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VIA FEDERAL EXPRESS

September 5, 2001

Dr. Linda S. Kahl
Division of GRAS Notice Review
Office of Food Additive Safety
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C St, SW
Washington, DC 20204

Re: NOTIFICATION OF CLAIM FOR GENERAL RECOGNITION OF SAFETY OF CARBON MONOXIDE IN A MODIFIED ATMOSPHERE SYSTEM FOR PACKAGING FRESH MEAT

Dear Dr. Kahl:

This letter is written as a supplement to the Notification Of Claim For General Recognition Of Safety Of Carbon Monoxide In A Modified Atmosphere System For Packaging Fresh Meat (consisting of pages 000001.001-000250), submitted by Pactiv Corporation by letter dated August 29, 2001.

The data and information that are the basis for Pactiv's GRAS determination are available for the Food and Drug Administration's review and copying at reasonable times at the office of Eric F. Greenberg, 3500 Three First National Plaza, Chicago, Illinois 60602, or will be sent to FDA upon request.

Moreover, please note that Pactiv withdraws its claim of protection as Confidential Business Information for each and every portion of the submission that was previously redacted (redactions are listed on page 000001.002), and that the GRAS Notice no longer contains information for which Pactiv is asserting Confidential Business Information protection. We understand that FDA may make an independent determination that portions should be protected from disclosure under the Freedom Of Information Act and implementing regulations.

If you have any questions, please contact me at (312) 977-4647.

Sincerely,

Eric F. Greenberg

efgreenberg@uhlaw.com
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PHONE: 312-977-4647 · FAX: 312-977-4405

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Contains Confidential Business Information

August 29, 2001

Division of GRAS Notice Review
Office of Food Additive Safety
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C St., SW
Washington, DC 20204

Re: NOTIFICATION OF CLAIM FOR GENERAL RECOGNITION OF SAFETY OF CARBON MONOXIDE IN A MODIFIED ATMOSPHERE SYSTEM FOR PACKAGING FRESH MEAT, submitted by Pactiv Corporation

To the FDA:

Enclosed is the NOTIFICATION OF CLAIM FOR GENERAL RECOGNITION OF SAFETY OF CARBON MONOXIDE IN A MODIFIED ATMOSPHERE SYSTEM FOR PACKAGING FRESH MEAT, submitted by Pactiv Corporation, 1900 West Field Court, Lake Forest, Illinois 60045, c/o the undersigned counsel, consisting of pages 000001.001 through 000250.

Please note that this submission contains Confidential Business Information that Pactiv Corporation desires not to be revealed to Freedom of Information Act requestors and other members of the public. In the first copy of the submission following this letter, the Confidential Business Information has been redacted. For ease of reference, a list indicating which pages contain redactions is attached.

Five complete copies of the submission are enclosed, including the one that has been redacted.

If you have any questions, please contact me at 312 977-4647.

Sincerely,

Eric F. Greenberg
Enc.

000001.001

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Notification of Claim for General Recognition of Safety of Carbon Monoxide in A Modified Atmosphere System for Packaging Fresh Meat

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Attachment 5 Certificate of Conformance, Carbon monoxide, Haun Welding Supply, Inc., Syracuse, New York, May 8, 2001. . . . . **000190**

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August 29, 2001

Division of GRAS Notice Review
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Center for Food Safety and Applied Nutrition
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200 C St, SW
Washington, DC 20204

Re: **NOTIFICATION OF CLAIM FOR GENERAL RECOGNITION OF SAFETY OF CARBON MONOXIDE IN A MODIFIED ATMOSPHERE SYSTEM FOR PACKAGING FRESH MEAT**

To the FDA:

This letter and its attachments contains the notification, pursuant to the Federal Food, Drug and Cosmetic Act and FDA's regulations, by Pactiv Corporation, 1900 West Field Court, Lake Forest, Illinois 60045, c/o attorney Eric F. Greenberg, 3500 Three First National Plaza, Chicago, Illinois 60602[1], for the General Recognition of Safety of carbon monoxide ("CO") at a level of 0.4% in a modified atmosphere system for packaging fresh meat.

[1] Attachment 1 contains Pactiv's authorization of undersigned counsel, as well as a Summary regarding Pactiv Corporation.

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As set forth more fully below and in the attachments to this document, Pactiv believes its intended use of CO is GRAS based on scientific procedures within the meaning of 21 U.S.C. Sec. 201(s) and FDA's implementing regulations in 21 CFR Sec. 170.30, and including FDA's proposed rule published on April 17, 1997 (62 FR 18937). FDA regulations provide that the scientific evidence available and reviewed for a GRAS determination is of the same quantity and quality as that required for a food additive approval, and that the scientific evidence of safety be generally known and accepted by qualified experts in the appropriate scientific and technical fields. 21 CFR Sec. 170.30(a).

I. Claim of Exemption

a. Name and address of the notifier.

Pactiv Corporation
1900 West Field Court
Lake Forest, Illinois 60045
c/o Eric F. Greenberg
Attorney at Law
3500 Three First National Plaza
Chicago, IL 60602

b. Common or usual name of the notified substance.

Carbon monoxide ("CO")

c. Conditions of use (foods, levels, purposes).

When used as described in this Notice, CO meeting appropriate purity specifications is a processing aid in packaging of fresh cuts of muscle meat and ground meat, as a component of a gas mixture utilized in a specific modified atmosphere packaging system. 21 CFR Sec. 170.3(o)(24). A technology utilizing 0.4% CO within a modified atmosphere packaging system will maintain wholesomeness, permit greater flexibility in distribution, and reduce shrinkage, all within a system that results in traditional product display to consumers. All elements of the system, excluding the CO, are already in use in the United States as part of a modified atmosphere meat packaging system called ActiveTech™. Notifier refers to the new system incorporating CO as "AT2001".

Summary

ActiveTech™ is a system that is designed to permit more extended storage of meats, but, as explained below, has no effects on retail display time or characteristics as compared with other modified atmosphere technologies currently in use. It employs materials that are either approved additives used consistently with their approvals, or GRAS substances. AT2001 adapts that system for additional storage scenarios. AT2001 serves to reduce the time needed for enzymatic reduction after modified

atmosphere packaging, and allows consistent display color of whole muscle meats. AT2001's advantages are in the resulting flexibility and consistency during storage and distribution.

The GRAS use of CO described in this Notice involves use as a component of the flush gas mixture used in replacement of ambient air in the packaging for distribution of refrigerated fresh red meat. The meats are in all instances fresh, and are intended to be cooked prior to consumption.

"Traditional" ActiveTech™

The ActiveTech™ modified atmosphere system, in commercial use in the United States since 1998, is a modified atmosphere system for packaging fresh cuts of muscle meat, or portions of ground meat. AT2001 is a refinement of ActiveTech™, and differs from it only in the addition of 0.4% CO to the modified atmosphere.

In the "traditional" ActiveTech™ system, the meats are placed in polystyrene trays and covered with oxygen-permeable, flexible polyvinyl chloride ("PVC") overwraps. The wrapped trays of meat are then placed within an outer barrier bag from which ambient air is removed and replaced with a blend of 30% carbon dioxide (CO_2) and 70% nitrogen (N_2). An activated oxygen-absorbing sachet is also added within the outer bag.

This modified atmosphere maintains the packaged meat in an oxygen-free deoxymyoglobin state, with its distinctive purplish appearance that is generally considered undesirable by consumers. The traditional ActiveTech™ system relies on the rapid reduction of the oxygen content of the outer bag. Once the oxygen is removed, a "seasoning" phase begins during which enzymatic effects take place so that the meat will be able to "re-bloom" when once again in the presence of oxygen. As the residual oxygen in the package is consumed by the activated oxygen scavenger, red meat oxymyoglobin is first subject to rapid conversion to metmyoglobin (brown) at very low partial pressures of oxygen, e.g. 0.5% oxygen. This low partial pressure region of oxygen is necessarily passed through prior to ultimately reaching 0% in the package and the conversion to deoxymyoglobin (purple). This seasoning phase can take up to 5 days.

Before display to consumers at retail, the outer bag, and thus the modified atmosphere, is removed, and the traditionally wrapped product (in polystyrene foam tray with PVC overwrap) is permitted to "re-bloom" to its familiar appearance through creation of oxymyoglobin on the meat's surface.

AT2001

In the AT2001 modified atmosphere system, as with traditional ActiveTech™, fresh cuts of muscle meat, or portions of ground meat, are placed in polystyrene trays and covered with oxygen permeable flexible PVC overwraps. The wrapped trays are placed within the outer barrier bag, the air is removed and replaced with a blend of 0.4% CO, 30% carbon dioxide (CO_2) and the balance nitrogen (N_2). As with the traditional AT system, 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.

As noted, meat packaged in traditional ActiveTech™ undergoes a myoglobin pigment conversion from oxymyoglobin (red) to metmyoglobin (brown) to deoxymyoglobin (purple) in the oxygen free environment. The metmyoglobin formed generally will convert to deoxymyoglobin in the oxygen free storage environment in about 5 days, a period of time referred to as the "seasoning period". However, the meat's ability to convert all of the metmyoglobin formed to deoxymyoglobin during the seasoning period and then fully rebloom to oxymyoglobin upon re-exposure to normal, oxygen-rich atmosphere at retail, is a function of a multitude of unpredictable, uncontrollable factors in the meat such as age, muscle

location, and enzyme energy level. This is a key weakness of all current low oxygen packaging systems.

Meat packaged in the AT2001 atmosphere will instead convert from oxymyoglobin to carboxymyoglobin (red) in the package due to the inclusion of 0.4% CO in the modified atmosphere. This conversion occurs during the initial 24 hours as the free oxygen in the headspace is consumed. Thus, the CO effectively protects the myoglobin from converting to metmyoglobin as the oxygen in the package is removed. This feature is especially important for the most pigment sensitive meats such as those from the round. The meat will continue to maintain its red color while in storage until the package is opened for retail display, when the outer bag (and modified atmosphere) is removed. Since carboxymyoglobin and oxymyoglobin are essentially the same colors, no seasoning period is necessary. The meat can be opened for retail display the day following packaging.

Once in retail display, the meat's myoglobin will begin the rather slow, natural conversion to metmyoglobin (brown), akin to that seen with untreated meat, allowing for a conventional retail display life of 3 to 4 days, closer to consumers' expectations of color than results from use of high

oxygen packaging systems. Attachment 2 consists of photographs depicting the ActiveTech™ and AT2001 systems.

The AT2001 formulation will assure that the meat will have the familiar color during and following storage, eliminating the seasoning period, allowing for placement in retail display beginning at 1 day, and up to 30-40 days, after packing. For cuts of meat from the round, and other color sensitive cuts, the AT2001 will help them have a more uniform red color for retail display.

In AT2001 (as in traditional ActiveTech™), the trays and films utilized are made from familiar, FDA-approved polymers that are used in accordance with their existing approvals or GRAS status. 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 some GRAS status or food-related approvals.

Thus, the AT2001 system adds a refinement to the existing ActiveTech™ system that will allow its utilization with whole and ground meat products that meet the processors' desire to get to market as soon as the day following processing.

d. Basis of GRAS determination: Scientific procedures

CO safety

Pactiv believes its proposed use of CO is GRAS based on scientific procedures within the meaning of 21 U.S.C. Sec. 201(s) and FDA's implementing regulations in 21 CFR Sec. 170.30 and including FDA's proposed rule published on April 17, 1997 (62 FR 18937).

CO is a colorless, odorless gas that is poisonous to humans if inhaled at much higher levels than are involved with the use that is the subject of this Notice. It is formed when carbon is not completely burned, for example, in the combustion of fuels.

It is well known that CO creates negative health effects at elevated levels because it out-competes oxygen for attachment to the hemoglobin molecule. The resulting carboxyhemoglobin levels in the blood are associated with severe health effects. In addition, the equilibrium rate for the exchange of carboxyhemoglobin for oxyhemoglobin is very slow, and the resulting level of carboxyhemoglobin is a function of the CO level in the respired air, the time of exposure and the level of activity of the individual. Typical atmospheric CO levels are <20 mg/m^3 as an 8 hour mean (higher in

urban and high traffic areas), and typical carboxyhemoglobin levels due to natural background CO range between 1.2 and 1.5%.

CO is recognized as a significant air pollutant at higher levels. Automobile exhausts, industrial processes and boilers and incinerators all contribute to air quantities of CO. According to the U.S. EPA Office of Air and Radiation:

> Carbon monoxide enters the blood stream and reduces oxygen delivery to the body's organs and tissues. The health threat from exposure to CO is most serious for those who suffer from cardiovascular disease. Healthy individuals are also affected, but only at higher levels of exposure. Exposure to elevated CO levels is associated with visual impairment, reduced work capacity, reduced manual dexterity, poor learning ability, and difficulty in performing complex tasks. EPA's health-based national air quality standard for CO is 9 parts per million (ppm) [10 mg/m^3] measured as an annual second-maximum 8-hour average concentration.

"Summary regarding carbon monoxide" as part of discussions of 6 principal pollutants, U.S. EPA Office of Air and Radiation.

No health effects result when carboxyhemoglobin levels are under 4% to 5% in healthy adults. Carboxyhemoglobin levels of 2 to 3% may have negative effects on those with cardiovascular disease or other sensitivity. See, Environmental Health Criteria 13, Carbon Monoxide, World Health Organization, Geneva, Switzerland (1979), p. 15.

The US Occupational Safety and Health Administration's air contaminants regulation, 29 CFR Sec. 1910.1000, lists 50 ppm and approximately 55 mg/m^3 of CO as the 8-hour Time Weighted Average of exposure for the substance. 29 CFR Sec. 1910.1000.

By contrast, as explained below, the worst case estimated intake of CO attributable to AT2001 is 1.88 mg CO/meal.

The US FDA has not established an Acceptable Daily Intake for CO. Nevertheless, CO exposure, at levels much higher than those attributable to AT2001, for decades has been permitted within the existing FDA and USDA food additive regulatory provisions:

- Wood smoke ("smoke flavoring"), conventionally including CO as a component, is permitted by regulation as an ingredient in meat and poultry products pursuant to 9 CFR Secs. 318.7(c)(4)[meat], 381.147(c)(4)[poultry], 424.21(c).
- The specifications for Combustion product gas in 21 CFR Sec. 173.350 permit CO up to 4.5 percent by volume in such gases, which may be used in the processing and packaging of beverages and other foods except fresh meats, to remove and displace oxygen. Such gases are commonly used to package fruits and vegetables.

- In 2000, FDA responded favorably to GRAS Notice 000015 from Hawaii International Seafood, Inc. for the use of tasteless smoke, before freezing of tuna, as a preservative, specifically to preserve taste, aroma, texture and color. GRAS Notice (GRN) No. 000015, March 10, 2000. CO is a primary component of conventional smoke, which that Notice asserts is Generally Recognized As Safe based on decades of safe use in a variety of foods, which uses are recognized by FDA and incorporated into numerous food standards that permit smoking of cheeses. CO is also a primary component of tasteless smoke, along with nitrogen, oxygen, carbon dioxide and methane. The tasteless smoke is used to impart a "preservative effect." As noted in FDA's March 10, 2000 letter about the GRAS Notice, "In Hawaii International's view, tuna treated with tasteless smoke and tuna treated with conventional smoke contain comparable levels of carbon monoxide, carbon dioxide, hydrocarbons, and phenols." FDA's letter notes that it "has no questions at this time" regarding Hawaii International's conclusion that the use described is GRAS, though, in keeping with current regulatory practice, it had not made its own determination.

CO is listed as a reproductive toxicant by the State of California pursuant to its Safe Drinking Water and Toxic Enforcement Act of 1986 ("Proposition 65"). California law contemplates that exposures to listed reproductive toxicants will be accompanied by a warning, unless the exposure is less than 1/1000th of an established no observable effect level. Cal. Health and Safety Code, Sec. 25249.6. No such level has been established for CO. Almost without question, though, any such future level (which will have a dubious connection to safety principles in any event, due to the design of Prop. 65), will be more than 1,000 times any possible exposure that could result from AT2001. The worst-case potential exposures from AT2001 are tiny fra[illegible] occupational and environmental exposure levels (see below), which [illegible]elves are certain to be well below any level at which reproductive toxicity is ultimately is deemed to result.

Effects on Fresh Meat and Consumption

Analysis of the AT2001 system makes plain the lack of any safety issue from consumption of treated meats. Additionally, similar technologies employing CO as part of a modified atmosphere gas mixture analyzed the technologies for effects on meat in terms of microbial load and organoleptic

properties including color, and for the safety of consumption of treated meats, specifically, any tendency of the consumed meat to expose consumers to levels of carboxymyoglobin. Further important evidence is obtained from examination of the actual experience since 1985 in Norway of packaging fresh red meats in 0.3 – 0.5 % CO for retail.

Safety: Effects on carboxymyoglobin levels

Consumption of meat treated with AT2001 is not expected to result in any measurable levels of carboxymyoglobin in the blood of those who consume treated meat.

An Estimated Daily Intake ("EDI") of CO attributable to the AT2001 use can be calculated as follows. First, we assume the following reasonable values for the exposure parameters:

(1) An AT2001 bag contains 1.5 L modified atmosphere with a CO concentration of 0.4%, that is equivalent to approximately 0.006 L of CO in the bag (= 6 mL CO).

(2) At 28 g CO per mole and approximately 22.4 L per mole, the mass of CO per unit volume may be calculated: (28 g/mol)/(22.4 L/mol) = 1.25 g/L = 1.25 mg/mL.

(3) The AT2001 bag contains 2 lbs (approximately 1.0 kg) of ground meat.

(4) Approximately 30% of the total amount of CO is absorbed into the meat (based on Watts, D.A.; Wolfe, S.K.; Brown, W.D., "Fate of [^{14}C] Carbon Monoxide in Cooked or Store Ground Beef Samples", J. Agric. Food Chem., Vol. 26, No. 1 (1978), pp. 210-214). Therefore, the amount of CO taken up by the meat is [(0.3)*(6 mL/bag)*(1.25 mg/mL)] / [1.0 kg meat/bag] = 2.25 mg CO / kg meat.

(5) If we assume that a person consumes an 8.8 oz steak (250 g = 0.25 kg meat), or ground equivalent, at a single meal, that 85% reduction in CO content occurs during cooking, and that 100% of the ingested CO is absorbed, then the maximum amount of CO exposure is

(0.15)*(2.2.5 mg CO /kg meat)*(0.25 kg meat/meal) = 0.084 mg CO/meal.

Next, comparison may be made of the of the consumer EDI for CO to that amount inhaled during an 8-hour period at the EPA's National Ambient Air Quality Standard ("NAAQS") level. 40 CFR Sec. 50.8, National primary ambient air quality standards for carbon monoxide:

[2] Note that this is a conservative assumption. The EDI of beef for the 90th percentile intake per user is 139.2 g/d based on the most recent USDA national survey of food intake by individuals. Pactiv chose to use a larger value for beef consumption to simulate a typical to above-average consumption incident rather than an average over all meats.

(1) The EPA NAAQS of 9 ppm CO is equivalent to approximately 10.4 mg CO per m^3 air.

(2) The typical person breathes 15 m^3 air per day or approximately 5 m^3 air per 8-hours.

(3) The exposure under these circumstances may be calculated as follows: (10.4 mg/m^3)*(5 m^3/8-hr) = 52 mg CO / 8-hr.

Thus, the ingestion of residual CO from the cooked meat is a small fraction of the exposure level at EPA's NAAQS: (0.084 mg) / (52 mg) = 0.0016 = 0.16%.

Even using worst-case assumptions, the expected exposure is exceedingly low. Assuming again 6 mL/bag; 1.25 mg/mL is the mass of CO per unit volume; and assuming 2 lbs (approximately 1.0 kg) of ground beef per bag; and consumption of an 8.8 ounces of meat; but now assuming no reduction in CO during cooking, and 100% of CO absorbed, the maximum theoretical CO exposure is 1.88 mg CO/meal [(7.5 mg CO/kg meat)x(0.25 kg meat/meal) = 1.88 mg CO/meal.

In turn, using this figure to compare with the EPA's NAAQS, we find that ingestion of residual CO from the cooked meat would be at worst 3.6% of EPA's NAAQS. [(1.88 mg)/(52 mg) = 0.036 = 3.6%)

The calculated, worst case consumer EDI for CO may be compared to that amount inhaled during an 8-hour period at the American Conference of Governmental Industrial Hygienists ("ACGIH") Threshold Limit Value ("TLV"). Documentation of the Threshold Limit Values and Biological Exposure Indices, p. 23, ACGIH, 1330 Kemper Meadow Drive, Cincinnati, Ohio.

(1) The ACGIH TLV is 25 ppm CO is equivalent to approximately 28.9 mg CO per m^3 air.

(2) The typical person breathes 15 m^3 air per day or approximately 5 m^3 air per 8-hours.

(3) The exposure under these circumstances may be calculated as follows:

$$(28.9\ mg/m^3)*(5\ m^3/8\text{-}hr) = 145\ mg\ CO\ /\ 8\text{-}hr.$$

Thus, the ingestion of residual CO from the cooked meat is merely 1.3% of the exposure level at ACGIH TLV ((1.88 mg) / (145 mg) = 0.013 = 1.3%)

Finally, the calculated worst case consumer EDI for CO may be compared to that amount inhaled during an 8-hour period at the OSHA PEL:

(1) The OSHA PEL is 50 ppm CO is equivalent to approximately 58 mg CO per m^3 air.

(2) The typical person breathes 15 m^3 air per day or approximately 5 m^3 air per 8-hours.

(3) The exposure under these circumstances may be calculated as follows:

$$(58\ mg/m^3)*(5\ m^3/8\text{-}hr) = 290\ mg\ CO\ /\ 8\text{-}hr.$$

Thus, the ingestion of residual CO from the cooked meat is 0.65% of the exposure level at OSHA PEL. ((1.88 mg) / (290 mg) = 0.0065 = 0.65%).

Thus, the consumer EDI of CO from a eating meat packaged in the Active Tech 2001 bag is a small fraction of any of the currently allowed exposures by authoritative agencies. As these various limits were established to protect individual safety and health, it is plain that the worst case exposures that may result from AT2001 present no safety concerns whatsoever.

In the 1997 study, "Technological, hygienic and toxicological aspects of carbon monoxide used in modified-atmosphere packaging of meat" Trends in Food Science and Technology, September 1997 [Vol. 8], pp. 307-312, Sørheim, et al. concluded that meat packaged and displayed in an atmosphere combining 60 to 70% carbon dioxide, 30 to 40% nitrogen, and less than 0.5% CO "will result in only negligible levels of carboxyhemoglobin in the blood."

The authors note that there was sparse information in published literature on exposure to CO after consumption of meat treated with CO gas. They note that "the inhalation of air containing CO at a level of 55 mg per m^3 (the acceptable level in working environments in the USA) would provide a COHb level for a prolonged time period (hours) of at least 14 times that of the level reached temporarily on the consumption of 225 g of meat that has been packaged in CO at the saturation level for myoglobin." That estimate assumed saturation of meat myoglobin and hemoglobin was maximal and the transfer of CO from the gastrointestinal tract to the blood was 100%. Sørheim, et al. (1997), p. 310. The authors concluded, "Consequently, even for such a "worst case" scenario, the treatment of meat with CO gas appears to contribute very little to COHb levels, relative to levels that are considered safe in the working environment." Sørheim, et al. (1997), p. 310.

The authors report that "CO is lost from previously CO-treated meat during storage in the absence of CO, with a half life of ~3d." Sørheim, et al. (1997), p. 310. As these fresh meats are to be cooked before consumption, CO lost during cooking is also relevant. The authors report that "When the beef was cooked at 195° C, only 0.1 mg of CO remained

per kg of meat. The loss of CO amounted to ~85%." Sorheim, et al. (1997), p. 310.

The authors also compared CO exposure from the air and estimated exposure from CO-treated meat. Their comparative table is shown below.

Table 5. Theoretical Uptake of Carbon Monoxide (CO) in Blood

Exposure method	**CO intake in 1 h**	**CO intake in 8 h**
Lungs ($15m^3$)	24 mg x 0.625 = 15.1 mg	9.2 mg x 5 = 46.0 mg
Meat (250 g CO treated)	0.025 mg	0.025 mg

Sørheim, et al. (1997), p. 311, Table 5.

Part of the authors' analysis was the premise that absorption of CO from the gastrointestinal tract into blood will in all probability be less effective than absorption from the lungs. The authors summarized the comparison as follows:

> In order to prevent a maximum COHb level in the blood of 1.5% being exceeded, the CO concentration in air for a 1h period of moderate physical activity should not exceed 24 mg/m^3, or 9.2 mg/m^3 in 8h (according to Table 4). In contrast, the consumption of meat that had been treated for 3d in an atmosphere containing 1% CO yielded ~0.1 mg of CO per kg of meat on storage and cooking.

Sørheim, et al. (1997), p. 310, citing Watts, D.A.; Wolfe, S.K.; Brown, W.D., "Fate of [^{14}C]Carbon Monoxide in Cooked or Stored Ground Beef Samples", *J. Agric. Food Chem.*, Vol 26, No. 1 (1978), pp. 210-214.

The authors calculate that CO intake in 1h through the lungs taking in 15m^3 per day would result in 15.1 mg of CO, as compared with 0.025 mg of CO from intake of 250 g of CO treated meat. In 8 hours, the authors say the lungs will take in 46.0 mg, and the figure for meat would still be 0.025 mg. As the authors conclude,

> Estimates detailed above indicate that, even assuming an improbable 100% absorption of CO from the gastrointestinal tract into the blood, the consumption of meat that has been treated with 1% CO will result in COHb levels that are negligible (approximately 3 orders of magnitude lower) compared with those resulting from exposure in the working environment to CO at an acceptable level. Consequently, it is highly improbable that CO exposure from meat packaged in an atmosphere containing up to 0.5% will represent a toxic threat to consumers through the formation of COHb.

Sørheim, et al. (1997), p. 310.

In another published report, the storage life and characteristics of meats packaged in a modified atmosphere including 0.4% CO were studied, but under circumstances distinguishable from AT2001. Sørheim O; Nissen, H; Nesbakken, T, "The Storage Life of Beef and Pork Packaged in an Atmosphere With Low Carbon Monoxide and High Carbon Dioxide", 52 Meat Science 157-164 (1999). In the study, the meats were packed in

modified atmosphere into retail-ready packages. This study examined off odor and microflora, as well as color, comparing the 0.4% CO/ 60% CO_2 /40% N2 gas mixture with a gas mixture of 70% oxygen and 30% CO_2.

Among the points made by these authors was that there is sometimes an objection raised against using CO in retail ready meats because "the colour stability can exceed the microbiological shelf life, with the risk of masking spoilage of the meat." Sørheim, et al. (1999), p. 163. (Citing Kropf, D.H. (1980), "Effects of retail display conditions on meat colour", *Proceedings of the Reciprocal Meat Conference, 33, pp. 15-32.*) The authors assert that in those circumstances, consumers would need to rely on off odors to evaluate microbiological conditions of meat. In addition, they caution, "When a MA with CO is applied commercially, it is important to have a proper control of hygienic condition of the meat raw materials and the chill chain temperatures." See Sørheim, et al. (1999), p. 163.

AT2001, by contrast, presents no such similar problems or needs for caution. AT2001 does not mask spoilage of the meat. AT2001 does not involve use of a modified atmosphere including CO in the retail package. Moreover, as noted below, Pactiv's own commissioned experimentation with AT2001 demonstrates that AT2001 retail packages will deteriorate in color beginning almost immediately after removal of the modified

atmosphere, and that microbial load will not reach unsafe levels while the color of AT2001 meat is still acceptable to the consumer.

Safety: The Norwegian experience

In Norway, CO has been used to package fresh meats, even at retail, since 1985, with commercially satisfactory and safe results.

The 2000 submission by the Norwegian Meat Cooperative and Norwegian Independent Meat Association to the EU Commission seeking Europe-wide approval of the use of CO, "Application For Assessment Of The Food Additive Carbon Monoxide (CO) Prior To Its Authorization", is Attachment 3. The evaluation undertakes a detailed analysis of the CO exposure expected through the described packaging use. See section entitled "IV. Report by Tore Aune: "Fresh Meat in Consumer Packaging-A Toxicological Evaluation of the Use of Up to 0.5% CO in a Gas Mixture".

As the Norwegian risk assessment analysis concludes, assuming a worst-case exposure of 0.1 mg/kg from consumption of 250 grams of heated CO-treated meat, CO intake can be expected to be 0.025 mg in 1 hour or even after 8 hours. Attachment 3, p. 000154. The cited study, Sørheim, et al. (1997), utilized meat that had been treated with 1% CO. According to the authors, to stay under maximum blood levels of carboxyhemoglobin of 1.5%, "the CO concentration in the air must be 24

milligrams per mg/m^3 for 1 hour at moderate physical activity at 9.2 mg/m^3 for 8 hours...." Attachment 3, p. 000154. Assuming an adult inhales 15 m^3 per 24 hours, this translates to 15.1 mg of CO taken in 1 hour, or 46.0 mg of CO taken in 8 hours. This is in dramatic contrast to the miniscule amount expected to be ingested through meat. The Norwegian authors conclude, "From a health perspective, the use of CO in concentrations below 0.5-1% for fresh meat thus represents no toxicological risk." Attachment 3, p. 000155.

Safety: Exposure in environment

As a basis for comparison, the possible effect on ambient CO concentration associated with the release from a typical AT2001 barrier bag was estimated. A typical AT2001 barrier bag contains approximately 1.5 liters of modified atmosphere with a CO concentration of 0.4 percent, which is equivalent to approximately 0.006 liters of CO within the bag. On a mass basis, this volume of CO is equivalent to approximately 0.0075 g (7.5 mg) CO per bag.

Consider the possible use of the bag for storage of meat prior to retail display (e.g., at a supermarket). Any unassociated CO within the bag, it can be assumed, would be released to the meat processing area when the bag is opened, resulting in possible exposure by the employee(s) to the

released CO. The extent of such exposure is dependent on several factors, including the size of the meat processing area, air-mixing within the area and between adjacent areas, the number of bags opened, and the amount of free CO unassociated with the meat in the package. For these calculations, it has been conservatively assumed that none of the CO has become associated with the meat and is therefore all free to the ambient atmosphere upon opening of the package.

Assume, however, that the air volume within a meat processing area may reasonably range from 150 m^3 to 1,500 m^3, which would represent several hundred to several thousand square feet of processing area. If each bag introduces 7.5 mg CO to the air within the processing area, the corresponding concentration of CO in air would be in the range of 0.005 mg/m^3 to 0.05 mg/m^3, assuming conservatively that there is no air exchange between the processing area and other rooms or the outdoors. Thus, to exceed the occupational safety standard (i.e., threshold limit value, or TLV) of 25 ppm (29 mg/m^3), 580 to 5,800 1.5 liter bags would need to be opened within an 8-hour period. As noted above, this assumes no mixing with other areas of the building or with outdoor air.

Thus, applying the reasonable assumption that the air volume within the processing area will be exchanged with external air once per hour,

opening of 580 to 5,800 bags per hour would be required to exceed the TLV, or 4,600 to 46,000 bags per work day. The number of bags opened within a given processing area will be a function of the size of the processing area, to a given extent, but is unlikely to even approach the number of bags required to result in air concentrations at the TLV. Actual concentrations in the work area of a secondary processing facility would likely be one to two orders of magnitude below the standard. Thus, opening of bags within a work area will not alter significantly the environmental exposure to CO.[3]

Regardless, the opening of the bags does not alter significantly the environmental exposure to CO. This action qualifies for a categorical exclusion from preparation of an environmental assessment pursuant to 21 CFR Sec. 25.32 (i), which provides an exemption for, in pertinent part, "Approval of a ...GRAS affirmation petition...." 21 CFR Sec. 25.32(i). The regulation makes no specific mention of the GRAS Notice procedure, but similar treatment is warranted for a GRAS Notice. (We also note that CO as used here also qualifies for exclusion under 21 CFR Sec. 25.32(r), as CO "occurs naturally in the environment" and the noticed use "does not alter significantly the concentration or distribution of the substance, its

[3] As an aside, there is no reason to expect any difficulty achieving compliance with the OSHA Threshold

metabolites, or degradation products in the environment." 21 CFR Sec. 25.32(r).)

Corroborative information about AT2001

The specific AT2001 system has been thoroughly tested to confirm that it results in the expected limited exposures to CO, and has no adverse effects on the treated meats. A study of meats treated with AT2001 commissioned by Pactiv examined its effects on initial product color, stability of color during display, and the central safety consideration of the relationships between color deterioration and microbial populations.

The study, conducted by faculty of the Department of Animal Sciences & Industry of Kansas State University, Manhattan, Kansas, examined steaks from three cuts of beef (strip loin, tenderloin, and inside round steaks), as well as ground beef. The study report is Attachment 4. The meats were packaged in AT2001 atmosphere, then stored at 35° F or 43° F for up to 35 days. Cuts were then placed under simulated retail conditions by being removed from the AT outer package and displayed at 34° F until their color approached consumer unacceptability. Comparisons

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Limit Value at plants using the AT2000 technology to fill bags. Experimental use of an exhaust hood over the machinery has resulted in no measurable increase in CO ppm levels near the line.

were made to similar products that had been exposed to oxygen but not CO.

Among the study's conclusions were:

(1) Color: AT2001 *system resulted in products that were equally red to products packaged with traditional oxygen permeable overwrap.* When the AT2001 outer bag was removed, the product's conversion to oxymyoglobin occur red in 60-90 minutes and then had a typical bright red color. Visual appearance was improved, especially in the tenderloin and inner part of the inside round steaks, throughout display. Color deterioration compared well to baseline products exposed to oxygen. For tenderloin and inside round steaks, and to a lesser degree for ground beef, display time was increased only slightly in the AT2001 samples.

(2) Bacterial growth: Bacterial growth was neither encouraged nor suppressed by the addition of CO to the ActiveTech™ *gas blend (nitrogen and carbon dioxide)*, although microbial growth curves changed in slope and exponential growth according to the environment in the packages. Aerobic bacteria and facultative anaerobes followed typical patterns of growth according to environmental conditions.

(3) Spoilage indicators: CO neither masked spoilage, nor extended color life beyond the point of wholesomeness (i.e., the point of microbial soundness).

A summary of the study follows.

A random selection of all steaks and ground beef packaged using oxygen-permeable polyvinyl chloride ("PVC") film were placed in display to serve as a baseline for color and microbiological comparisons. Products were expected to have the lowest microbiological load and ideal color stability using traditional packaging and display conditions for products exposed only to atmospheric oxygen. The inherent muscle chemistry responsible for good color life also was optimal. If the product exposed to CO were to have extended meat color life, then it will be compared to the baseline "control" with the "best" possible color.

To measure color changes, visual scores were considered the "standard" with instrumental color being discussed relative to its agreement or disagreement with the visual panel, ie, did the objective measurements confirm what the color panel saw? Visual scores of ≥ 3.5 were considered borderline acceptable. When samples reached this discoloration, they were removed from display. Normally, a* values (higher values indicate more redness) are highly correlated to visual appraisal.

Inside round steaks typically are two-toned in color. The inner portion (ISM) is much less color stable than the outer portion (OSM). These portions were scored separately since one portion may have acceptable color while the other has unacceptable color that would be discriminated against by consumers resulting in the whole cut being judged unacceptable in color. The effects of CO on this bi-colored muscle were needed to confirm that color was not excessively extended in either portion.

Average fat and moisture contents of the ground beef were 19.5 and 61.6%, respectively. The pH of both intact muscles and the ground beef ranged from 5.3 to 5.7. The initial aerobic plate counts and lactic bacteria counts for all products were relatively low and indicative of good microbial quality of the raw materials and good sanitation. Furthermore, coliforms and *E. coli* were below the detection limit throughout the study.

The color of ground beef and steaks entering display (after MAP storage at 2 temperatures) was an attractive, typical red color. Although there were several significant differences in visual scores and a* values (Attachment 9, Table 2 and Figures 1-10 at day 0) for product CO vs. baseline cuts, the variation in color was usually within $\pm$ 0.5 of a color score.

Color results: In general, the initial color of product exposed to CO was very similar to the color of steaks from the baseline display (never exposed to CO). When differences occurred, they were more related to either storage temperature or postmortem age of the product.

Panelists did not consider the color of product exposed to CO atypical. Cuts exposed to CO generally appeared more uniformly bright-red and would be expected to have high consumer appeal. These results were expected, as CO is known to preferentially form a ligand with the colored pigment (myoglobin) in meat resulting in a more intense red pigment known as carboxymyoglobin.

In the AT2001 system, Pactiv uses a low level of 0.4% CO, and obtains a red color very similar to the normal red oxymyoglobin pigment of fresh meats exposed to oxygen.

Color stability results: A critical next question was whether the carboxymyoglobin formed on the surface was more stable than the oxymyoglobin formed in baseline product. Further, did the carboxymyoglobin deteriorate in a predictable way that consumers could continue to use visual color to judge freshness or potential spoilage?

Product exposed to CO during MAP storage had color deterioration during display. (See visual panel scores (Attachment 4, Figures 1-5) and

instrumental color (a* values, Attachment 4, Figures 6-10).) As expected, visual scores increased (color deteriorated) and a* values decreased (loss of redness) as days in display increased. In several instances, color appeared to improve late in display – as indicated by a decrease in visual scores (see ground beef, strips loins and tenderloins at 43°F). These decreases were not a return of redness, but resulted from removal of discolored packages the preceding period, leaving product with less overall discoloration remaining in the case.

In general, the color deterioration profiles followed an expected pattern. Namely, the freshest product (baseline packages) had the most stable, red color and the most days in display needed to reach borderline discoloration of all treatments. (Attachment 4, Table 3 scores to 3.5) Exceptions occurred for the inside portion of the inside round and tenderloin products, where the product exposed to CO had slightly more stable color than the baseline product (Attachment 4, Table 3). These two muscle areas are well known by retailers as having short color life. Thus, CO appeared to improve color life when the inherent muscle chemistry desired for color was limited.

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 43°F, which was a mildly abusive temperature, color deterioration would be expected to accelerate. This phenomenon also is illustrated in Attachment 4, Figures 1-10.

There was no evidence the color shelf life was unexpectedly lengthened by exposure of meat to CO in MAP. Changes in a* values (and other instrumental measures of color not shown) followed the same pattern of color deterioration observed by the visual panelists.

Color and microbial data: Initial, pre-display microbiological data suggested that the raw materials were fresh and processed using good hygienic practices. For intact cuts, lactic acid bacteria, generic *E. coli*, and total coliform counts were below the detection limit of 1.76 colony forming units (CFU)/in^2. Initial, pre-display aerobic plate counts ("APC") for intact muscles ranged from 1 to 1.63 $\log_{10}$ CFU/in^2 . Post-display counts were higher ($P<0.05$) than pre-display APC which was an increase in bacterial proliferation and typical deterioration. However, all product had sufficient microbes to be susceptible to spoilage.

Baseline products were pulled from display when the visual panel scores reached ≥ 3.5. However, the APC did not exceed 5 $\log_{10}$ CFU/unit as shown in Attachment 4, Figures 15-18. Furthermore, off-odor scores for

product at end of display (Attachment 4, Table 3) ranged from no to slight off odor.

Thus, color life in this base population did not exceed microbial soundness, which is generally accepted as < 100 million CFU/g hamburger ($<1 \times 10^8$). (Principles of Meat Science, 3d Ed., Hedrick, H.B.; Aberle, ED, Forrest, JD; Judge, MD; Merkel, RA, Eds, Kendall/Hunt Publishing Co., Dubuque, Iowa.

Similar trends in microbial growth occurred in post-displayed samples stored in MAP compared to baseline products. Microbial patterns for product deterioration are shown in Attachment 4, Table 4 and Figures 11-18. Products stored under MAP at a slightly abusive temperature showed, as expected, a more rapid increase ($P<0.05$) in microbial counts compared to samples stored at 35°F. For post-MAP (pre-display) and post-display samples, APC were higher at 45°F than 35°F (Table 4), and during the later days of storage at the higher temperature, differences were more obvious. Significant changes ($P<0.05$) occurred in all cuts and ground beef with the exception of semimembranosus muscle. Counts for the SM muscle were lower than expected and no significant changes occurring until day 35 of MAP storage. This suggests that quality products that have been handled

in a sanitary fashion can be stored in the AT2001 system up to 35 days without comprising microbial quality.

The APCs for intact strip loin and tenderloin steaks stored at 35°F were lower ($P<0.05$) on all days of display on days 21 and 35 post-MAP than steaks stored at 43°F (Attachment 4, Figures 12 and 14). Although products did not show a difference in APCs 7 days post-MAP, those products stored at the higher temperature (43°F) were more inferior 21 and 35 days post-MAP.

One goal of this research was to see if the color of CO-treated meat might mask spoilage. Visual color scoring was considered as the "standard" for determining the time to remove products from display. Because the visual panel scores were the deciding factor for length of shelf life, the interdependence between visual color and APC, LAB, and odor were considered quite important.

Attachment 4, Figures 19-21 show aerobic and lactic bacterial growth and odor scores at the end of display plotted against their corresponding visual color scores. All data observations were summed over storage temperature, storage time, and product type and plotted in one graph. If color masked spoilage, then there would be multiple points in the upper left

quadrant of the plot, the area represented by unacceptable microbial counts and off odors but with acceptable color (i.e., scores <3.5).

This did not occur with any frequency in any of the three plots. Thus, it does not appear that exposure of meat to CO during extended (up to 35 days at either 35° or 43°F) caused meat color to hide spoilage.

e. Statement of availability of information

Notifier has relied on published studies and generally accepted scientific data and information as the basis of its conclusions, and those of its panel of experts, about the safety and the general recognition of a modified atmosphere system for meat incorporating 0.4% CO in the gas mixture.

II. Identity of notified substance

1. Chemical name: Carbon monoxide
2. Chemical Abstracts Service: **630-08-0**
3. Composition Specifications for food-grade material: The CO employed in this system is to be of suitable purity for food contact. Specifically, this will mean a 99.99% minimum purity, as supplied by Pactiv's commercial gas supplier, Haun Welding Supply, Inc., 6481 Ridings

Road, Syracuse, NY 13206. Attachment 5. The supplier's CO meets the following specifications, and will be referred to as "commercial grade":

Component	Specification
Carbon Monoxide	99.99% min.
Oxygen	≤ 0.5 PPM
Nitrogen	≤ 10 PPM
Carbon Dioxide	≤ 20 PPM
Methane	≤ 5 PPM
Ethane	≤ 1 PPM
Propane	≤ 1 PPM
Dimethyl Ether	≤ 1 PPM
Hydrogen	≤ 1 PPM
Moisture	≤ 1 PPM

4. Properties:

Relative molecule mass	28.01
Critical point	–140.2 °C at 34.5 atm (3.5 MPa)
Melting point	–205.1 °C
Boiling point	–191.5 °C
Density, at 0 °C, 1 atm	1.250 g/litre
at 25 °C, 1 atm	1.145 g/litre
Specific gravity relative to air	0.967
Solubility in water at 0 °C, 1atm	3.54 ml/100 ml
at 25 °C, 1 atm	2.14 ml/100 ml
at 37 °C, 1 atm	1.83 ml/100 ml[a]
Conversion factors:	
at 0 °C, 1 atm	1 mg/m^3 = 0.800 ppm[b]
	1 ppm = 1.250 mg/m^3
at 25 °C, 1 atm	1 mg/m^3 = 0.873 ppm
	1 ppm = 1.145 mg/m^3

[a] Value obtained by graphic or calculated interpolation (Altman et al., 1971).
[b] Parts per million by volume

5. Analyses: ASTM D1946, "Analysis of Reformed Gas by Gas Chromatography (GC) with Thermal Conductivity Detection (TCD)", may be utilized to measure the quantity of CO present in gas mixtures. A copy of the method is Attachment 6.

III. Self-limiting levels of use

Studies of modified atmospheres for packaging meat that contained both higher and lower levels of CO have established that the 0.4% used in the AT2001 system both has advantageous characteristics and avoids disadvantages seen with lower or higher levels. A CO level of 0.4% is sufficient to produce stable, cherry red color, (Sørheim, et al. (1997), and use of CO through retail display time may result in masked spoilage.

IV. Basis of GRAS determination.

Pactiv believes its use of CO is GRAS based on scientific procedures, 21 CFR Sec. 170.30(b), and convened a panel of experts qualified by scientific training and experience to evaluate the safety of food, food additives and food ingredients. The experts have reviewed and evaluated the publicly available information summarized in this GRAS Notice. Their testimonial

letters are attached as Attachments 7 through 10. The above discussion and citations to generally available accepted scientific data, information, methods and principles relied upon, together with the anticipated consumption levels for both CO and meat treated with CO, provide ample basis to conclude that the use of CO at 0.4% in a modified atmosphere for packaging fresh meats is both safe and generally recognized as such by qualified experts.

The panel consisted of the following experts, whose GRAS opinions and curricula vitae are attached as attachments 7 through 10.

1. Daren Cornforth, Ph.D.
   Professor
   Department of Nutrition and Food Sciences
   Utah State University
   750 N. 1200 E.
   Logan, Utah 84322-8700

Dr. Cornforth is a professor in Nutrition and Food Sciences at Utah State University, Logan, Utah, and received his Ph.D. in food science and human nutrition from Michigan State University. He has performed extensive research and published multiple articles on the subject of meat color.

2. Vasilios Frankos, Ph.D.
   Principal
   Environ Corp.
   4350 N. Fairfax Dr.

Suite 300
Arlington VA 22203

Dr. Frankos is a Principal at ENVIRON corporation, Arlington, Virginia, a scientific consulting firm, and has over 20 years of experience in the toxicological and pharmacological evaluation of data used to assess the risks posed by foods, food additives, and other substances. He holds a Ph. D. from the University of Maryland Pharmacy School in Pharmacology and Toxicology.

3. Melvin C. Hunt, Ph.D
Professor
Weber Hall
Dept. of Animal Sciences and Industry
Kansas State University
Manhattan, KS 65506

Dr. Hunt is a professor of food science at the Department of Animal Sciences and Industry at Kansas State University, Manhattan, Kansas. He received his Ph.D. in food science at the University of Missouri. Among his many research projects and publications are multiple studies relating to meat color and the effects of various environments on meat color.

4. Oddvin Sørheim, Ph.D.
Senior Research Technologist
MATFORSK – Norwegian Food
Research Institute
Osloveien 1

N-1430 Ås
Norway

Dr. Sørheim is a Senior Research Technologist at the Norwegian Food Research Institute, Osloveien, Norway. He received his Ph.D. in food science from the Agricultural University of Norway, and has performed extensive research and industry consultation, and published numerous articles on meat, including extensive experience with the use of CO in modified atmosphere packaging of meat.

Pactiv is not aware of any reports of investigations that are inconsistent with the GRAS determination relating to the use described.

Conclusion

Based on all the above information, Pactiv Corporation has concluded that its use of 0.4% CO within the AT2001 modified atmosphere system for packaging fresh meat is Generally Recognized as Safe within the meaning of 21 U.S.C. Sec. 321(s).

Sincerely,

Eric F. Greenberg

Attachments:

Attachment 1	Authorization letter from Pactiv Corporation for representation by Eric F. Greenberg
Attachment 2	Photographs of meats treated with ActiveTech™ and ActiveTech™ 2001
Attachment 3	"Application for Assessment of the Food Additive Carbon Monoxide (CO) Prior to its Authorization", Norwegian Meat Cooperative; Norwegian Independent Meat Association (1999)
Attachment 4	"Evaluation of Beef Steaks and Ground Beef in the Pactiv ActiveTech™ Packaging System: Effects of Carbon Monoxide in the Package Atmosphere", Hachmeister, K; Hunt, M.; Milliken, G; May 2001.
Attachment 5	Certificate of Conformance, Carbon monoxide, Haun Welding Supply, Inc., Syracuse, New York, May 8, 2001.
Attachment 6	"Standard Practice for Analysis of Reformed Gas by Gas Chromatography", ASTM D 1946-90 (Reapproved 2000).
Attachment 7	Daren Cornforth, Ph.D., letter and curriculum vitae
Attachment 8	Vasilios H. Frankos, Ph.D., letter and curriculum vitae
Attachment 9	Melvin C. Hunt, Ph.D., letter and curriculum vitae
Attachment 10	Oddvin Sørheim, Ph.D., letter and curriculum vitae

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List of Attachments

Attachments:

Attachment 1 — Authorization letter from Pactiv Corporation for representation by Eric F. Greenberg **000050**

Attachment 2 — Photographs of meats treated with ActiveTech and ActiveTech 2001 ..... **000053**

Attachment 3 — "Application for Assessment of the Food Additive Carbon Monoxide (CO) Prior to its Authorization", Norwegian Meat Cooperative; Norwegian Independent Meat Association (1999) **000058**

Attachment 4 — "Evaluation of Beef Steaks and Ground Beef in the Pactiv ActiveTech Packaging System: Effects of Carbon Monoxide in the Package Atmosphere", Hachmeister, K; Hunt, M.; Milliken, G; May 2001 ..... **000157**

Attachment 5 — Certificate of Conformance, Carbon monoxide, Haun Welding Supply, Inc., Syracuse, New York, May 8, 2001 ..... **000190**

Attachment 6 — "Standard Practice for Analysis of Reformed Gas by Gas Chromatography", ASTM D 1946-90 (Reapproved 2000) **000192**

Attachment 7 — Daren Cornforth, Ph.D., letter and curriculum vitae **000198**

Attachment 8 — Vasilios H. Frankos, Ph.D., letter and curriculum vitae **000205**

Attachment 9 — Melvin C. Hunt, Ph.D., letter and curriculum vitae **000221**

Attachment 10 — Oddvin Sorheim, Ph.D., letter and curriculum vitae **000247**