sense to attempt to trick consumers into purchasing and bringing home spoiled product.

- Additionally, product shelf life is not a static issue that is addressed with one or two studies and then forgotten. Responsible companies, such as Precept Foods, maintain aggressive quality control programs in which product shelf life is continually monitored at the retail level and adjusted on a case-by-case basis. As part of this monitoring program, the 28 and 35-day guidelines for ground beef and whole muscle cuts represent only targets. At present, Precept Foods is currently using more conservative dates, such as 24 days for most whole muscle cuts of beef and pork. The conservative nature of this approach is apparent when one considers that low oxygen systems potentially allow for a much longer shelf life. For example, a shelf life of 50 to 60 days is routinely achieved for chilled meat products for overseas export.
- **Low oxygen systems with CO offer unique benefits.** Low oxygen systems with CO are used to combine the color benefits of high oxygen systems with the quality and shelf life benefits of low oxygen systems. The combination has the potential to expand the case-ready category, meaning that more products will be produced (1) directly under FSIS inspection, (2) under a HACCP program, (3) with a centrally applied “use or freeze by” date, and (4) without further handling, thus reducing the potential for cross contamination after packaging. Further, low oxygen systems with CO can achieve these important benefits without the disadvantages of high oxygen systems. Though high oxygen systems are safe and suitable, they do have certain drawbacks, including promotion of off odors and flavors and the potential for premature browning of meat.

II. DETAILED SUPPORT FOR LOW OXYGEN PACKAGING SYSTEMS WITH CO

In addition to disregarding the general commercial, regulatory, and consumer landscape in which low oxygen CO packaging is used, Kalsec’s submissions are inaccurate or incomplete with respect to many of the specific details supporting the current regulatory status of CO. To address issues raised by Kalsec in greater detail, a point-by-point assessment of the June 14, 2006 letters to FDA and FSIS is attached (Attachment 1).

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Laura M. Tarantino, Ph.D.
Robert C. Post, Ph.D.
August 17, 2006
Page 8

We appreciate FDA's and FSIS's consideration of these additional comments. Please do not hesitate to contact us if there are any questions or if additional information would be useful.

Sincerely,



Gary Jay Kushner
Ann Mileur Boeckman
Counsel to Precept Foods, LLC

Enclosures

cc: FDA Division of Dockets Management

cc (w/o encls.):

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