ERIC F. GREENBERG, P.C.
A professional corporation

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fdadockets@oc.fda.gov
Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

RE: ADDITIONAL COMMENTS OF PACTIV CORPORATION, LAKE FOREST, ILLINOIS ON KALSEC, INC. CITIZEN PETITION "REQUESTING FDA TO ENFORCE BAN ON CARBON MONOXIDE GAS IN FRESH MEAT PACKAGING" (Docket 2005P-0459)

To the FDA:

These additional comments of Pactiv Corporation, Lake Forest, Illinois, are submitted to Docket 2005P-0459 in opposition to the Citizen Petition of Kalsec, Inc. in which Kalsec asks FDA to impose a ban on carbon monoxide gas ("CO") in fresh meat packaging.

Introduction

In June 2006, Kalsec, Inc. filed a letter to the FDA into Docket 2005P-0459, along with several hundred pages of accompanying information, which it says, "responds to comments by Precept Foods, L.L.C. submitted on April 11, 2006."[1] Pactiv offers this response to Kalsec's most recent materials that, in part, attack the safety and GRAS status of Pactiv's unique CO meat packaging system.

[1] See Letter from Kalsec, Inc. to Laura M. Tarantino, PhD, Director, CFSAN, re: Citizen Petition Requesting FDA to Enforce Ban on Carbon Monoxide in Case-Ready Fresh Meat Packaging; Docket No. 2005P-0459, June 14, 2006, at 1 [*hereinafter* June 14 letter.]

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efgreenberg@uhlaw.com
SUITE 3500, 70 WEST MADISON STREET, CHICAGO, ILLINOIS 60602-4224

To summarize, it is Pactiv's belief that Kalsec's petition is misguided, being neither legally nor factually supported. Pactiv believes that the modified atmosphere packaging systems being challenged by Kalsec are safe and "Generally Recognized As Safe" when used as intended. Pactiv also believes that, because Pactiv's CO system ("Pactiv CO System") removes CO from meat packaging before the meat is displayed to consumers on the retail shelf, most of Kalsec's arguments are inapplicable to the Pactiv CO System.

Many of the arguments contained in Kalsec's submission already have been addressed by earlier comments filed by Pactiv Corporation, Precept Foods, L.L.C. and others. In fact, hundreds of pages from Kalsec's most recent submission merely constitute a resubmission of materials by Kalsec. As FDA reviews Kalsec's arguments and responses to them, we believe that it will become apparent that those arguments are largely speculative and conclusory, and often founded upon mistakes of law and/or fact. In fact, actual retail marketplace experience with CO systems demonstrates that they do not create unsafe meat or deceive consumers.[2] Specifically with respect to Pactiv's CO System, for example, meat ages naturally from the time that it is put on display at retail,

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[2] The centerpiece of Kalsec's newly filed materials is a study it commissioned that compares retail packages of CO-packed meat (i.e., although, not packed using Pactiv's CO System) on the one hand, with high-oxygen ("Hi-O2") packed meat, on the other. Kalsec evidently saw the need to supplement the record with information intended to bolster the reputation of Hi-O2 systems, because Hi-O2 systems impact meat coloration much the same as CO. That is, Kalsec's challenge of CO systems is based upon its contention that CO keeps meat red in the retail package beyond the time during which that naturally would occur. It is indisputable that Hi-O2 packaging does that, but Kalsec does not challenge Hi-O2 technologies. That is understandable, since Kalsec sells its additives to parties who employ those technologies. Importantly, however, it should be noted that, unlike Hi-O2 systems, Pactiv's CO System does not impact meat coloration at retail, because the packaged meat is removed from the CO environment before it is put on display at retail. Perhaps in trying to muster evidence to support the safety of Hi-O2 systems, Kalsec is hoping to divert attention from the fact that the most serious health issue presented by MAP packaging of meat is premature browning, which is associated with Hi-O2 packaging; a problem not associated with CO packaging that contains low-oxygen.

so consumers can observe changes in coloration from that time just as they would with a fresh cut of meat. Additionally, further indicators of spoilage, such as odor, slime and gases, are unaffected by CO packaging technologies.

Specific arguments

Pactiv's GRAS Notice clearly establishes that CO is a processing aid, and the Pactiv system is GRAS

Without citing authority of any kind, Kalsec asserts that CO cannot be a "processing aid" under applicable laws and regulations, because it is not added "during processing." June 14 letter, at 23. It is unclear upon what basis Kalsec makes that assertion, since Kalsec cites no authority to support it. Pactiv is unaware of any. In fact, the US FDA ("FDA") and the US Department of Agriculture ("USDA") deemed CO, as used in Pactiv's CO System, to be a "processing aid" within the meaning of the laws and regulations those agencies administer.[3] That is particularly noteworthy, since that was not done with respect to the CO in any other CO system they reviewed.[4] Kalsec apparently doesn't realize that the distribution and storage of meat is part of its processing, particularly when meat is transported in a modified atmosphere that continues to have an effect on the product during storage and distribution. Consequently, CO used in Pactiv's CO System

[3] *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 887 (1984).
[4] See Letter from Laura M. Tarantino, Director, CFSAN, to Gary J. Kushner and Anne M. Boekman, Hogan and Hartson (July 29, 2004) regarding GRN 000143: GRAS Notice of Precept Foods, LLC; Letter from Laura M. Tarantino, Director, CFSAN, to Mark L. Itzkoff, Olsson, Frank and Weeda, P.C., (September 29, 2005) regarding GRN 000167: GRAS Notice of Tyson Foods, Inc.

has been deemed to be (i.e., by the FDA and USDA), and is, under applicable law, a "processing aid" that is exempt from ingredient labeling requirements.[5]

Kalsec states that Pactiv GRAS Notice No. GRN000083 contains conflicting information about the rate at which carboxymyoglobin converts to other pigment forms, which will allow for normal color deterioration. That misses the point of the information that was shared in Pactiv's GRAS Notice. That information established that, in the Pactiv CO System, CO is not present and has no functional effect on fresh meats displayed at retail. That is, from the time of display at retail, meat packaged using the Pactiv CO System will age normally in terms of color deterioration. "[T]he rate at which carboxymyoglobin converts to other pigment forms," therefore, is irrelevant, since consumers of meat packaged using Pactiv's CO System are observing normal color deterioration of that meat.

A study conducted by Kansas State University ("KSU") that was used in support of Pactiv's GRAS Notice demonstrated that CO in a MAP does not affect meat color after the meat is removed from the MAP and exposed to air for 60 to 90 minutes. Pactiv's GRAS Notice, as supported by that study, demonstrated that meat packaged using Pactiv's CO System will age naturally and its color will change, accordingly, from the time that it is removed from the presence of CO. In the case of Pactiv's CO System, that point in time is when the meat is put on display at retail.

[5] 21 CFR 101.100(a)(3)(ii)

The graphs in the KSU study illustrate that the color of meat that is removed from the modified atmosphere of a CO system changes to brown like meat that hasn't been impacted by CO.[6] Any differences in color change between meats that *have* and meats that *have not* been stored in CO, as those graphs illustrate, are insignificant or nonexistent. Only while in the presence of CO and for a period of between 60 to 90 minutes thereafter will meat color be impacted by CO in the Pactiv CO System. Since meat stored in Pactiv's CO System is removed from the presence of CO when it is placed on display at retail for sale to consumers, from that point the meat looks, behaves and ages just as would a fresh cut of meat.

As meat chemists and other industry experts know, the expected color of any particular cut of meat is subject to extreme variations. Even within a single cut of meat there can be a range of meat color readings; and it is very difficult to be precise in taking those readings. Practically speaking, therefore, curves of data that are near to each other, such as many of those shown in the KSU data, are functionally equivalent. That was a conclusion reached by the "Expert Panel" with respect to the KSU study, and FSIS and FDA reviewers concurred. Thus, the KSU study demonstrates that CO packaging has no significant functional effect on the color of meat after it is removed from the presence of CO.

Kalsec says, in its June 2006 letter (i.e., at footnote 70), that Pactiv's GRAS Notice implies that carboxymyoglobin "disappears" when the outer bag is removed. Kalsec

[6] See, KSU Study, Figures 6-10.

asserts that, "The report does not contain any information as to the identity of the pigments on the meat surface or description of experiments to make such measurements." Kalsec is correct that the KSU study did not address that issue. As discussed above, the KSU study demonstrates that, contemporaneously with the removal of meat from the modified atmosphere of Pactiv's CO System (i.e., within 60 to 90 minutes of removal from the presence of CO), the CO has no impact on the color of the meat. Rather, the behavior of the meat from that point, in terms of color deterioration, is essentially identical to that of a fresh cut of meat. Thus, this issue raised by Kalsec about "the identity of the pigments on the meat surface or description of experiments to make such measurements" is irrelevant for purposes of FDA's review of Pactiv's CO System.

Consumers are not misled by meat packaged using Pactiv's CO System, because that meat stays red on the retail shelf no longer than the few days that would be expected of a fresh cut of meat. Even meat that has not been handled properly within the cold chain (e.g., kept out of refrigeration for extended periods of time while on its way to the retail shelf) will show evidence of that mishandling, because it will brown faster.[7] These facts were presented in Pactiv's GRAS Notice and supported by a study that specifically examined the effects of temperature abuse conditions on meat packaged using Pactiv's CO System.

[7] Pactiv's GRAS Notice, p. 000034-35: "For product from MAP, the longer the storage time, the faster the deterioration, especially at the higher storage temperature (Attachment 4, Tables 2 and 3). For packages stored at 43F, which was a mildly abusive temperature, color deterioration would be expected to accelerate. This phenomenon also is illustrated in Attachment 4, Figures 1-10."

Kalsec says that literature cited by Pactiv in its GRAS Notice indicates that the half-life of carboxymyoglobin in CO-treated meats that subsequently are exposed to air is 3 days. Kalsec, however, is referring to a study involving exposure of meat to 1% CO, which is more than double the 0.4% CO level in Pactiv's CO System. That citation to a 3-day period, therefore, has no bearing on Pactiv's CO System. Rather, the relevant point made by the literature cited was simply that meat will age and brown in a normal manner over the course of several days, when it is removed from the presence of CO and in an atmosphere that contains oxygen. That is, in the case of the Pactiv CO System, changes in the color of meat will occur naturally (i.e., with respect to color and the rate of its change) from the time that meat packaged using the Pactiv CO System is put on display at retail.

Kalsec cites to three case decisions as helpful authority for its arguments. Those authorities are misapplied and inapposite. For example, Kalsec's citation to U.S. v. Randazzo[8], implies that it stands for the proposition that the definition of "processing aid" excludes an ingredient that changes a food's color. In that case, a defendant, on appeal, challenged a jury instruction that he *rightfully* believed mischaracterized the language of the regulation that defined "processing aid." The Court in that case stated, "This takes us to the question whether the district court was right in glossing the regulation to exclude from the definition of 'processing aid' an ingredient that 'change[s] [the food's] color.'" In rejecting defendant's appeal, the Court said that it was "[defendant's] responsibility to *make some showing* that an error has been committed

[8] 80 F.3d 623 (1st Cir. 1996),

[emphasis added]." In that regard, the Court noted that, "However, [defendant] offer[ed] nothing--by way of textual analysis, precedent, administrative interpretation, policy argument, or anything else--to support his underlying position." Consequently, the Court held that, "*We have no basis* here for finding that the instruction was error and that is enough to decide this case [emphasis added]." Said another way, the Court did not find that the jury instruction (i.e., which included a mistaken definition of "processing aid") was correct. Rather, it simply found that the defendant failed to meet its burden (i.e., because he presented no evidence) of demonstrating that the jury instruction was wrong.

Similarly, Kalsec misapplies Sea Snack Foods, Inc. v. U.S.[9] In that case, the district court reviewed the FDA's finding that sodium hydroxide used in preparing shrimp was not a "processing aid," because it caused water retention and enhanced weight in the final product. Since shrimp is purchased by the pound, the FDA rightfully determined that sodium hydroxide caused a form of economic adulteration of the shrimp that was detrimental to consumers. By contrast, CO used in MAP packaging adds nothing to the weight or volume of fresh meat. That is not only true with respect to the final product, but at any point in time. Significantly, as to Pactiv's CO System, CO is not present at all in, and has no effect on, meat after it is put on display to consumers.

Finally, in Stauffer Chemical Co. v. FDA[10], the district court found that sodium tripolyphosphate was not a "processing aid," when used in processing tuna. That

[9] Food Drug Cosm. L. Rep. (CCH), 1988-1989 Transfer Binder, ¶38,062 at p. 37,901 (D.D.C. 1987).
[10] Food Drug Cosm. L. Rep. (CCH), 1980-1981 Transfer Binder, ¶38,065 at p. 38,304-5 (D.D.C. 1980).

conclusion was based on the Court's finding that, when sodium tripolyphosphate is not removed from tuna before canning, it significantly increases the level in the tuna of a chemical called "orthophosphate" that continues to have an effect on the finished food product (i.e., canned tuna). Consequently, the Court determined that the sodium tripolyphosphate could not be viewed as a "processing aid" under any of the subsections of 101.100(a)(3)(ii). It is not established that impacting color of a cut of meat constitutes a "technical or functional effect in that food." Moreover, with respect to Pactiv's CO System, CO is not present at all in, and has no effect on, meat after it is put on display to consumers.

FSIS, FDA and the "Expert Panel" cited to by Pactiv in its GRAS Notice all agreed that the color of meat packaged using Pactiv's CO System is unaffected by CO at the time of retail display (i.e., unaffected by CO from between 60 and 90 minutes of removal from the CO used in Pactiv's CO System), so that from that point meat packaged using Pactiv's CO System browns in a timeframe that is substantially identical to that of a fresh cut of meat. Since CO, as used in the Pactiv CO System, has no technical or functional effect on the finished food product (i.e., the meat that is put on display at retail), it is a "processing aid" (i.e., as opposed to an "ingredient") that is not required to be listed on the meat's label.[11]

[11] For the same reason, contrary to Kalsec's argument, its use is not a material fact requiring a label statement any more than for other modified atmosphere gases used in the distribution of meat or any other food product. Despite multiple examples of other foods that utilize modified atmospheres in their distribution and storage, the fact that those gases are present and have an effect on freshness and color, and the fact that those gases often remain in retail packages, none of those modified atmosphere gases is labeled. Similarly, Pactiv's CO System does not call for any special labeling.

CO is not a color additive as used in Pactiv's system

In its June filings, Kalsec repeats an argument (i.e., from its original November 2005 Citizen Petition) that CO used in meat packaging is a "color additive." Pactiv and others previously refuted that argument in comments already submitted to the FDA. Pactiv stands by its prior comments and points out that the FDA and FSIS both concluded that CO, as used in Pactiv's CO System, *is not* a color additive. Since those two agencies have primary responsibility for interpreting and implementing the relevant statutory and regulatory provisions, their conclusions are entitled to considerable deference.[12]

There is no "scientific controversy" about the safety of this use of CO

Kalsec claims that there is "scientific controversy" documented in published literature about the safety of CO when used for the purpose of packaging fresh meat. Consequently, Kalsec argues, CO as used in Pactiv's CO System cannot be GRAS. In support of that argument, Kalsec cited to Dr. Oddvin Sorheim's 1997 and 1999 articles, and to a report of the European Commission's Scientific Committee on Food. All of those articles, however, dealt with systems where CO was still present in the meat package when it was seen by consumers at retail. This is not true of the Pactiv CO System, so Kalsec's citations here are inapposite. It is noteworthy, too, that the Sorheim

[12] A court reviewing an agency decision will give considerable weight to such a fact. *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 887 (1984)("We have long recognized that considerable weight should be accorded to an executive department's construction of a statutory scheme it is entrusted to administer, and the principle of deference to administrative interpretations. *Chevron* at 844, internal citations omitted.)("... the Administrator's interpretation represents a reasonable accommodation of manifestly competing interests and is entitled to deference: the regulatory scheme is technical and complex, the agency considered the matter in a detailed and reasoned fashion, and the decision involves reconciling conflicting policies." *Chevron* at 865, internal citations omitted).

articles state that consumers can detect meat spoilage via off-odors even in systems where CO is still present at retail. That is contrary to assertions made by Kalsec.[13]

Kalsec says that published scientific literature indicates that spoilage indicators other than color (i.e., in packages containing CO) are unreliable, so even the Pactiv CO System presents concern in the event that there is a problem in the cold chain (i.e., refrigerated storage in distribution through the point of retail). Pactiv, however, contends that sufficient spoilage indicators will always be present in meat held in any of the CO systems at issue, even under conditions of temperature abuse. Those indicators include odor, slime and gases. Additionally, in Pactiv's CO System, color remains as much of a reliable spoilage indicator as it is for fresh cut meat. That is, just as with fresh cut meat, meat packaged using Pactiv's CO System will turn less red and more brown over the course of between 2 to 4 days. That period of color deterioration accelerates if meat packaged using Pactiv's CO System is subjected to temperature abuse.[14]

In response to Kalsec's comments concerning the microbiological safety of CO-containing meat packaging systems, Pactiv notes the following:

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[13] See O. Sorheim *et al., Technological, Hygienic and Toxicological Aspects of Carbon Monoxide Used in Modified-Atmosphere Packaging of Meat,* 8 Trends Food Sci. Tech. 307, 311 (September 1997); See June 14 Kalsec letter at pages 12-13).

[14] K. Hachmeister, M. Hunt, G. Milliken, *Evaluation of Beef Steaks and Ground Beef in the Pactiv ActiveTech Packaging System: Effects of Carbon Monoxide in the Package Atmosphere,* May 2001, *see especially* Figures 1-10 [*hereinafter* KSU study.] .

- Kropf (1980) recommends "a combination of CO with other gases, such as CO2" (i.e., to control microbial growth). Pactiv's and Precept's CO systems employ CO combined with CO2 and nitrogen.

- Kalsec highlights that Nissen (2000) found *Salmonella* strains in inoculated ground beef that were higher in a high CO2/low CO gas mixture than in a Hi-O2 mixture. Kalsec, however, selectively draws from that report by: (i) citing to the one organism that grew in count more aggressively in a high CO2/low CO gas mixture than in a Hi-O2 mixture, (ii) failing to mention that was not the case with two other types of organisms (i.e., Y(ersinia) enterocolitica and L(isteria) monocytogenes), and (iii) failing to mention that Y. enterocolitica grew more rapidly <u>and</u> actually was higher in count in a Hi-O2 environment than in a high CO2/low CO mixture, at both 4° C and 10° C.

Finally, Kalsec argues that the use of CO to package meat is not GRAS, because scientific literature documents significant incidents of temperature abuse. As noted above, however, in the Pactiv CO System the same spoilage indicators (i.e., including color, odor, slime and gases) are available for consumers to rely upon, as would be available with respect to a fresh cut of meat.

The "Combustion product gas" regulation does not prohibit finding CO to be GRAS

Kalsec incorrectly asserts that the combustion product gas food additive regulation (i.e., at 21 CFR 173.350) prohibits a finding that the use of CO in meat packaging is GRAS. GRAS status is a freestanding and separate status that is based upon evaluation by relevant scientists of the use of a substance. The essence of a GRAS determination is that

a particular use of a substance (i.e., as opposed to the substance itself) is safe and generally recognized as such.[15] Relevant experts can examine a particular use of a substance that is regulated as a food additive by FDA and determine that it is GRAS. Companies, in turn, can then rely on that expert conclusion to support their ability to use that substance in the manner that was found to be GRAS, regardless of the otherwise applicable food additive regulation.[16]

Kalsec's argument for labeling doesn't apply to the Pactiv CO System

Kalsec argues that meat products packaged using a CO system should be required to carry a label expressly notifying consumers of that fact. Kalsec contends that the CO in such systems has a "functional effect" in the finished meat product food and, therefore, constitutes an "ingredient." As such, Kalsec argues, it must be listed on the meat's label.[17]

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[15] FDA explicitly confirms, "Importantly, under section 201(s) of the act, it is the use of a substance, rather than the substance itself, that is eligible for the GRAS exemption." Substances Generally Recognized as Safe; Proposed Rule, 62 FR 18937 (April 17, 1997) at 18939; FDA/CFSAN Guidance for Industry: Frequently Asked Questions About GRAS, December 2004. Question: "If an ingredient is GRAS for one use, is it GRAS for all uses?" Answer: "Not necessarily. Under section 201(s) of the Act, it is the use of a substance, rather than the substance itself, that is eligible for the GRAS exemption (62 Fed. Reg. 18939; April 17, 1997). A determination of the safety of the use of an ingredient includes information about the characteristics of the substance, the estimated dietary intake under the intended conditions of use, and the population that will consume the substance (proposed 21 CFR 170.36 (c)(1)(iii))."

[16] FDA has explicitly confirmed this point as well, in FDA/CFSAN Guidance for Industry: Frequently Asked Questions About GRAS, December 2004. Question: "If I submit a GRAS notice about a food substance, must I wait until I receive a response from FDA before I market that substance?" Answer: "No. If one is correct in determining that the intended use of an ingredient is GRAS, use of the ingredient is not subject to any legal requirement for FDA review and approval. Your decision to submit a GRAS notice is voluntary, and FDA's response to a GRAS notice is not an approval. You may market a substance that you determine to be GRAS for a particular use without informing FDA or, if FDA is so informed, while FDA is reviewing that information (62 Fed. Reg. 18951; April 17, 1997). We recognize, however, that some firms prefer to know that FDA has reviewed its notice of a GRAS determination, without raising safety or legal issues, before marketing."

[17] See, June 14 letter, at 35-40.

As described above, however, the CO used in Pactiv's CO System has no "functional" or other effect in the finished food (i.e., meat on the retail shelf). That is why, appropriately, the FDA and USDA agreed that the CO in Pactiv's CO System is simply a "processing aid" that need not be listed on the meat's label.

Kalsec's "New" Citizen Petition

Kalsec's June 2006 submission is, in fact, a "new" Citizen Petition, since it requests a new form of relief (i.e., notice and comment rulemaking). FDA regulations require that, "A request for alternative or different administrative action must be submitted as a separate petition." 21 CFR 10.30(d). Kalsec's original Citizen Petition did not ask for notice and comment rulemaking. Rather, it asked for a ban on the use of CO in packaging fresh meat and for the termination of "the agency's unlawful responses to the . . . GRAS notifications."[18]

Conclusion

For the reasons noted above, Pactiv Corporation respectfully asks FDA to:

- deny Kalsec's request, particularly with respect to Pactiv's CO System, to ban the use of CO in systems used for packaging fresh meat;
- deny Kalsec's request to terminate FDA's acceptance of Pactiv Corporation's GRAS Notice No. 000083;

[18] FDA Docket No. 2005P:0459 (Citizen Petition of Kalsec, Inc.) (Nov. 15, 2005), at 1.

- deny Kalsec's request, particularly with respect to Pactiv's CO System, for meat labels to indicate if meat has been packaged using a CO system; and
- deny Kalsec's request for the FDA to initiate notice and comment rulemaking regarding the use of CO in connection with the packaging of fresh meat.

Sincerely,

Eric F. Greenberg
Counsel to Pactiv Corporation

EFG/dmw

cc: Dr. Andrew C. von Eschenbach, Acting Commissioner of Food and Drugs, FDA
Dr. Barbara J. Masters, Administrator, FSIS, USDA
Sheldon Bradshaw, Chief Counsel, FDA
Dr. Robert E. Brackett, Director, CFSAN, FDA
Dr. Laura M. Tarantino, Director, OFAS, FDA
Dr. Robert C. Post, Director, Labeling & Consumer Protection Staff, FSIS, USDA
Scott Gottlieb, Deputy Commissioner for Policy, FDA
Michael Landa, Deputy Director for Regulatory Affairs, CFSAN, FDA
Dr. Robert L. Martin, Deputy Division Director, OFAS, FDA
Dr. Rudolph Harris, Supervisor, OFAS, FDA
Dr. Robert L. Buchanan, Senior Science Advisor, CFSAN, FDA
Dr. Lane Highbarger, Consumer Safety Officer, OFAS, FDA
Dr. Bill Jones, chemist, FSIS, USDA
Philip Derfler, Assistant Administrator, FSIS, USDA