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BY:

Division of GRAS Notice Review
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Reference Number
027422.00001

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. Name and address of the notifier

Vincent Mercogliano
8310 Shorecrest Drive
Fort Myers, Florida 33912

b. Name of the notified substance

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 as 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


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SUBMISSION END

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