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January 23, 2006

BY ELECTRONIC MAIL & FEDERAL EXPRESS

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Food and Drug Administration
5100 Paint Branch Parkway
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Re: Use of Carbon Monoxide (CO) in Case-Ready Fresh Meat Packaging; Docket No. 2005P-0459

Dear Dr. Tarantino:

On behalf of our client, Precept Foods, LLC ("Precept Foods"), we are responding to the Citizen Petition submitted by Kalsec, Inc. ("Kalsec") concerning the use of carbon monoxide (CO) in fresh meat packaging. 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%). We have carefully reviewed the Kalsec petition and find it to be a transparent, misguided, and misleading attempt to challenge a competitive product. 2/ As described more fully below, the petition should be summarily denied.

1/ FDA Docket No. 2005P-0459 (Citizen Petition of Kalsec, Inc.) (Nov. 15, 2005).

2/ As noted in the petition, Kalsec produces spice, herb, and vegetable extracts for use in various food and other applications. Of particular relevance to this submission, the petitioner produces extracts used as antioxidants in high oxygen packaging systems, but that are unnecessary in low oxygen systems. Thus, the petitioner appears to have a substantial commercial interest in preventing an industry shift to low oxygen packaging.

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The use of CO in an MAP system is generally recognized as safe (GRAS) and lawful. 3/ Further, MAP systems containing low levels of CO provide important consumer benefits not attainable with other packaging systems, such as a centrally applied and scientifically valid "Use or Freeze By" date code. Despite the established status of CO for this type of application, including numerous reviews of CO by both the Food and Drug Administration (FDA) and U.S. Department of Agriculture (USDA)/Food Safety and Inspection Service (FSIS), Kalsec alleges that CO intended for use in fresh meat packaging is an unapproved "color additive," is subject to an FDA "ban" on CO in fresh meat packaging, will mask spoilage, is otherwise unsafe, and will promote deception by making product appear fresher than it is.

These assertions are without merit. Indeed, the petition reflects a serious misunderstanding of both the facts and applicable FDA and FSIS requirements. In short, the petition provides no new information that calls into question the safety or suitability of CO as used in existing MAP systems marketed by Precept Foods, nor does it otherwise cast doubt on FDA's and FSIS' previous reviews of CO for this intended use. To provide for a balanced public record, the factual, legal, and scientific bases for these conclusions are described in detail below.

I. THE COLOR ADDITIVE REQUIREMENTS DO NOT APPLY

Kalsec's primary complaint, on which most of its allegations rest, is that CO is used in fresh meat packaging to "impart color" to meat and therefore constitutes an unapproved color additive under section 721 of the Federal Food,

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3/ *See, e.g.*, Agency Response Letter, GRAS Notice No. GRN 00143 (July 29, 2004) (advising that FDA had "no questions" concerning Precept Foods' determination that CO is GRAS under the intended conditions of use in fresh meat packaging); Agency Response Letter, GRAS Notice No. GRN 00083 (Feb. 21, 2002) (advising that FDA had "no questions" concerning the Pactiv Corporation's determination that CO is GRAS under the intended conditions of use in fresh meat packaging); Agency Response Letter, GRAS Notice No. GRN 00167 (Sept. 29, 2005) (advising that FDA had "no questions" concerning the conclusion of Tyson Foods, Inc. that CO is GRAS under the intended conditions of use in fresh meat packaging); FSIS Directive 7120.1, Safe and Suitable Ingredients Used in the Production of Meat and Poultry Products (identifying CO as suitable under its intended conditions of use in MAP systems for fresh meat and poultry).

Drug, and Cosmetic Act (FFDCA). 4/ In support of this assertion, the petition describes a determination FDA made in 1979 that nitrites "impart" color by reacting with the naturally occurring myoglobin in meat tissue to form a third substance. The petition argues that CO, which interacts with myoglobin to form carboxymyoglobin, has a comparable mode of action and therefore also imparts color to meat within the meaning of the "color additive" definition. Based on this conclusion, the petition discusses at length why FDA's and FSIS' responses to the GRAS notices submitted by Precept Foods and others are procedurally deficient and not in line with the safety requirements for color additives. Despite the considerable detail and analysis provided, the petition completely fails to mention that FDA reversed its position on nitrites in 1980 and that this reversal was subsequently upheld in federal court. Thus, the petition relies on a faulty legal basis and erroneous precedent.

Specifically, in a 1980 *Federal Register* notice addressing the color additive status of nitrites in bacon and other meats, FDA revisited its 1979 determination that nitrites impart color. In response to comments, FDA decided that it "agrees that its tentative conclusion was incorrect and now concludes that nitrites do not 'impart' color to bacon within the meaning of section 201(t)(1) of the act." 5/ The basis for this reversal was the agency's decision to return to its long standing position (and that of FSIS) that substances that merely "fix" color do not "impart" color to food and therefore are not "color additives":

> [N]itrites 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. The color of the nitrite-cured bacon is not readily distinguishable, however, from the color of the uncured pork belly at or shortly after slaughter. On these grounds, it was reasonable for FDA officials not to regard nitrites to be 'color additives'

4/ A "color additive" is defined in pertinent part as a "substance . . . when added or applied to a food . . . capable (alone or through reaction with other substances) of imparting color thereto." FFDCA § 201(t)(1).

5/ 45 Fed. Reg. 77043, 77044 (Nov. 21, 1980).

> and to continue to regulate them under the more logically applicable Food Additives Amendment. 6/

Kalsec cites this 1980 *Federal Register* notice but omits this important change of agency interpretation. The petition also apparently overlooks a subsequent judicial decision upholding FDA's determination. 7/ The rationale followed in FDA's nitrite determination is directly applicable to CO and reflects current FDA and FSIS policy that substances that merely maintain color are not "color additives." Like nitrites, CO stabilizes product color by reacting with myoglobin to form a more stable form of the pigment (carboxymyoglobin), thereby maintaining the natural cherry red color of fresh meat. 8/ Accordingly, CO as used by Precept Foods and companies similarly situated is not a "color additive."

II. USE OF CO IS NOT PROHIBITED BY THE REGULATION FOR COMBUSTION PRODUCT GAS

The petition also alleges that FDA's food additive regulations "prohibit" CO in fresh meat packaging. The petitioner cites 21 C.F.R. § 173.350, which provides that "combustion product gas" can be used to displace oxygen in the "packaging of beverage products and other food, except fresh meats." It is suggested that this exception for fresh meats is not merely a limit on the scope of the regulation, but affirmatively prohibits use of CO in packaging for fresh meats. We disagree.

The cited regulation specifically addresses "combustion product gas." Although CO is a component of combustion product gas, the two are not equivalent

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6/ *Id.* at 77046.

7/ *Public Citizen v. Hayes*, Food Drug Cosm. L. Rep. (CCH) ¶ 38,161 (D.D.C. 1982) (upholding FDA's determination that nitrites merely "fix" rather than "impart" color and are therefore appropriately not regulated as "color additives").

8/ Because CO is a packaging gas used in a modified atmosphere, it is not subject to ingredient labeling. For example, the majority of case-ready packaging today utilizes a high oxygen gas mixture (at oxygen levels four times the levels found in ambient air) to stabilize the color of fresh meats. As discussed more fully in section IV, oxygen is not required to be identified on the label, nor should it be, as it simply stabilizes the meat pigment. The same is true for CO.

in fact or as a matter of law. According to the regulation, combustion product gas is manufactured simply "by the controlled combustion in air of butane, propane, or natural gas." 9/ Combustion product gas comprises a mixture of gases, including nitrogen, carbon dioxide, and hydrogen, in addition to CO. In contrast, the CO used by Precept Foods is a purified gas produced in a steam methane reformer, in which a nickel-based catalyst is used to convert a hydrocarbon/steam mixture to hydrogen and carbon oxides. Once hydrogen and CO are formed, the components are separated via such techniques as cryogenic separation. With a minimum CO content of 98%, the CO used by Precept is a highly purified material that is distinct from the mixture known as "combustion product gas."

It is readily apparent from agency regulations that FDA considers "combustion product gas" to be a separate material from its component gases. For example, FDA has separately affirmed nitrogen and carbon dioxide, both of which are components of combustion product gas, as GRAS for use in foods generally, including meats.10/ Kalsec's interpretation of the combustion product gas regulation as effectively "banning" the use of CO in fresh meat would apply equally to nitrogen and carbon dioxide—a result that cannot be squared with FDA's regulations. The agency's regulations must be interpreted in a manner that makes sense of the overall regulatory framework.

Moreover, even if the regulation for combustion product gas applies to CO, it most certainly does not prohibit the use of CO in case-ready packaging for fresh meat. The plain language of the regulation provides 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*." 11/ This means simply that "fresh meats" were an exception to the "food additive" approval for combustion product gas. An exception is not a prohibition—where FDA intends to prohibit a substance from use in food, the agency does so through a regulation codified in 21 C.F.R. Part 189, which unambiguously addresses "Substances

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9/ 21 C.F.R. § 173.350(a).

10/ 21 C.F.R. §§ 184.1540 (affirming nitrogen as GRAS for use as a propellant, aerating agent, and gas with no limitation other than good manufacturing practice); *id.* § 184.1240 (affirming carbon dioxide as GRAS for use as a processing aid, propellant, aerating agent, and gas with no limitation other than good manufacturing practice).

11/ 21 C.F.R. § 173.350(c) (emphasis added).

Prohibited from Use in Human Food." 12/ In other words, in 1961, combustion product gas may have been classified as an unapproved food additive with respect to uses in fresh meats; however, this additive could nonetheless be used for fresh meats if it were subsequently established to be GRAS for this purpose.

Kalsec's arguments that CO is affirmatively prohibited from use in fresh meats misconstrue FDA precedent concerning the scope of the "food additive" and GRAS categories in two important ways. First, Kalsec suggests that because combustion product gas intended for use in fresh meats was an unapproved food additive in 1961, it remains an unapproved "food additive" today. Second, Kalsec suggests that the "food additive" and GRAS categories are mutually exclusive—that is, that a substance cannot be both a food additive and GRAS for the same specified conditions of use. Both interpretations are incorrect as a matter of law and FDA policy.

The primary difference between a "food additive" and a GRAS substance is "general recognition" of safety by qualified experts. General recognition of safety requires a showing that pivotal evidence supporting safety is publicly available and generally accepted by qualified experts. 13/ It is undisputed that a substance that is a "food additive" may become GRAS over time as qualified experts become aware of and accept evidence of its safety. 14/ For example, in 1999, FDA issued a food additive regulation authorizing use of sucrose acetate isobutyrate (SAIB) as a stabilizer of emulsions of flavoring oils used in non-alcoholic beverages; in 2002, FDA had no questions concerning the GRAS status of SAIB for the same use in alcoholic beverages. 15/ The principle holds true even where the conditions of

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12/ Even if FDA had intended to use a food additive regulation to affirmatively prohibit the use of combustion product gas in fresh meats, as is now suggested, the agency would have been expected to do so in an unambiguous manner (e.g., by providing that "use in fresh meats is prohibited").

13/ Expert consensus does not require unanimity. 62 Fed. Reg. 18937, 18939 (Apr. 17, 1997).

14/ It is also unquestioned that a substance that is GRAS may be the subject of a food additive regulation. For example, vitamin D intended for use as a nutrient supplement in cheese is regulated as both a GRAS ingredient and a "food additive." 70 Fed. Reg. 69435 (Nov. 16, 2005).

15/ Agency Response Letter, GRAS Notice No. GRN 000104 (Aug. 16, 2002).

use are identical: the ingredient mycoprotein gradually achieved GRAS status while FDA reviewed a food additive petition seeking agency approval for its use. 16/ Although FDA ultimately had no questions concerning GRAS status, the agency nonetheless expressed an intent to proceed with a food additive regulation to codify food grade specifications and similar matters for mycoprotein. 17/

Accordingly, the regulation for "combustion product gas" does not apply in any way to the use of purified CO. Even if the regulation is arguably applicable, however, it does not affirmatively prohibit the use of any individual gas in fresh meat packaging, nor does the lack of a "food additive" approval for a substance in 1961 preclude a finding that the substance has become GRAS more than forty years later. As described below, Precept Foods' intended use of CO is GRAS and provides many important consumer benefits.

III. THE INTENDED USE OF CO IS GENERALLY RECOGNIZED AS SAFE (GRAS) AND LAWFUL

In addition to the dubious "color additive" and "combustion product gas" arguments detailed above, the petition attempts to call into question the safety of case-ready MAP systems with CO. 18/ In numerous respects, the arguments advanced by Kalsec reflect an incomplete understanding of the facts, pertinent science, and agency requirements. The petition does not provide new information or raise issues not already addressed by Precept Foods, other companies using CO in similar MAP systems, or FDA and FSIS in reviewing CO-related applications. Not surprisingly, the petition also fails to take into account the considerable benefits—including safety benefits—that are made possible by the use of CO.

16/ Agency Response Letter, GRAS Notice No. GRN 000091 (Jan. 7, 2002).

17/ *Id.*

18/ The petition addresses safety primarily in the context of FDA's color additive requirements, which, as noted previously, are inapplicable. Nonetheless, to correct the public record and the misstatements made by Kalsec, we are responding to the petition's safety-related allegations as well.

A. Precept's Intended Use of CO Is GRAS

As detailed in GRAS Notice No. 143, Precept Foods' use of CO at a target concentration of 0.4% in MAP systems for fresh meat is GRAS. Precept Foods reached this conclusion only after carefully examining the safety of CO for the intended use, the safety and suitability of finished case-ready systems containing CO, generally available and accepted information regarding CO for this intended use, and studies undertaken specifically to confirm the expected performance of the Precept Foods' system. Other GRAS determinations addressing similar conditions of use have taken a comparable approach.

The Kalsec petition identifies no safety concerns related to the toxicological profile of CO, per se. Rather, the petition's focus is the microbial safety of meat products packaged with CO under actual conditions of use. The petitioner's safety arguments may be summarized in the following points:

- MAP systems containing CO are a type of reduced oxygen packaging and therefore necessarily present increased risk of pathogen growth, particularly *Clostridium botulinum* and *Listeria monocytogenes*, as explained in FDA's Food Code.
- Currently marketed CO-containing MAP systems for fresh meat do not conform to safety controls recommended by FDA in the Food Code, such as a refrigeration advisory; however, even compliance with Food Code guidelines would not be sufficient as a result of widespread temperature abuse and "an intended longer shelf life."
- Growth of pathogens may occur, but the MAP systems with CO will simultaneously suppress spoilage organisms that produce odor, slime, and other organoleptic indicators of spoilage. Meanwhile, the color-stabilizing effects of CO will not allow consumers to identify spoiled meat and may lead to consumption of unsafe products.

On each of these points, the petition again misses the mark. The arguments presented reflect neither the long history of safe use of reduced oxygen packaging nor the important controls (such as safe handling instructions) that enhance the safety of all raw meat products. With specific regard to spoilage, the petitioner disregards the studies, noted by FDA in its response to GRAS Notice No. 143,

confirming that the Precept Foods system does not mask spoilage. The petition also mischaracterizes color as a critical safety factor for raw meat. In fact, meat color changes are unrelated to the microbial quality or safety of raw meat products; consumers are better served by relying on validated "Use or Freeze By" dates and signs of temperature abuse. Finally, the safety calculus presented in the petition does not account for the safety advantages made possible by CO, such as the production and packaging of fresh, raw meats in a central location subject to continuous FSIS inspection.

1. Reduced Oxygen Packaging, Including CO-containing MAP Systems for Fresh Meat, Is Safe

With extensive—and selective—references to FDA's 2005 Food Code, the petition suggests that reduced oxygen packaging presents "substantial food safety concerns." Alleged concerns with fresh meat are specifically highlighted, which Kalsec conclusively states "is known to potentially host a wide range of pathogens, including *Clostridium botulinum*." These and similar statements are seemingly intended to imply that reduced oxygen packaging in general, and CO-containing MAP systems in particular, pose unacceptable hazards when used for fresh meats.

The Food Code makes no such point. Contrary to the petition's highly selective depiction of the Food Code and scientific opinion, reduced oxygen packaging has a long history of safe use. The Food Code states explicitly that "[p]roducts packaged using [reduced oxygen packaging] may be produced safely if proper controls are in effect." 19/ The Food Code also recognizes that reduced oxygen environments offer "unique advantages and opportunities." 20/ Similar references can be found in other authoritative sources. 21/

19/ FDA, 2005 Food Code 544 (Annex 6).

20/ *Id.*

21/ *See, e.g.*, J.M. Jay, Modern Food Microbiology 288-89 (6th ed. 2000)("Overall, the storage of fresh meats under vacuum or MAP has been very successful and safe. The latter is in large part a reflection of the existence of lactic acid and related bacteria on fresh meats, and when these products are stored under low O_2 and high CO_2 conditions at low temperatures, the normal biota prevents the growth of pathogens by virtue of depressed pH, competition for O_2, possible production of antimicrobial substances, and other factors.")(Attachment 1).

The petition similarly misrepresents the risk posed by specific pathogens, particularly *C. botulinum* and *L. monocytogenes*. Although these pathogens may present significant challenges for some foods packaged in modified atmospheres, neither presents a realistic or unique threat to the safety of raw meat products marketed in MAP environments.22/ As with products marketed in other types of packaging, standard meat industry practices and controls used to ensure food safety (e.g., Sanitation Standard Operating Procedures (SSOPs)) are sufficient and appropriate.

To the best of our knowledge, *C. botulinum* has never been a cause of foodborne illness associated with the consumption of a fresh, unprocessed meat product, regardless of packaging type. 23/ Obviously, this includes considerable quantities of fresh meat products that have been distributed for decades in vacuum and other MAP packages. Numerous factors contribute to this impressive safety record, including, most notably, the low overall incidence of *C. botulinum* in fresh meat. 24/ Moreover, of the two types of *C. botulinum* linked to foodborne illness

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22/ *See, e.g.*, G. Molin, *Modified Atmospheres*, in The Microbiological Safety and Quality of Food 229 (B. Lund, et al., eds. 2000)("[T]he earlier presumed hazards for growth and toxin formation by clostridia in refrigerated meats . . . packaged in modified atmospheres seem exaggerated.")(Attachment 2); *id.* ("[T]he problem with *L. monocytogenes* is more connected to products that are consumed directly without heat treatment and in products where the normal spoilage flora has been inhibited.").

23/ *See, e.g.*, F.K. Lücke and T.A. Roberts, *Control in Meat and Meat Products*, in Clostridium botulinum: Ecology and Control in Foods 178 (A.H.W. Hauschild and K.L. Dodds, eds. 1992)(Attachment 3). Noting reports of botulism linked to raw, putrid seal meat consumed in northern Canada and Alaska, the authors observed that "no case of botulism due to the consumption of fresh meat has ever been reported from any other part of the world, even from countries where consumption of raw unprocessed meats is common (e.g., Germany, Belgium, and the Netherlands)." *Id.*

24/ *See, e.g.*, J.M. Jay, *supra* note 21, at 472 ("A summary of published data on the incidence of botulinal spores in meat and poultry reveals that the numbers are extremely low—well below 1 spore/g . . . "); B.M. Lund and M.W. Peck, *Clostridium botulinum*, in The Microbiological Safety and Quality of Food 1069, 1071 (B. Lund, et al., eds. 2000)(Attachment 4); F.K. Lücke and T.A. Roberts, *supra* note 23, at 179-81 (noting that estimates of *C. botulinum* in raw meats range from less than 0.1 spore/kg to 7 spores/kg); A.H.W. Hauschild, *Clostridium Botulinum*, in Foodborne Bacterial Pathogens 143 (M.P. Doyle, ed. 1989)(describing the ratio of putrefactive anaerobe spores to botulinal spores in raw meats to be 20,000 to 1)(Attachment 5). Although the incidence of *C. botulinum* in meat has not been studied as extensively as other foods, the

(i.e., proteolytic and non-proteolytic), only non-proteolytic clostridia can grow at refrigerated temperatures, but these organisms are nearly always associated with marine foods such as fish. 25/ For proteolytic *C. botulinum*, extreme temperature abuse (greater than 10-12°C for extended periods of time) would be necessary for growth and toxin production. 26/

In the unlikely event that *C. botulinum* is present in fresh meat, the organism would not be expected to compete well with the natural flora. Under vacuum or other low oxygen conditions, the primary flora would be lactic acid bacteria, many of which produce bacteriocins and organic acids that inhibit *C. botulinum* growth and toxin production. 27/ Obvious signs of spoilage (such as a putrid odor) would develop well before toxin production could occur. 28/ In fact, the "high levels of nonpathogens" in raw meat and poultry are considered to be an "antibotulinal hurdle" for MAP systems. 29/

The critical role of competitive inhibition is also evident from the Food Code, which recognizes competing microflora as an important limit on pathogen growth, similar to a low water activity, a low pH, or use of curing agents.

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low reported incidence is consistent with the public health record, which contains no reports of outbreaks linked to fresh meats.

25/ *See, e.g.*, J.M. Jay, *supra* note 21, at 467-71.

26/ *Id.*

27/ *See, e.g., id.* at 471 ("It appears that this organism [*C. botulinum*] cannot grow and produce its toxins in competition with large numbers of other organisms. Toxin-containing foods are generally devoid of other types of organisms because of heat treatments."); F.K. Lücke and T.A. Roberts, *supra* note 23, at 184 ("Psychrotrophic lactobacilli are most competitive on perishable meat products. They tend to lower the risk of botulinum toxin formation by acid production if the products are stored under insufficient refrigeration.").

28/ *See, e.g.*, G. Molin, *supra* note 22, at 228-29.

29/ J.M. Jay, *supra* note 21, at 290. The classification of spoilage microflora as a safety factor for MAP systems flies in the face of the petition's suggestion that important spoilage microorganisms are inhibited by low oxygen atmospheres, especially those containing CO_2. Significantly, organisms such as Lactobacillus spp. are highly resistant to inhibitory effects of CO_2. *Id.* at 286, 288-89.

Specifically, the Food Code provides that most foods packaged in a reduced oxygen atmosphere must meet one of four criteria intended to limit pathogen growth. One of the four criteria is a classification of the packaged food as having "a high level of competing organisms, such as raw meat or raw poultry." 30/ Thus, the Food Code unambiguously acknowledges the protective role of competing microflora in raw meat and poultry packaged in reduced oxygen environments. The petition makes no mention of this important characteristic of raw meat products.

An additional factor that protects fresh meat products from both types of *C. botulinum* is the heat sensitivity of the neurotoxins. In the extremely unlikely event that *C. botulinum* is present and able to grow and produce toxins despite refrigeration temperatures and competing organisms, the cooking procedures to which raw meat products are routinely subject will help to inactivate those toxins.31/ This explains why nearly all cases of foodborne botulism are caused by pre-formed toxin that is consumed with no or very minimal subsequent heat treatment.

30/ FDA, 2005 Food Code § 3-502-12(B)(2)(d).

31/ *See, e.g.*, FDA, Foodborne Pathogenic Microorganisms and Natural Toxins Handbook ("The Bad Bug Book")("The toxin is heat labile and can be destroyed if heated at 80°C [176°F] for 10 minutes or longer."). Although USDA typically recommends that meat and poultry be cooked to minimum internal temperatures that range from 145°F-180°F (depending upon the product), the surface of the meat will reach a higher temperature. Moreover, a cook designed to inactivate botulinal toxins completely is unnecessary in light of the numerous other hurdles to *C. botulinum* in fresh meat packaged in MAP environments.

L. monocytogenes similarly does not present a realistic hazard with respect to the Precept Foods MAP system because this organism is readily destroyed by cooking. For this reason, government and industry efforts to address *Listeria* focus on ready-to-eat foods that will receive no further heat treatment. 32/ With specific regard to fresh meats, FSIS considers *L. monocytogenes* a hazard reasonably likely to occur in many ready-to-eat, but not raw, meat and poultry products. Accordingly, facilities that produce raw meat do not typically consider *L. monocytogenes* to be a hazard reasonably likely to occur for purposes of a Hazard Analysis Critical Control Point (HACCP) plan.

Finally, Kalsec exaggerates the potential for temperature abuse by suggesting that temperature control in the distribution chain is so poor that meat cannot be safely distributed in reduced oxygen packaging. Such a position is obviously inconsistent with the Food Code, which explicitly states that reduced oxygen packaging may be safely used, as well as the long history of safe use of reduced oxygen packaging such as vacuum packaging. It is telling that the Food Code, on which the petition relies so heavily, states that supermarket fresh meat cases "appear to have a relatively good record of temperature control." 33/ Although the Food Code also notes that there is room for improvement in terms of temperature control, as even fresh meat products "can occasionally be found above 10°C (50°F)," 34/ it nonetheless suggests that fresh meat is more likely than not to be distributed with good temperature control.

In summary, Kalsec is simply incorrect in implying that MAP systems for raw meat are inherently unsafe and will result in the presence and growth of pathogens such as *C. botulinum* and *L. monocytogenes*. The proper use of MAP systems to package raw meat does not pose an elevated risk of these pathogens. Moreover, even if pathogens are present in MAP systems including CO, as described next, appropriate controls are in place to provide the same assurances of safety available with other, well-accepted packaging systems.

32/ For example, FDA's Listeria Action Plan focuses on ready-to-eat foods. FDA, Center for Food Safety and Applied Nutrition, Reducing the Risk of *Listeria monocytogenes*: FDA/CDC 2003 Update of the Listeria Action Plan (Nov. 2003). USDA similarly focuses its resources relating to *L. monocytogenes* control on ready-to-eat meat and poultry products.

33/ FDA, 2005 Food Code 547 (Annex 6).

34/ *Id.*

2. Safe Handling Instructions and Other Controls Guard Against the Risk of Temperature Abuse

The petition charges that the various GRAS notices for CO "ignore the safety concerns [FDA] stresses in the Food Code." Arguing in the alternative, the petition simultaneously decries FDA's failure to require a refrigeration statement as a condition of GRAS status (e.g., "Important—Must be kept refrigerated at 5°C (41 °F)") while also insisting that such a statement would offer no protection due to temperature abuse in the distribution chain and in home refrigerators. It is implied that such abuse is of particular concern for "meats packaged in modified atmospheres with an intended longer shelf life, which provides more opportunities for the food to encounter abusive temperature variation during distribution and storage, thereby increasing the likelihood of microbial spoilage." Once again, these allegations reflect a poor understanding of the facts and pertinent regulatory requirements.

Concerning the need for a refrigeration statement, all raw meat products are required by federal law to bear extensive safe handling statements. Specifically, FSIS requires that refrigerated raw meat products such as those distributed by Precept in MAP systems bear (1) an instruction on the principal display panel that the product should be refrigerated (e.g., "Keep Refrigerated"), and (2) the following safe handling instructions (together with certain accompanying graphics that serve to underscore these important messages): 35/

> Safe Handling Instructions: This product was prepared from inspected and passed meat and/or poultry. Some food products may contain bacteria that could cause illness if the product is mishandled or cooked improperly. For your protection, follow these safe handling instructions.
>
> Keep refrigerated or frozen. Thaw in refrigerator or microwave.
>
> Keep raw meat and poultry separate from other foods. Wash working surfaces (including cutting

35/ 9 C.F.R. §§ 317.2(k)-(l); 381.125(a)-(b).

> boards), utensils, and hands after touching raw meat or poultry.
>
> Cook thoroughly. Keep hot foods hot. Refrigerate leftovers immediately or discard.

These statements go far beyond the simple statement recommended in the Food Code to address not merely refrigeration, but safe handling and cooking as well.

Concerning the risk of temperature abuse, as the petition notes, FDA has advised that "[i]t must be assumed . . . for purposes of assessing risk, that occasionally temperatures of 10°C (50°F) or higher may occur for extended periods" in the distribution chain. 36/ We agree. In fact, in determining CO to be GRAS for use in fresh meat packaging, Precept Foods did just that, commissioning a study to examine the performance of an MAP system containing CO under abusive conditions. As described in GRAS Notice No. 143, this study found that temperature-abused product packaged in a CO-containing environment does spoil and does evidence tell-tale signs of spoilage, including odor, gas formation (evident through bulging packages), and slime. In short, the packaging atmospheres used by Precept Foods do not mask spoilage and will afford consumers the same opportunity to identify product that has been subject to temperature abuse as other packaging systems long considered to be safe.37/

That CO-containing MAP systems can spoil in a perceptible way is demonstrated not only by the Precept Foods' studies, but also by the broader

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36/ FDA, 2005 Food Code 547 (Annex 6).

37/ The petition draws sweeping conclusions regarding the effect of the Precept Foods MAP system on spoilage—all of them incorrect. See Petition at 20 ("Even upon opening the package . . . consumers would not be able to rely upon odor, slime, or other organoleptic indicators of spoilage, because carbon dioxide containing anaerobic packaging systems such as those that are the subject of the Pactiv and Precept GRAS notifications suppress the growth of aerobic spoilage organisms that produce these signals, while allowing other harmful yet imperceptible pathogens to flourish."); *id.* at 21 ("[C]arbon monoxide in fresh meat packaging presents a serious public health risk because consumers will not be able to rely upon their accustomed indications of spoilage."); *id.* at 22 ("[U]nder real world conditions, it is unavoidable that carbon monoxide in fresh meat will mask spoilage . . ."). As demonstrated by the studies commissioned by Precept Foods, meat packaged in MAP systems with CO can spoil in a perceptible way, signaling that temperature abuse may have occurred.

literature. Published studies show that the CO levels used by Precept are expected to have no meaningful effect on microflora, including spoilage organisms.38/ Further, contrary to Kalsec's suggestion that carbon dioxide-containing anaerobic systems will suppress the growth of spoilage organisms, meat packaged in anaerobic atmospheres with carbon dioxide still has indicators of spoilage such as odor and slime. 39/ The study commissioned by Kalsec, although problematic for many reasons, actually confirmed that growth of spoilage organisms does occur in MAP environments containing both CO and carbon dioxide. 40/

Kalsec also misstates the significance of meat color from a safety perspective. Meat color is a poor measure of safety because it reflects only oxidation, not the presence of pathogens or even spoilage organisms. The presence of pathogens does not affect color in any way; moreover, color changes triggered by exposure to oxygen (i.e., the transformation of oxymyoglobin to metmyoglobin) typically predate the end of the microbial shelf life of meat. Thus, regardless of the packaging system, meat exhibiting a cherry red color can be unsafe, but meat exhibiting a brown color can be perfectly safe to consume. As explained more fully below, production at a central location, use of a consistent and validated date code, indicators of spoilage such as odor and slime formation, and proper handling offer far better ways to assure safety and wholesomeness than color.

38/ Sorheim, et al., *The storage life of beef and pork packaged in an atmosphere with low carbon monoxide and high carbon dioxide*, Meat Sci. 52, at 157-64 (1999)(Attachment 6).

39/ *Id.*; *see also* J.M. Jay, *supra* note 21, at 286, 288-89 and note 25.

40/ *See* Petition Attachment 1, at 3 ("The growth of spoilage organisms appears to be slightly faster in those samples containing the 0.4% carbon monoxide, 30% carbon dioxide, and 69.6% nitrogen atmosphere, but the effect is not pronounced."). This study concluded that meat packaged in MAP systems including 0.4% CO had microbial levels indicative of spoilage yet presented "the appearance of fresh red meat." The study, however, did not examine odor or other indicators of spoilage, such as gas formation or slime. The study was problematic for additional reasons, as well—for instance, it is highly questionable that the authors reported the pathogen challenge data in a scale that appears to mischaracterize differences in pathogen growth. Had the authors selected a more traditional scale, such as a log scale, the reported data would show an insignificant difference in the effect of environment on pathogen growth.

Finally, the petition mischaracterizes the intended shelf life of meats packaged in the Precept Foods MAP systems. Contrary to Kalsec's suggestion, Precept Foods does not use CO for the purpose of extending the shelf life of meats beyond that of other low oxygen systems. The shelf life timeframes stated on the Precept MAP products are consistent with shelf life utilized in other forms of low oxygen packaging that have long been accepted as safe. For example, the intended shelf life for CO-containing systems is no longer than that used for vacuum packaging. The color of vacuum-packaged meat does not change to indicate spoilage, but as a consumer opens the package, spoilage (if any) is evident by odor and gas formation. This is precisely the same scenario presented to the consumer in a low oxygen system containing CO. Odor formation presented in a CO package during abuse is virtually the same as with vacuum packaging.

In summary, the available evidence demonstrates that the use of CO at low levels in MAP systems is safe. As it did with its "color additive" and "combustion product gas" arguments, Kalsec has misrepresented or misunderstood the facts, the science, and the law.

B. Precept's MAP System Offers Meaningful Consumer Benefits

In assessing any material or packaging system, it is important to consider not only risks that may be presented, but also ways in which a material or system may actually enhance safety. Case-ready packaging systems offer more than advantages of product quality, presentation, and convenience to both retailers and consumers—they also allow for several important safety benefits.

Most significantly, the use of CO at low levels allows case-ready packaged products to be prepared in a central facility. This means that the case-ready products are prepared under continuous FSIS inspection and in compliance with applicable FSIS requirements. Among these are requirements for HACCP plans for raw meat products, SSOPs, and Good Manufacturing Practices.

In addition, use of a central facility eliminates any handling of meat and poultry products after the USDA mark of inspection is applied. The Food Code recognizes that post-production handling can present a risk of cross-contamination:

> Even if foods . . . receive adequate thermal processing, a particular concern is present at retail when employees open manufactured products and

> repackage them. This operation presents the potential for post-processing contamination by pathogens.41/

In addition to preventing cross-contamination, preparation in a central location also enhances food security by reducing the risk of product tampering.

An important consumer benefit made possible by CO is the use of a single date code throughout the distribution system. Application of a validated and controlled "use or freeze by" date addresses a major drawback of traditional meat packaging—lack of consistent code dating because the point at which a product will be prepared and displayed for sale is unknown. Reliance on a centrally applied open date code offers a far more objective means of assessing product age and quality than highly subjective measures such as color. Consumers are accustomed to relying on code dates in numerous contexts, including hot dogs, deli meats, and dairy products. Fresh meat products such as whole muscle cuts and ground beef are no different.

IV. USE OF A MODIFIED ATMOSPHERE IS NOT A MATERIAL FACT REQUIRING LABELING

The petition contends that use of CO in a modified atmosphere triggers a requirement to disclose the presence of CO on the product label. The basis for this proposed requirement is said to be sections 403(a) and 201(n) of the FFDCA. Labeling requirements for fresh meat, however, are governed by FSIS pursuant to the Federal Meat Inspection Act (FMIA). Under the FMIA, FSIS does not require declaration of gases used in MAP systems. This is true regardless of whether the MAP gas is used to stabilize product color during distribution. High oxygen systems stabilize product color in the same manner as CO, but have never triggered an ingredient labeling requirement. FDA similarly has not required declaration of packaging gases. 42/

41/ FDA, 2005 Food Code 547 (Annex 6).

42/ For example, FDA has advised that carbon dioxide that is merely incorporated into the headspace of cottage cheese containers need not be declared in the ingredient line of finished proudcts. Milk Safety Branch, Center for Food Safety and Applied Nutrition, FDA, Milk Memorandum M-I-03-17, Q. 5(a) (Dec. 2003).

The intended conditions of use also are not reasonably viewed as deceiving consumers or omitting material information. As discussed previously, the intended use of CO is safe and functions merely to stabilize meat's natural color. It is used only in conjunction with a validated "Use or Freeze By" date that objectively assures consumers of the precise timeframe during which the product is wholesome and safe to consume. In the event that product is temperature abused—which, as the Food Code notes, is less likely to occur in the fresh meat case than in other areas—spoilage will occur and will be evident through means other than color, including odor, gas formation, and slime formation. Finally, as an added protection, all products packaged in MAP systems including CO are raw and will require thorough cooking that is likely to destroy or inactivate any pathogens or toxins that may be present. Under these carefully defined conditions, use of CO is not deceptive, does not constitute material information for which disclosures are indicated, and does not make food appear to be better or of greater value than it is.

V. SUMMARY

In summary, Precept Foods has developed and carefully substantiated conditions for the safe use of low levels of CO in MAP systems for fresh meat. Use of CO under these conditions is generally recognized as safe and otherwise lawful. It does not constitute an unapproved color additive, nor is it prohibited for any other reason. Indeed, use of CO makes it possible to distribute fresh meat from a central location in a way that enhances product quality and safety.

We would be pleased to discuss with FDA any of the points made in these 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

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Dr. Barbara J. Masters, Administrator, FSIS, USDA
Sheldon Bradshaw, Chief Counsel, FDA
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