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

To the FDA:

These comments are submitted on behalf of Pactiv Corporation, 1900 West Field Court, Lake Forest, Illinois 60045, in opposition to the Citizen Petition filed with the Food and Drug Administration ("FDA") on November 15, 2005 by Kalsec, Inc., Kalamazoo, Michigan ("Kalsec"), entitled "Citizen Petition Requesting FDA To Enforce Ban On Carbon Monoxide Gas In Fresh Meat Packaging."

For the reasons set forth below, Kalsec's Citizen Petition should be denied in its entirety because the relevant facts and law do not justify the relief it seeks.

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Executive Summary

Kalsec has petitioned FDA seeking a ban on the use of carbon monoxide ("CO") to package fresh meats, alleging that all uses of CO to package fresh meat are misleading to consumers and unsafe. Kalsec's arguments attack CO technologies that are significantly different from Pactiv's system, and yet Kalsec makes no distinction among the different systems. Pactiv's comments below will demonstrate that Kalsec's arguments are inapplicable to Pactiv's system, or are based on misapprehension of relevant facts or law.

Pactiv's is the only CO system in which the modified atmosphere is removed from the meat before consumers see the meat. With the Pactiv system, there is no opportunity for consumers to be misled because the system has no effect on retail display time, and does not artificially maintain the meat's red color while it is on retail display. [1]

Kalsec's Citizen Petition fails to recognize this crucial distinction between the Pactiv system and other companies' systems. In this and other respects, Kalsec misleadingly fails to accurately describe the Pactiv system, and has further compounded the problem by misinterpreting and misapplying the relevant legal provisions. Kalsec's careless lack of precision has already caused Pactiv's system to be the subject of wholly unjustified doubts and suspicions in media reports and among consumers.

[1] As FDA is aware, there are other modified atmosphere systems in use that incorporate elevated levels of oxygen (but not carbon monoxide). Those systems, too, keep the meat in the modified atmosphere at retail display, and through the time consumers open the package. Kalsec raises no objection to any such high-oxygen systems. It is Pactiv's understanding that Kalsec supplies herb extracts to users of such systems.

Meat packaged in Pactiv's system incorporating CO is safe, wholesome and not misleading to consumers. The Pactiv system has been thoroughly tested and reviewed by independent experts. In addition, both FDA and the United States Department of Agriculture ("USDA") have reviewed the Pactiv system's features and safety. For the past several years, the Pactiv system has been used safely and without any deception of consumers. As explained below, Kalsec's assertion that the Pactiv system's use of CO to package fresh meat creates dangerous meat in anaerobic environments (that is, wholesome-looking meat that is contaminated with high levels of anaerobic pathogens) is simply wrong.

As used in the Pactiv system, CO is not a color additive, and is not prohibited by any existing regulation. No retail label statement about the presence and purpose of CO, such as Kalsec requests, is needed here because the CO in the Pactiv system is a processing aid, and does not artificially maintain the meat's red color while it is on retail display.

Summary of Pactiv Corporation's System Incorporating Carbon Monoxide

Pactiv's system is designed to permit shipment of meats to retailers in retail-ready packages. Under more traditional systems, employees at the retailer would have to cut and portion larger pieces of meat, or create individual portions of ground meat, and place them onto individual trays. With the Pactiv system, the retailer faces significantly less

labor to prepare the meat for sale.[2] As explained below, the Pactiv system has no effects on retail display time and does not artificially maintain the meat's red color while it is on retail display. Other modified atmosphere technologies currently in use can extend the retail display time and red color of the meat while it is on retail display.

In the Pactiv system, retail cuts of muscle meat, or retail portions of ground meat, are placed in packaging trays and covered with oxygen permeable flexible overwraps.[3] The wrapped trays are placed within an outer barrier bag, and the air is removed and replaced with a blend of carbon dioxide (CO_2), nitrogen (N_2), and CO. An activated oxygen-absorbing sachet is added within the outer bag to create and maintain an oxygen-free environment for the packaged meat during storage.[4] At the grocery store, a grocery employee opens and discards the outer bag containing the modified atmosphere, and places the overwrapped tray of meat in the store's display case.

Once on retail display, the Pactiv system meat's myoglobin will begin the natural conversion to metmyoglobin (brown), akin to that seen with meat that has not been held in a modified atmosphere. Because the modified atmosphere containing CO is removed before retail display, the meat has a conventional retail display life of 2 to 4 days, and the Pactiv system does not artificially maintain the color of meat while it is on retail display.

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[2] "Notification of Claim for General Recognition of Safety of Carbon Monoxide in A Modified Atmosphere System for Packaging Fresh Meat," at section I(c) (August 29, 2001) [hereinafter *GRN 83*].
[3] Id.
[4] The activated oxygen-absorbing sachet inserted into the outer bag to absorb oxygen does not contact food and is not expected to become a component of the food. Therefore, it is not a food additive under the definition in 21 USC Sec. 321(s). As an added assurance of safety, each of the sachet's components has GRAS status or food-related approvals.

Therefore, Kalsec's allegations that meat packaged with CO will stay red longer than usual while on retail display is misplaced as concerns the Pactiv system.

As part of their GRAS analysis, Pactiv unquestionably demonstrated that the system does not mask spoilage and that meat samples held at both refrigerated temperatures, and under abuse temperature conditions, and then opened for retail display, turned brown before any of the aerobic or anaerobic bacteria reached spoilage levels.[5] In other words, if meat that had been held in Pactiv's system was not held under proper refrigeration conditions during storage or distribution, it would turn brown and be unattractive and unpalatable before it reached microbial spoilage . Therefore, Kalsec's allegation that temperature abuse of meat held in CO would result in unsafe meat that appears wholesome to consumers is also misplaced as concerns the Pactiv system.

Points and Authorities in Opposition to Kalsec's Legal Arguments

I. Carbon Monoxide is not a color additive as used in the Pactiv system

The Kalsec petition goes to great lengths in describing why Kalsec believes CO as used in the Pactiv system is a color additive, and offers several further, derivative arguments based on that assumption. Indeed, Kalsec says that FDA has recognized as color additives "ingredients which impart color to meat products through chemical

[5] GRN 83, *supra* note 2, at section I(d).

reactions with the naturally occurring myoglobin in meat tissues...."[6] Kalsec goes on to describe a determination made by FDA in 1979 that nitrites "impart" color because they react with myoglobin in the meat thereby forming a third substance that gives the meat its red appearance.[7]

Kalsec misleadingly fails to inform FDA, however, that just a short time later, FDA reversed this determination and concluded that nitrites are not "color additives" in that they do not "impart" color within the meaning of the Federal Food, Drug and Cosmetic Act (FFDCA).[8] FDA's decision was based on its determination that substances that "fix" color (that is, maintain an existing color of food) are not color additives, while those that "impart" color are color additives.

Even so, the Pactiv system does not even "fix" a red color, because, as noted, immediately upon retail display, the meat previously packaged in the modified atmosphere begins to brown and age in a normal manner.[9] Moreover, as fully explained in Pactiv's GRAS Notice and above, Pactiv's system is essentially designed to enhance distribution flexibility before, but not during, retail display to consumers.[10]
Not surprisingly, Kalsec fails to acknowledge that even if CO was a color additive, such status would not preclude it from also being a GRAS substance. It is possible for a substance to be approved for use as a color additive and also affirmed as GRAS, with

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[6] FDA Docket No. 2005P:0459 (Citizen Petition of Kalsec, Inc.) (Nov. 15, 2005), at 9 [hereinafter Kalsec Citizen Petition].
[7] Id.
[8] 45 Fed. Reg. 77043, 77044 (Nov. 21, 1980).
[9] GRN 83, *supra* note 2, at section I(c).

beta-carotene being one example of such a classification. Beta-carotene is approved for use as a color additive under 21 CFR 73.95 and is also affirmed as GRAS for use as a nutrient under 21 CFR 184.1245.[11]

II. "Fast-track" listing is irrelevant because carbon monoxide is not a color additive

One of the arguments raised in the Kalsec petition is that the GRAS notifications for CO cannot support "fast-track" listing of CO for color additive purposes. In making this argument, Kalsec refers to a provision in FFDCA Section 721(b)(4) allowing for fast-track FDA approval for color additives where FDA has already determined the ingredient to be GRAS. This argument is completely irrelevant because, as clearly established above, CO is not a color additive as used in the Pactiv system. The existence of the section also refutes Kalsec's argument that CO's alleged status as a color additive would preclude its status as GRAS for this use.

III. The safety of the Pactiv system is properly addressed in the Pactiv GRAS analysis

Kalsec asserts that FDA and USDA have never approved "colorants" for meat because colorants "would promote deception by making meat appear fresher than it is."[12] Aside from the fact that CO is not a colorant, Kalsec's position that meat under the Pactiv system would be deceptive to consumers ignores the fact that the modified atmosphere is

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[10] Id.
[11] *See* 21 CFR 73.95 and 21 CFR 184.1245.

not present at the retail level and it does not artificially maintain the color of meat while on retail display.

Kalsec also argues that FDA has failed to show that CO would be safe under actual conditions of use. However, any allegation that the system is somehow unsafe is refuted by the GRAS status of this use of CO. That GRAS status reflects the facts that the Pactiv system was thoroughly studied and reviewed by an expert panel of four independent, recognized authorities in the fields of meat science and toxicology.[13] In keeping with FDA regulatory requirements, Pactiv convened an Expert Panel for just this purpose, and the content of the Pactiv GRAS Notice largely reflects their work.

In addition, Pactiv's system and similar systems have been used for several years in the United States without any harm to the public.

Kalsec particularly questions the safety of the system under temperature abuse conditions. As part of their GRAS analysis, Pactiv specifically demonstrated to both FDA and USDA that such concerns were not valid.[14] With the Pactiv system, meat held at abuse temperature conditions, and then opened for retail display, turned brown before aerobic and anaerobic bacteria reached spoilage levels. On the other hand, the CO_2 utilized in the Pactiv system is known to suppress both aerobic and anaerobic bacteria while the meat is in transit to retailers' display cases.

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[12] Kalsec Citizen Petition, at 12.
[13] See GRN 83, *supra* note 2, at Attachments 7-10.
[14] GRN 83, *supra* note 2, at section I(d).

However, as thoroughly explained in GRN 000083, the CO in the system neither masks spoilage nor extends color life beyond the point of wholesomeness, i.e., the point of microbial soundness.[15] If extreme temperature abuse does occur in distribution, and, despite the suppressing effects of the modified atmosphere gases, bacterial loads are high enough, off-odor or poor appearance or both will occur. These conditions will be readily identified by the retailer upon opening the outer package.

In a final attempt to attack the safety of the use of CO, Kalsec refers to a decision by the European Commission's Scientific Committee on Food to disallow the use of CO with fresh meat. The European Union's (EU) 2003 action prohibiting the use of CO with fresh meat is irrelevant to Pactiv's system. The EU action dealt with systems in which CO was still present when the meat was on retail display. Moreover, significantly, the EU authorities' decision was based on concern with the possibility of misleading consumers when packages of such a type were utilized, not with any basic safety concern about CO.[16] Indeed, as further evidence that safety is not a valid concern, packers in Norway had been packaging fresh meat in a modified atmosphere including CO for many years until the EU ban was adopted by Norway - again, though, in a system of the type where the modified atmosphere was still present at retail display.

[15] GRN 83, *supra* note 2, at section I(d).
[16] *See* EFTA Surveillance Authority Annual Report 2003 at 24.

IV. The existence of 21 CFR Sec. 173.350 does not prohibit finding of GRAS

Kalsec argues that FDA lacks the authority to permit the use of CO in fresh meat because 21 CFR 173.350 regulates the conditions of use of CO in food packaging to remove or displace oxygen, and that the regulation contains a prohibition on the use of CO with fresh meat.

The regulation in 21 CFR Section 173.1350 regulates uses of Combustion product gas, which is a specific combination of gases that includes CO. The regulation does not regulate, and therefore does not apply to, CO as used separately, or in other gas mixtures with fresh meat. There is no FDA regulation prohibiting the use of CO with fresh meat.

Contrary to Kalsec's arguments, the prohibition in 21 CFR Section 173.350 is also inapplicable to Pactiv's use because Pactiv's system does not mask spoilage or promote consumer deception. Moreover, even if the use of CO was regulated under this section, there is no reason that CO cannot be both regulated under the cited regulation and also GRAS for specified uses, and Kalsec cites no authority saying otherwise.

In fact, FDA's GRAS regulations contemplate this very idea. GRAS regulations make clear that substances will be GRAS and food additives at the same time for different uses:

> If an ingredient is affirmed as GRAS in part 184 or Sec. 186.1 of this chapter with specific limitation(s), it may be used in food only within such limitation(s) (including the category of food(s), the functional use(s) of the ingredient, and the level(s) of use). *Any use of such an ingredient not in full compliance with each such established*

limitation shall require a food additive regulation.

21 CFR 170.30 (j) (emphasis added)

Therefore, contrary to what Kalsec contends, it is indeed possible for a substance to be GRAS for one use and also regulated under a food additive regulation for a different use.

V. FDA and USDA consider the use of CO in the Pactiv system to be a processing aid and therefore labeling is not necessary

Kalsec contends that the use of CO requires declaration of that fact on the retail label. Once again, Kalsec ignores the obvious and fully supported counter to this argument: the Kalsec Citizen Petition fails to acknowledge that both FDA and USDA determined that the CO within the Pactiv system is a "processing aid" under their regulations because there will be no lasting functional effect in the food and the amount of CO present in the finished product is insignificant.[17] FDA clearly states this position in its Agency Response Letter for GRN 000083:

> In FSIS' view, Pactiv has demonstrated that this MAP system complies with FDA's definition of a processing aid that appears in labeling regulations (21 CFR 101.100(a)(3)). There is no lasting functional effect in the food and there is an insignificant amount of carbon monoxide present in the finished product under the proposed conditions of use.[18]

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[17] Letter from Alan M. Rulis, Director, CFSAN, Office of Food Additive Safety, to Eric Greenberg (Feb. 21, 2002), available at http://www.cfsan.fda.gov/~rdb/opa-g083.html.
[18] Id.

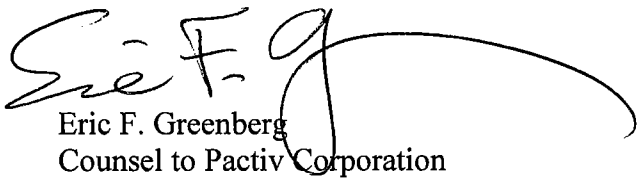
Moreover, because it is a processing aid, FDA regulations do not require listing of it as an ingredient or otherwise on the product package label. In other words, the labeling issue was addressed by FDA and by USDA, and handled in the manner described. To read the Kalsec Citizen Petition is to be left with the impression that the labeling issue was utterly ignored by the reviewing agencies. Therefore, Kalsec's alternative request for relief in the form of retail labeling should be denied.

Conclusion

For all the foregoing reasons, Pactiv Corporation respectfully requests FDA to:

- deny Kalsec's requests to ban the use of carbon monoxide in fresh meat packaging, and to deny its request to terminate FDA's acceptance of the Pactiv Corporation GRAS Notice No. 000083; and
- deny Kalsec's request to require labeling of fresh meats that have been packaged using the Pactiv system.

Sincerely,



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cc: Dr. Andrew C. von Eschenbach, Acting Commissioner of Food and Drugs, FDA
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Attachments

1. GRAS Notice 000083 ["Notification of Claim for General Recognition of Safety of Carbon Monoxide in A Modified Atmosphere System for Packaging Fresh Meat," (August 29, 2001).]

2. 45 Fed. Reg. 77043, 77044 (Nov. 21, 1980).

3. 21 CFR 73.95.

4. 21 CFR 184.1245.

5. Excerpts from EFTA Surveillance Authority Annual Report 2003 p. 24.

6. Letter from Alan M. Rulis, Director, CFSAN, Office of Food Additive Safety, to Eric Greenberg (Feb. 21, 2002).