GR

ORIGINAL SUBMISSION

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BY:

May 2, 2008

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Reference Number
027422.00001

Division of GRAS Notice Review
Attn: Dr. Robert Martin
Office of Food Additive Safety
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street, SW
Washington, DC 20204

Re: NOTICE OF CLAIM FOR GENERAL RECOGNITION OF SAFETY OF CARBON MONOXIDE IN A MODIFIED ATMOSPHERE SYSTEM FOR TREATMENT OF FRESH MEAT PRIOR TO VACUUM-PACKAGING

Dear Dr. Martin:

This letter follows up on your phone conversation with Vincent Mercogliano in the past few weeks. As directed by you, we are submitting a notice of a claim, pursuant to the Federal Food, Drug and Cosmetic Act and applicable FDA regulations, for the general recognition of safety of carbon monoxide (CO) at a level of 0.4% in a modified atmosphere of helium, for treatment of fresh red meat prior to vacuum packaging for retail sale. This letter refers to the meat treatment at issue as the Mercogliano-Verdi ("M-V") system. We are submitting this Notice on behalf of Vincent Mercogliano, for whom we are acting as legal counsel.

As set forth below, the intended use of CO in a modified atmosphere of the inert gas helium should be deemed to be generally recognized as safe ("GRAS") based on scientific procedures within the meaning of 21 U.S.C. §201(s) and agency "no objection" letters to GRAS Notices no. 000083 (Pactiv Corporation), 000143 (Precept Foods, LLC) and 000167 (Tyson Foods, Inc.)

I. Claim of Exemption

a. <u>Name and address of the notifier</u>

Vincent Mercogliano
8310 Shorecrest Drive
Fort Myers, Florida 33912

b. <u>Name of the notified substance</u>

Carbon monoxide (CO)

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

When used as described below, CO meeting appropriate purity specifications has been accepted for use s a component of a modified atmosphere packaging (MAP) system for treating one side of fresh ground and muscle red meat, the balance of the modified atmosphere consisting of carbon dioxide and nitrogen. The M-V system is virtually identical to these processes, except that the M-V process uses 0.4% CO in an atmosphere of the inert gas helium in combination with vacuum packaging. This helps maintain the wholesomeness of fresh ground and muscle red meat by retarding spoilage. It should also be noted that the vacuum in this system would provide an added measure of protection against food tampering or consumer deception because only one side is treated. Thus any broken vacuum would rapidly show the consumer a color change on the untreated side, signifying spoilage.

In the M-V process, batches of meat are processed according to size, cut and animal type. Each batch of meat is placed in a controlled refrigerated environment in a process chamber. The cuts are placed on a flat non-porous surface, preventing gas treatment from reaching the underside of each cut. A vacuum is then applied to remove atmospheric gases from the process chamber and the exposed surfaces of each cut of meat. An inert atmosphere of helium containing 0.4% carbon monoxide is introduced into the vacuum process chamber. The overall goal is to achieve a limited penetration of carbon monoxide and helium into the treated surfaces of each meat cut. The depth or level of penetration of the carbon monoxide and helium gas mixture will vary somewhat with each cut and type of meat, but the probable depth of penetration will be no greater than one to three millimeters (mm). The meat cuts are exposed to the gas mixture for a predetermined length of time based upon the size, cut and animal type.

The length of exposure to the helium/carbon monoxide mixture is typically six to eight hours at atmospheric pressure. Following the exposure, the helium/carbon monoxide mixture is removed from the process chamber by application of a second vacuum. The meat is then vacuum-sealed in a wrapped package using standard, non-permeable, heavy-duty plastic vacuum-packaging. When kept refrigerated at 4° C, packages of meat treated by this M-V process will maintain their fresh qualities for at least twenty-one days after packaging. This will be reflected in the "Use-by" date that is applied to the package, directing the consumer to either use or freeze the contents by that date.

Because the M-V process allows only extremely shallow penetration of the treated meat surfaces by the treatment gas, any unreacted carbon monoxide will be readily removed in the second vacuum treatment. Moreover, any unreacted carbon monoxide would form carboxymyoglobin at the surface of the meat. Such carboxymyoglobin would be destroyed immediately upon grilling or roasting the meat.

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As noted above, the underside of each cut of meat is not treated in the M-V process. Accordingly, the consumer can easily determine whether the meat is still wholesome, by simply turning the opened cut over and looking at and smelling the untreated other side of the meat.

d. Basis of GRAS determination

Like the M-V process, both the Pactiv and Precept processes described in GRAS Notices 000083 and 000143, respectively, use MAP systems of 0.4% CO. (The Tyson process described in GRAS Notice 000167 uses a variable level of CO, depending on the weight of the cut of meat.) All three processes use a mixture of carbon dioxide and nitrogen as the carrier gas. Such a gas mixture replaces oxygen in the packaging atmosphere and thereby inhibits the growth of the aerobic bacteria associated with meat spoilage, and also the oxidation of fat associated with rancidity. The M-V process uses helium as the carrier gas. Helium is GRAS for use as a processing aid in food with no limitations other than current good manufacturing practice (21 CFR §184.1355). Helium is both chemically and biochemically inert, and by completely replacing oxygen in packaging atmosphere it will inhibit aerobic bacterial growth and fat oxidation at least as much as the mixture of carbon dioxide and nitrogen in the three accepted GRAS processes.

The M-V process adds a final vacuum packaging step applied after a predetermined period of time in the modified atmosphere. This further aids in removing any residual oxygen and also any unreacted carbon monoxide. Vacuum packaging has long been used in the food industry to remove oxygen from cut meat and thereby reduce spoilage by inhibiting the growth of anaerobic bacteria, yeasts and molds, and by preventing the oxidation of fats. The low oxygen permeability of the material used in vacuum packaging prolongs the oxygen-free environment. In the Pactiv process, by contrast, the meat is placed on a tray and wrapped in oxygen-permeable PVC, still within the modified atmosphere of CO, carbon dioxide and nitrogen. Although the meat packaging is initially protected from oxygen permeation during storage by means of an outer bag containing the modified atmosphere and an oxygen adsorbent, this protection is removed prior to retail display, allowing oxygen to permeate the PVC wrapping and reenter the packaging. The Precept and Tyson processes also involve wrapping the meat, still within the modified atmosphere, while placed on a tray. Thus, the M-V process is the only one of these four processes which limits the contact time between the CO-containing atmosphere and the meat, physically removes any excess CO during packaging, and prevents the reentry of oxygen into the package during retail display.

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e. Statement of availability of information

Notifier has relied on FDA's response letters to related GRAS notices, on published studies, on the generally accepted method of vacuum packaging for extending the shelf-life of meat, and on generally accepted scientific data as the basis for its conclusions on the safety of a modified atmosphere packaging system for fresh meat that utilizes 0.4% CO in the inert gas helium, followed by vacuum packaging.

II. Identity of notified substance

a. Chemical name and formula

Carbon monoxide (CO)

b. Chemical Abstracts Services Registry no.

630-08-0

c. Specification for food-grade material

The CO employed in the proposed MAP system is of a purity suitable for food contact, namely, 99.99% minimum purity.

d. Physical properties

Molecular weight	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/L
at 25 °C, 1 atm	1 .145 g/L
Specific gravity relative to air	0.967
Solubility in water:	
at 0 °C, 1 atm	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

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III. M-V Process ensures limited levels of use

Because the M-V process allows only shallow penetration of the treated meat surfaces by the treatment gas, any unreacted carbon monoxide will be readily removed in the second vacuum treatment. Moreover, carboxymyoglobin forms only on the very surface of the meat, and is readily destroyed immediately upon grilling or roasting the meat. This is in contrast to MAP systems that allow uncontrolled penetration by CO, since overcooking may then be required to decompose all carboxymyoglobin (as evidenced by color change).

IV. Basis for GRAS determination

The above discussion, in combination with information on MAP systems utilizing 0.4% CO provided by other notifiers, about which the Agency had no questions, provides an acceptable basis for concluding that the use of CO at 0.4% in a modified atmosphere packaging system for fresh meats, followed by vacuum packaging, can be generally recognized as safe.

Sincerely,

Marsha C. Wertzberger, Esq.
Counsel for Vincent Mercogliano

SUBMISSION END

Highbarger, Lane A

From: Edwards, Robert G. [Edwards.Robert@ARENTFOX.COM]
Sent: Monday, July 06, 2009 5:43 PM
To: Highbarger, Lane A
Cc: 'Robert.Ragland@FSIS.USDA.gov'; Wertzberger, Marsha
Subject: GRN 000251
Attachments: Document.pdf

Dear Dr. Highbarger,

Please find attached a letter responding to your letter to Marsha Wertzberger of May 13, 2009, regarding GRAS Notice No GRN 000251. I have discussed this matter with Mr. Robert Ragland of the Office of Policy and Program Development at FSIS, and I am providing him with a copy of this letter in electronic form, at his request. Please do not hesitate to contact Marsha Wertzberger or me if you have any questions or need any additional information

Sincerely,

Robert Edwards

Robert G. Edwards, Ph.D.
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July 6, 2009

VIA FIRST CLASS AND ELECTRONIC MAIL

Lane A. Highbarger, PhD
Office of Food Additive Safety
Division of Biotechnology and GRAS Notice Review
Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration
5100 Paint Branch Parkway, HFS-255
College Park, MD 20740

Re: GRAS Notice No. GRN 000251

Dear Dr. Highbarger:

Thank you for your letter of May 13, in which you conveyed certain concerns of the USDA's Food Safety Inspection Service (FSIS) regarding the modified atmosphere packaging system (the Mercogliano-Verdi or "M-V" system) described in GRN 000251. In particular, FSIS appears to have expressed concerns about the "chamber" referred to in GRN 000251, and asks for specific information about temperature, pressure, and microbial loading conditions in the chamber.

We believe that FSIS has misinterpreted the term "process chamber" as it used in GRN 000251 to mean a separate room or similar facility in which the meat treatment and packaging takes place, and this has led to these questions about conditions within such a chamber. In fact, the "process chamber" referred to in GRN 00251 is not a separate room, but simply a compartment within a vacuum packaging machine such as a Koch Ultravac® 3000 Double Chamber Vacuum Packaging Machine[1] or a Cryovac system using the Koch Ultravac® 2100 (8" chamber-depth model) with gas-flush option for bulk packaging.[2] The packaging machine is kept in the packing room.

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[1] See: http://www.kochequipment.com/site/equipment/product_info.php?id_product=68&id_industry=10&id_category=154 and http://www.kochequipment.com/common/products/Ultravac_3000.pdf.
[2] See: http://www.cryovac.com/products/food/equipment/single_frm.html and http://www.kochequipment.com/common/products/Ultravac_2100.pdf.

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The walk-in holding cooler, which houses the meat prior to packaging, is kept at 34°-36°F (1-2°C) at all times, and the packing room is kept below 40°F (4.4°C) at all times. Thus, the ambient temperature inside the process chamber of the packaging machine, and the temperature of the product while present in that process chamber, are both below 40°F. GRN 000251 pertains only to whole fresh meat, not to ground meat, and therefore the question about the core temperature of ground product is not relevant to our specific situation. Accordingly, we have not supplied any information on that point. The modified atmosphere of helium and carbon monoxide simply replaces the regular atmosphere inside the process chamber of the packaging machine after the initial vacuum is applied, and it remains at atmospheric pressure during the 6- to 8-hour treatment period.

As for microbial loading of the meat during the 6- to 8-hour treatment period in the chamber of the packaging machine at <40°F (<4.4°C), there is no reason to expect it to be any higher than if the meat had been maintained in a holding cooler or packing room at a similar temperature for the same length of time. Moreover, since helium, unlike air, is totally inert in both the chemical and biological sense, it will not support growth of aerobic organisms. Thus, microbial loading of the meat at the end of the process is likely to be lower than that of meat that had simply been maintained in air in a holding cooler or packing room for the same length of time.

We reviewed the literature and found that James and James[3] note that pseudomonads are the most common form of meat spoilage bacteria, and suggest generation times as long as 5 hours at 5°C (which is actually higher than the maximum temperature of the packing chamber) and 8 hours at 2°C (the upper temperature of the holding cooler). Any such growth should be considered insignificant for the length of time that the meat will be in the packing chamber. Moreover, since pseudomonads are aerobic, any growth will cease in the helium atmosphere. Even in large vacuum packs that usually contain about 1% oxygen, and thus could (in theory) support the growth of pseudomonads, continuing respiration by the meat rapidly depletes the oxygen, preventing further growth.[4] A helium atmosphere should have a similar effect on bacterial growth.

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[3] James, SJ and James, C. "Meat Refrigeration." CRC/Woodhead Publishing, 2002. Part 1. Refrigeration and Meat Quality. Section 1. Microbiology of refrigerated meat (pp. 3-19).
[4] Id., p. 9

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I hope this information fully addresses the concerns of FSIS. Please do not hesitate to contact us if there is any additional information that you need prior to approval of GRAS Notice No. GRN 000251.

Sincerely,

(b)(6)

Marsha C. Wertzberger

(b)(6)

Robert G. Edwards, PhD

cc: Mr. Robert Ragland
OPPD/FSIS/USDA

Mr. Vincent Mercogliano