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Division of Dockets Management (HFA-305)
Food and Drug Administration
Department of Health and Human Services
Room 1061
5630 Fishers Lane
Rockville, MD 20852

CITIZEN PETITION

A. Action Requested

This Citizen Petition is submitted by Kalsec, Inc. ("Kalsec") under Sections 201, 402, 403, 409, and 721 of the Food, Drug, and Cosmetic Act ("FDCA" or "the Act") and Section 10.30 of the Food and Drug Administration's ("FDA") implementing regulations. Kalsec produces spice, herb, hop, and vegetable extracts for use in food, beverage, and pharmaceutical applications. By this Citizen's Petition, Kalsec requests that FDA take immediate action to prohibit the use of carbon monoxide in the packaging of fresh meat, including to terminate the agency's unlawful responses to the Generally Recognized As Safe ("GRAS") notifications submitted by Pactiv Corp. and Precept Foods, Inc., GRAS Notice Nos. GRN 000083 and 000143 ("GRN 83" and "GRN 143"), and taking all such further actions as are necessary to effectively implement and enforce an immediate ban on carbon monoxide in fresh meat packaging, in coordination with USDA Food Safety and Inspection Service ("FSIS"). Kalsec advocates the actions requested to prevent serious harms to public health and consumer confidence in the integrity of the U.S. meat supply.[1]

B. Statement of Grounds

1. The Pactiv and Precept GRAS Notifications

FDA has failed to object to GRAS notifications for the unlawful use of carbon monoxide to impart color to fresh meat products. On February 21, 2002, FDA responded to a

[1] It is well established that carbon monoxide has effects on the color of fresh meat. *See, e.g.,* scientific literature cited at note 91, *infra*, and attached as Attachments 16-18; *see also* "Pathogen Inoculation Study of Ground Beef Under Modified Atmosphere Package (MAP) Conditions," S&J Laboratories, Inc. (November 14, 2005), examining the effects of carbon monoxide on the color of fresh meat under a variety of laboratory conditions (Attachment 1).

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GRAS notification submitted on behalf of Pactiv Corporation ("Pactiv"),[2] informing FDA of its GRAS determination for the use of carbon monoxide gas, at levels of 0.4 percent, to displace oxygen inside packaging for fresh, case-ready red muscle meat and ground meat products.[3] The FDA "no objection" letter expressly recognizes that the functional purpose of the carbon monoxide gas is to impart color to fresh meat, giving it "a desirable red color during storage."[4]

On July 29, 2004, FDA responded to a similar GRAS notification submitted on behalf of Precept Foods, LLC ("Precept")[5] informing FDA of its GRAS determination for the use of carbon monoxide gas at levels of 0.4 percent to displace oxygen inside packaging for fresh, case-ready beef and pork products intended for direct sale to consumers. As in the case of the prior Pactiv notification, the FDA "no objection" letter again expressly recognizes that the functional purpose of the carbon monoxide is to impart color to fresh meat.[6]

In evaluating the GRAS notifications of Pactiv and Precept Foods, FDA consulted with the USDA FSIS under new FDA/USDA joint fast track premarket clearance procedures governing the approval of ingredients for meat products.[7] FSIS subsequently issued "acceptability determinations" further implementing the unlawful allowance of carbon monoxide to impart color to fresh meat products,[8] and FDA also continues to consider and allow expanded

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[2] Letter from Alan M. Rulis, Director, CFSAN, Office of Food Additive Safety, to Eric Greenberg, Ungaretti and Harris (Feb. 21, 2002) ("Agency Response Letter to GRAS Notice No. GRN 000083"), available at http://www.cfsan.fda.gov/~rdb/opa-g083.html.

[3] Under the conditions of use specified in the Pactiv GRAS notification, 0.4 percent carbon monoxide gas is blended together with 30 percent carbon dioxide and 69.6 percent nitrogen gases in the modified atmosphere packaging ("MAP") system. The case ready meats are intended to be removed from the MAP system prior to retail display. No labeling requirements are specified under these conditions of carbon monoxide use. Agency Response Letter to GRAS Notice No. GRN 000083, at 1.

[4] *Id.* at 2.

[5] Letter from Laura M. Tarantino, Director, Center for Food Safety and Applied Nutrition ("CFSAN"), Office of Food Additive Safety, to Gary J. Kushner and Anne M. Boekman, Hogan and Hartson (July 29, 2004) ("Agency Response Letter to GRAS Notice No. GRN 000143"), available at http://www.cfsan.fda.gov/~rdb/opa-g143.html.

[6] *Id.* at 2.

[7] *See* 65 Fed. Reg. 3330 (May 23, 2000); "Memorandum of Understanding Between The Food Safety and Inspection Service United States Department of Agriculture and The Food and Drug Administration United States Department of Health and Human Services Regarding the Listing or Approval of Food Ingredients and Sources of Radiation Used in the Production of Meat and Poultry Products," ("Meat Ingredients MOU") (Jan. 18-31, 2000), available at http://www.fda.gov/OHRMS/DOCKETS/98fr/225002000.pdf.

[8] *See* FSIS Directive 7120.1, "Safe and Suitable Ingredients Used in the Production of Meat and Poultry Products," Amdt. 5 (October 13, 2005), listing FSIS acceptability determinations allowing two carbon monoxide packaging systems by Cryovac and two such systems by Cargill.

uses of carbon monoxide in fresh meat packaging based upon its improper responses to the Pactiv and Precept GRAS notifications.[9]

2. Summary of Argument

This Citizen Petition requests that FDA take immediate action to prohibit the use of carbon monoxide to displace oxygen in fresh meat packaging, including by withdrawing the agency's responses to the unlawful GRAS notifications submitted by Pactiv and Precept. The requested action is necessary to prevent serious harms to public health and consumer confidence in the safety and integrity of the U.S. meat supply. The requested ban of carbon monoxide in fresh meat packaging is required under FDCA provisions governing the use of color additives, food additives, and GRAS substances in food, and related provisions of the Federal Meat Inspection Act ("FMIA") governing the suitability of such ingredients in fresh meat products.[10]

The use of carbon monoxide in fresh meat packaging presents serious food safety and consumer deception concerns of the same kinds that historically justified the broad-based ban on color additives in fresh meat products. Carbon monoxide obscures the natural coloration of meat that is indicative of freshness and safety, by reacting with the natural myoglobin in meat to produce carboxymyoglobin, a bright red substance that hides the true colors of meat, simulating the appearance of freshness and masking meat spoilage. This color-masking effect is particularly dangerous in anaerobic packaging environments such as those described in the Pactiv and Precept GRAS notifications, which potentially allow the proliferation of pathogens such as *Clostridium botulinum* but inhibit the growth of aerobic spoilage organisms that provide the tell-tale signs of spoilage upon which consumers rely, in addition to color change, to determine that meat is no longer safe to consume. It is well established under the FDCA and FMIA that food ingredients are prohibited under conditions that are unsafe, conceal damage or inferiority, or make food appear better or of greater value than it is.[11]

The color-imparting effects of carbon monoxide under the conditions of use in fresh meat packaging render the substance an unapproved and prohibited color additive. Neither FDA nor FSIS has the legal authority to permit the use of carbon monoxide in the packaging of fresh meat, in the absence of FDA regulations listing carbon monoxide under FDCA section 721. FSIS lacks the authority to make a suitability determination permitting the use of a color additive in meat, except where it has first been approved by FDA under FDCA section 721.[12] In the case of carbon monoxide, not only has FDA failed to issue the rules necessary to approve the use in fresh meat packaging, but the agency has also disregarded the explicit prohibition on this very use in fresh meat under its own food additive regulations.

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[9] *See* CFSAN/Office of Food Additive Safety, Summary of All GRAS Notices, available at http://www.cfsan.fda.gov/~rdb/opa-gras.html.

[10] 21 U.S.C. 201, 348, 379e, and 601.

[11] 21 U.S.C. 342(a),(b)(3)-(4), and 601(m).

[12] *See* Meat Ingredients MOU, *supra* note 8.

Section 173.350 of FDA regulations specifies the conditions in which carbon monoxide can be safely used to displace oxygen in food and beverage packaging. This regulation authorizes the use of carbon monoxide for all food and beverage products at levels up to 4.5 percent,[13] including in meat products, with the sole exception that carbon monoxide is categorically prohibited for such use in "fresh meat products."[14] It is well established that the specification prohibiting carbon monoxide in "fresh meat" is required under the FDCA because of the serious public health risks attributable to the capacity of carbon monoxide to mask spoilage and promote consumer deception under these conditions.

These public health risks and consumer deception implications further mandate label declaration of the use of carbon monoxide in fresh meat packaging. Although there are no grounds upon which FDA could lawfully allow this use of carbon monoxide, even assuming *arguendo* that FDA had such authority, the agency would be required to implement FDCA labeling provisions mandating that the presence and purpose of the carbon monoxide in the packaging system be disclosed.

Because the use of carbon monoxide to displace oxygen in packaging for fresh meat products violates a catalog of provisions of the FDCA and runs afoul of the agency's own regulations, FDA's failure to object to the Pactiv and Precept GRAS notifications constitutes unlawful agency action under the Administrative Procedure Act ("APA").[15] FDA's Agency Response Letters are tantamount to unlawful color additive approvals, for they allow the use of deceptive colorants in violation of the FDCA and in the absence of a required color additive regulation.[16] The agency's failure to follow the statutorily-mandated procedures for color additive approval is an abuse of discretion, for as the Supreme Court has explained, "[i]t is rudimentary administrative law that discretion as to the substance of the ultimate decision does not confer discretion to ignore the required procedures of decisionmaking."[17]

Moreover, FDA's improper responses expressly allow a use of carbon monoxide that is explicitly prohibited by the agency's own food additive regulation at section 173.350, in violation of the well-settled rule that an agency must follow its own regulations.[18] As FDA has provided no justification for its deviation from that section's prohibition against the use of carbon monoxide-containing packaging gases in fresh meat, its Agency Response letters represent arbitrary and capricious agency action. Treating similar situations differently is the

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[13] 21 C.F.R. 173.350(b)(1).

[14] 21 C.F.R. 173.350(c).

[15] *See* 5 U.S.C. § 706(2).

[16] *See* 5 U.S.C. § 706(2)(C) & (D) (empowering courts to find unlawful any agency actions in excess of statutory limitations or without observance of procedures required by law).

[17] *Bennett v. Spear*, 520 U.S. 154, 172 (1997).

[18] *See, e.g., Mine Reclamation Corp. v. FERC*, 30 F.3d 1519, 1524 (D.C. Cir. 1994) (characterizing the "well-settled rule that an agency's failure to follow its own regulations is fatal to the deviant action").

essence of arbitrary and capricious agency action. The Court of Appeals for the District of Columbia Circuit has made clear that "[a]n agency must treat similar cases in a similar manner unless it can provide a legitimate reason for failing to do so."[19] For these reasons, FDA's failure to object to the Pactiv and Precept GRAS notifications is unlawful under the APA.[20]

In view of the serious public health issues presented and the requirements of the FDCA and APA, FDA has no legal authority to permit the use of carbon monoxide in fresh meat packaging, and the agency's unlawful responses to the Pactiv and Precept GRAS notifications must be terminated immediately.

3. Applicable Legal Standards

a. Regulatory Framework Governing the Ingredients of Fresh Meat Products

Under a Memorandum of Understanding between FDA and FSIS implemented in January, 2000 ("Meat Ingredients MOU"), the two agencies adopted joint procedures permitting the expedited approval of meat product ingredients, including color additives, food additives, and GRAS substances.[21] The new policy supplanted the longstanding procedures requiring independent and sequential premarket clearance first, by FDA, under the requirements of the FDCA, and second, by FSIS, under the requirements of the FMIA.

Under the FDCA, FDA has authority for making safety determinations with respect to food ingredients constituting "color additives," "food additives," and substances that are "generally recognized as safe" ("GRAS"), including those intended for use in fresh meat. Under the FMIA, FSIS has authority for making "suitability determinations" concerning ingredients intended for use in meat products.[22] The FSIS "suitability" evaluation considers consumer protection issues specific to meat products, and may impose limitations on ingredient uses in meat that are not required for more general use in food. FSIS guidance provides that, "suitability relates to the effectiveness of the additive in performing the intended technical purpose of use, at the lowest level necessary, and the assurance that the conditions of use will not

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[19] *Independent Petroleum Ass'n v. Babbitt,* 92 F.3d 1248, 1258 (D.C. Cir. 1996). *See also Kent County, Delaware v. EPA*, 963 F.2d 391 (D.C. Cir. 1992); *Green Country Mobilephone, Inc. v. FCC,* 765 F.2d 235, 237 (D.C. Cir. 1985) (same).

[20] Similarly, FSIS's failure to object to carbon monoxide as unsuitable for the purposes proposed in the Pactiv and Precept GRAS notifications contravenes the FMIA, its implementing regulations, and established USDA policy, and is likewise unlawful agency action under the APA.

[21] Meat Ingredients MOU, *supra* note 8.

[22] *See* 65 Fed. Reg. 3330 and Meat Ingredients MOU, *supra* note 8.

result in an adulterated product or one that misleads consumers."[23] Meat products may include only those ingredients that FSIS has expressly authorized.[24]

Under well established FSIS policy, ingredients that function in fresh meat to conceal damage or inferiority, or give the appearance the product is better or of greater value than is the case are prohibited.[25] Consistent with this policy, FSIS not only has declined to authorize the use of color additives in fresh meat,[26] but also has issued rules explicitly prohibiting such use. For example, despite FDA's determination that "paprika" is safe, including for color additive purposes in food generally, FSIS has prohibited the use of paprika in fresh meat products.[27] FSIS justified the restriction on paprika as "necessary to assure that federally inspected meats and meat food products are not adulterated through the use of substances that conceal damage or inferiority or make the product appear to be better or of greater value than they are."[28]

Under FDCA requirements, food ingredients that constitute either "food additives" or "color additives" are prohibited, including in fresh meat products, except where FDA has determined the ingredient to be safe under the conditions of intended use and has promulgated regulations authorizing such use.[29] Food ingredients that are established to be

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[23] *See* Guidance on the Procedures for Joint Food Safety and Inspection Service (FSIS) and Food and Drug Administration (FDA) Approval of Ingredients and Sources of Radiation Used in the Production of Meat and Poultry Products," available at http://www.fsis.usda.gov/OPPDE/rdad/FRPubs/00-022N/ApprovalofIngredients.htm.

[24] 9 C.F.R. 424.21.

[25] *See, e.g.*, 21 U.S.C. 601(m); 9 C.F.R. 424.23.

[26] FSIS regulations prohibit the use of color-imparting substances in meat products in the absence of authorizing regulations. See 9 C.F.R. 424.21(b)(3) ("No food ingredient, the intended use of which is to impart color in any meat or poultry product, shall be used unless such use is approved in 21 CFR Chapter I as a color additive . . . or in a regulation in this chapter."). While the FSIS regulation at 9 C.F.R. 424.22(a)(3) states that coloring matter and dyes other than those specified by regulation may be used if approved by the Administrator in specific cases, this approval process is available only for additives applied to meat mixed with rendered fat and to casings; this procedure is not a vehicle for approval of colorants to be used in fresh meat.

[27] 21 C.F.R. 73.340 and 73.345 (listing paprika and paprika oleoresin for use in coloring foods generally); 21 C.F.R. 182.10 (authorizing use of paprika for spice or other natural seasoning and flavoring purposes); 9 C.F.R. 424.23(a)& (b).

[28] 34 Fed. Reg. 20386 (December 31, 1969) (Final Rule); see also 65 Fed. Reg. 51758, 51759 (August 25, 2000) (FDA recognizing the established policy prohibiting the use of paprika in meat on consumer protection and public health grounds).

[29] 21 U.S.C. 348 (requiring FDA premarket approval of food additives that are not food contact substances, and authorizing such approval only where there is reasonable certainty that the substance is not harmful under the intended conditions of use); 21 U.S.C. 379e (requiring FDA premarket approval and listing of color additives, and authorizing such listing only where the substance is suitable and safe under the conditions of intended use).

GRAS under the conditions of intended use are excluded from the FDCA premarket clearance requirements that apply to "food additives" but not from those that apply to "color additives." This means that, for a food ingredient that is established to be GRAS under certain conditions of use, the food ingredient may lawfully be used under such conditions without an authorizing food additive regulation. In contrast, for the same ingredient to be used for color additive purposes, FDA must promulgate regulations listing the food ingredient for specified conditions of color additive use. For example, while the established GRAS status of paprika for seasoning purposes eliminates the need for a food additive regulation to authorize seasoning uses, paprika could not be used under similar conditions for coloring purposes in the absence of the FDA regulations listing paprika specifically for color additive purposes.[30]

The Meat Ingredients MOU implements streamlined premarket clearance procedures, but reflects no change in the legal standards governing authorizing the use of food additives, color additives, or GRAS substances under the FDCA and FMIA.[31] Under the new coordinated FDA/FSIS procedures for expedited food ingredient review, petitions for food additives and color additives must be submitted to FDA, which is responsible for promulgating regulations authorizing these substances when they are safe under the intended conditions of use. Where the intended conditions of use encompass fresh meat products, the MOU provides that FDA and FSIS will jointly review petitions, and final FDA regulations will specify appropriate restrictions concerning such uses, as recommended by FSIS.[32]

The Meat Ingredients MOU establishes fast track procedures for agency review of GRAS notifications for non-color additive uses in meat products. The coordinated FDA/FSIS procedures provide that GRAS notifications that are submitted to FDA be reviewed concurrently by FSIS for purposes of making suitability determinations. The MOU provides that the FDA letter responding to a GRAS notifier may convey FSIS concerns about the suitability of the ingredient use in meat products, and may specify restrictions on use that have been recommended by FSIS.[33] Color additives cannot be reviewed under these coordinated procedures for GRAS notifications. Under the FDCA, FDA can authorize color additives only under conditions that have been determined to be safe and are specified in regulations issued

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[30] 21 C.F.R. 73.340 (listing paprika for "the coloring of foods generally, in amounts consistent with good manufacturing practice . . ."); see also 21 C.F.R. 73.345 (listing paprika oleoresin for color additive purposes).

[31] Meat Ingredients MOU at 4 (stating that "[t]he provisions of this MOU are not intended to add to or detract from any of the authorities provided to either FDA or FSIS by the [FDCA or FMIA] . . . or the regulations promulgated by each agency under such authorities" and "[e]ach agency reserves the authority to review, independently of the other, matters of concern to their respective authorities.").

[32] Meat Ingredients MOU at 4.

[33] Meat Ingredients MOU at 5.

through notice and comment rulemaking procedures.[34] FSIS lacks authority to authorize the use of any color additive that has not been approved by FDA through this procedure.[35]

4. The FDCA Prohibits the Use of Carbon Monoxide in Fresh Meat Packaging

a. Carbon Monoxide Constitutes an Unapproved Color Additive

Under FDCA section 721, adopted under the Color Additive Amendments of 1960, color additives are prohibited from use in food except under the defined conditions of use specified in by FDA regulations "listing" the particular color additive.[36] Currently, there are no FDA regulations authorizing the use of carbon monoxide in fresh meat, as required by FDCA section 721.

Section 201(t)(1) of the FDCA defines "color additive" to mean any "substance made by a process of synthesis . . . or otherwise derived, with or without intermediate or final change of identity, . . . and when added or applied to a food . . . or to the human body . . . is capable (alone or through reaction with other substance) of imparting color thereto . . ."[37]

Under well established FDA policy, "color additives" include substances that impart color through chemical reactions occurring after the substance is applied under the intended conditions of use. FDA has explained that "any chemical that reacts with another substance and causes formation of a color may be a color additive."[38] For example, FDA has regulated colorless ingredients of sunless tanning lotions and hair dyes as color additives where these substances participate in color imparting reactions with chemicals naturally present in skin and hair during application.[39]

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[34] 21 U.S.C. 379e.

[35] Under the Meat Ingredients MOU, FSIS lacks authority even to independently authorize the use of food ingredients in meat products that are currently approved under FDA regulations, where the conditions of use do not expressly encompass meat and poultry products. The MOU specifies that where the regulation does not specifically authorize uses in meat and poultry products, FSIS first would be required to obtain a written statement from FDA confirming the scope of the agency's earlier safety determination and expressing no objections with respect to the safety of the proposed conditions of use in meat products.

[36] 21 U.S.C. 371e.

[37] 21 U.S.C. 321(t)(1).

[38] *See, e.g.*, "Color Additives: FDA's Regulatory Process and Historical Perspectives," reprinted from *Food Safety Magazine* (October/November 2003) ("Color Additives"), available at http://www.cfsan.fda.gov/~dms/col-regu.html.

[39] *See, e.g.*, 21 C.F.R. 73.2150 (regulating dihydroxyacetone ("DHA") as color additive where the colorless substance, when applied to the skin, reacts with natural skin proteins resulting in the formation of a brown coloring on the skin surface); 21 C.F.R. 73.2396 (regulating lead acetate (continued...)

FDA has also has regulated ingredients of food as color additives when the ingredient subsequently participates in color-imparting chemical reactions under the conditions of intended use. For example, ingredients of animal feed intended for consumption by poultry and salmon have been regulated as color additives where the ingredients participate in metabolic reactions which intensify the color of the animal tissues intended for use as human food (e.g., intensified gold in egg yolks and red in salmon fillets).[40]

FDA has recognized that ingredients which impart color to meat products through chemical reactions with the naturally occurring myoglobin in meat tissues are appropriately regarded as "color additives" within the meaning of FDCA section 201(t)(1). Specifically, in responding to a citizen petition requesting FDA to regulate nitrites in cured meat under FDCA section 721, FDA evaluated the color-imparting effects of nitrite under the "color additive" definition of the Act. While concluding that a "prior sanction" authorizing the use of nitrite in cured meat ultimately nullified the requirements of FDCA section 721 in this context,[41] FDA determined that nitrites did, in fact, "impart color" within the meaning of the color additive definition, as a result of reactions occurring with myoglobin. FDA stated, "nitrites 'impart' color . . . by reacting with a substance naturally present in the meat to form a third substance that gives the meat a reddish appearance . . . The fact that the color given meat by nitrites is similar to the natural color of meat does not warrant the conclusion that the effect of nitrites is merely to 'fix,' rather than 'impart,' color."[42]

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for use in hair dye as color additive); 21 C.F.R. 73.2110 (regulating bismuth citrate as color additive for use in hair dye); see also "Color Additives," *supra* note 39.

[40] *See, e.g.*, 21 C.F.R. 73.275 (regulating dried algae meal in chicken feed as color additive to enhance the yellow color of chicken skin and egg yolks); 21 C.F.R. 73.295 (regulating tagetes/Aztec marigold meal and extract in chicken feed as color additive to enhance the yellow color of chicken skin and egg yolks); 21 C.F.R. 73.35 (regulating astaxanthin meal in salmon feed as a color additive to enhance the pink to orange-red color of the fish flesh); 21 C.F.R. 73.185 (regulating haematococcus algae meal in salmon feed as a color additive to enhance the pink to orange-red color of the fish flesh).

[41] FDA ultimately concluded that the existence of a prior sanction for nitrites established under FDCA section 201(s)(4) provided an adequate legal basis for maintaining the established nitrite policy. The agency concluded that the long history of safe use of nitrites, the enhanced food safety of cured meat products, and consumer familiarity with the distinctive coloration of cured meats justified its decision to uphold the nitrite prior sanction. 45 Fed. Reg. 77043, 77045 (November 21, 1980) (Withdrawal of Proposed Rule). In contrast to nitrites, not only has no prior sanction been established for carbon monoxide in fresh meat, but such use in explicitly prohibited under section 173.350 of FDA regulations. In addition, carbon monoxide is not used to cure meat or otherwise preserve the safety and quality of meat. To the contrary, carbon monoxide obscures the natural coloration of meat and gives the appearance of freshness and safety when the natural colors would indicate otherwise.

[42] Letter from Donald Kennedy, Commissioner of Food and Drugs, to William B. Schultz, Public Citizen Litigation Group, at 12 (June 29, 1979) (Attachment 2).

Specifically, FDA determined that, in curing meats, nitrites function to displace water molecules that bind naturally to myoglobin, forming nitric oxide myoglobin, which imparts a red color to the meat. In contrast, in fresh meat, myoglobin naturally binds with oxygen to form oxymyoglobin under ambient conditions. In addition, when cured meat is cooked, nitric oxide myoglobin yields nitrosyl hemochrome, which is pink in color. In contrast, when fresh meat is cooked, oxymyoglobin yields denatured metmyoglobin, which is brown in color. FDA characterized the color imparting effects of nitrites in the context of cooked meat as follows, "[w]ere it not for the use of nitrites, the meat would have a brown color after heating rather than the pink attributed by the presence of nitrosyl hemochrome. Nitrites thus 'impart' color by giving the meat a color after heating that it would not otherwise have."[43]

Like nitrites, carbon monoxide in fresh meat packaging imparts color to meat through chemical reactions with the myoglobin naturally occurring in meat tissues. Myogloblin, which occurs in the a muscle fibers of living animals, is a biological oxygen carrier like hemoglobin, to which it is chemically related.[44] Like the hemoglobin in circulating blood, myoglobin functions to deliver oxygen to the tissues of living animals.[45] Just as the redness of blood varies with the degree to which hemoglobin is oxygenated, so also does the redness of meat vary with the oxygenation of myoglobin. As the myoglobin in fresh cut meat binds naturally with oxygen under ambient conditions, oxymyoglobin is formed, and is responsible for the red color indicative of fresh meat. Over time, the oxymyoglobin participates in further reactions with oxygen, gradually oxidizing to form metmyglobin, which is browner in color. As oxidation advances, the freshness and safety of fresh meat decreases in relationship to the progressive browning of meat color. Eventually, meat takes on the browned color that consumers have long relied upon to indicate that meat is spoiled and unsafe to consume.

When the oxygen in fresh meat packaging is displaced by carbon monoxide, the natural coloration provided by meat pigments is masked. Carbon monoxide binds firmly to myoglobin sites that otherwise would be bound more gently by oxygen, forming carboxymyoglobin in place of oxymyoglobin. Carboxymyoglobin imparts an intense red color to the meat which, in contrast to oxymyoglobin, resists the further reactions with oxygen that would form metmyoglobin. In this regard, carbon monoxide is categorically different from antioxidant color preservatives, which simply inhibit the oxygenation of myoglobin in meat, rather than reacting with the myoglobin to form a new chemical substance.

Just as breathing carbon monoxide endangers living animals through its stubborn displacement of oxygen in circulating hemoglobin, adding carbon monoxide to fresh meat endangers consumers by stubbornly displacing oxygen in meat myoglobin. Carboxymyoglobin imparts a sustained bright red color to meat that simulates the appearance of freshness and safety in meat when the natural pigments would warn consumers otherwise.

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[43] 44 Fed. Reg. 75659, 75660 (December 21, 1979) (Proposed Rule).

[44] Encyclopedia of Chemical Technology, Vol. 14, at 895 (4th Ed. 1995).

[45] *Id.*, Vol. 16, at 765.

b. The Pactiv and Precept GRAS Notifications Cannot Support Fast Track Listing of Carbon Monoxide for Color Additive Purposes

While the proviso at section 721(b)(4) provides for fast-track FDA approval for color additives where FDA previously has determined the ingredient to be GRAS, the abbreviated procedures have no application in the context of carbon monoxide use in fresh meat packaging. Section 721(b)(4) provides that, "a color additive shall be deemed to be suitable and safe for the purpose of listing under this subsection for use generally in or on food, while there is in effect a published finding of the secretary declaring such substance exempt from the term 'food additive' because of its being generally recognized by qualified experts as safe for its intended use, as provided in section 201(s)." This proviso was adopted to ensure that redundant regulatory approval procedures would not be compelled by the Color Additive Amendments made to the FDCA in 1960 for such common household food ingredients as salt, vinegar, and natural spices, which FDA had determined were GRAS.[46] Indeed, in FDA's responses to other GRAS notifications for substances whose use may constitute that of a color additive in certain applications, the agency makes clear that although some uses may be GRAS, other uses of the same substance will require premarket review, approval, and listing as a color additive.[47]

Section 721(b)(4) never was intended to provide fast track approval for such substances as carbon monoxide, which have historically been banned for use in fresh meat, much less lacking any history of safe use in such food. In addition, even if the unlawful Pactiv and Precept GRAS notifications were valid, they would provide no lawful basis for fast track listing of carbon monoxide for color additive uses in fresh meat products. FDA has repeatedly emphasized that the agency's "no objection" letter responding to a GRAS notification does not constitute an FDA "published finding" that an ingredient is GRAS, for purposes of FDCA section 721(b)(4).[48] Moreover, even where FDA has, in fact, issued a "published finding" of GRAS status, the provision makes no change in the standards for safety and suitability that must be satisfied for a color additive to be approved by FDA. Neither section 721 nor any other FDCA provision authorizes FDA to list a color additive that is unsafe or promotes consumer deception under the conditions of intended use.

In sum, the FDA lacks the legal authority to condone the GRAS status of carbon monoxide uses in fresh meat packaging. The FDCA obligates FDA to withdraw its responses to the GRAS notifications submitted by Pactiv and Precept and prohibit all such use of carbon

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[46] *See* H.R. Report No. 86-1761, at 15 (1960) ("House Report").

[47] *See, e.g.,* letter from Laura M. Tarantino, Acting Director, CFSAN Office of Food Additive Safety, to George A. Burdock, Ph.D., Burdock Group (February 7, 2005), at 4, available at http://www.cfsan.fda.gov/~rdb/opa-g156.html (Agency Response Letter to GRAS notice for tomato lycopene extract).

[48] *See, e.g.,* letter from Laura M. Tarantino, Acting Director, CFSAN Office of Food Additive Safety, to Dr. Dore, Cyanotech Corp. (Oct. 6, 2003), (Agency Response Letter to GRAS Notice No. GRN 000127), n.2, available at http://www.cfsan.fda.gov/~rdb/opa-g127.html ("no questions" response "does not constitute a 'finding of the Secretary' within the meaning of section 721(b)(4) of the [FDCA]").

monoxide in the absence of authorizing color additive regulations. Even if such color additive petitions were submitted, however, FDA would be unauthorized to list carbon monoxide as a color additive for use in fresh meat. Carbon monoxide fails to meet the statutory criteria of safety and suitability, as established for color additives under FDCA section 721.

c. The Use of Carbon Monoxide in Fresh Meat Packaging Cannot Satisfy the Safety and Suitability Requirements for Color Additive Listing

Section 721(b)(1) of the FDCA authorizes FDA to promulgate a regulation listing a color additive for use in food only "if and to the extent that such additives are suitable and safe for any such use when employed in accordance with such regulations."[49] Further, section 721(b)(6) prohibits FDA from listing a color additive for a proposed use if that use "would promote deception of the consumer in violation of this Act or would otherwise result in misbranding or adulteration within the meaning of this Act."[50] These provisions operate both independently and in conjunction to prohibit the listing of carbon monoxide for use in fresh meat packaging, for this use is neither safe nor suitable precisely because it promotes deception that results in serious food safety concerns.

i Colorants for Meat Have Never Been Approved by FDA or FSIS, Because They Would Promote Deception by Making Meat Appear Fresher Than It Is

Ensuring prevention of deception was an overarching principle behind the Color Additive Amendments, as revealed in the text and legislative history of those amendments, FDA implementing regulations, and interlocking FSIS meat additive regulations and suitability determinations. Significantly, Congress and FDA's predecessor agency were particularly concerned about the use of deceptive colorants in meat. "Examples of coloring practices that would promote deception of the consumer in violation of the basic act were cited by the Secretary of Health, Education, and Welfare as follows: . . . (4) the use of artificial color in stale red meat to make it appear fresh."[51] Additionally, Section 204 of those Amendments mandates that "[n]othing in this Act shall be construed to exempt any meat or meat food product, poultry or poultry product, or any person from any requirement imposed by or pursuant to the Meat Inspection Act of March 4, 1907, 34 Stat. 1260, as amended or extended . . . "[52] Thus, although the use of carbon monoxide in fresh meat packaging is relatively new, it gives rise to the precise type of deception anticipated and opposed by the drafters of the Color Additive Amendments.

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[49] 21 U.S.C. 379e(b)(1).

[50] 21 U.S.C. 379e(b)(6).

[51] House Report at 17.

[52] Pub. Law 86-618, 71 Stat. 441.

No coloring agents are authorized for use in fresh meats in FSIS's regulations enumerating substances permitted for use in meat and poultry products.[53] To the contrary, additives that have been recognized to impart color to fresh meat have been affirmatively prohibited.[54] The prohibition against colorants in fresh meat dates back to even before the enactment of the Color Additive Amendments of 1960. Before that time, colorants in meat were prohibited under the adulteration provisions of the FDCA and FMIA,[55] upon which the antideception provisions of the Color Additive Amendments were derived[56] and which continue to function as an alternative statutory basis upon which colorants in fresh meat are prohibited. For example, the ban on the use of sodium sulfite in meat products[57] has been documented as early as 1943, when FDA explained that "[d]ue to the effect of sulfites on meat products, that is, old and dull colored meat can be rendered red and fresh looking, we are of the opinion that its use in meat is likely to render such meat adulterated under the provisions of the Food, Drug, and Cosmetic Act in that damage and inferiority are concealed or the product made to appear better or of greater value than it is."[58] FSIS has never wavered from this position, and in its press release regarding a 1998 criminal action securing felony sentences for violators who used sodium sulfite, FSIS emphasized that "[s]odium sulfite is banned as a preservative in meat and poultry products because it masks the spoilage and color change due to aging."[59] FSIS banned the use of paprika for this same reason,[60] explaining that the spice "preserv[es] the red color

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[53] 9 C.F.R. 424.21(c); *see also* FSIS Directive 7120.1.

[54] *See* 9 C.F.R. 424.23(a).

[55] 21 U.S.C. 342(b)(3)&(4), 601(m)(8) (providing, in relevant part, that a food is adulterated "if damage or inferiority has been concealed in any manner; or if any substance has been added thereto or mixed or packed therewith so as to . . . make it appear better or of greater value than it is.").

[56] *See* House Report at 16-17 (explaining that, with respect to Section 721(b)(6), "[i]t should be emphasized that we are dealing here solely with deception which would violate the law," and citing sections 402(b)(3) & (4) of the FDCA as the relevant statutory provisions implicated by 721(b)(6)).

[57] 9 C.F.R. 424.23(a)(3) (prohibiting the use of sulfurous acid and salts of sulfurous acid in or on any meat because they conceal damage or inferiority or make products appear of better or of greater value than they are).

[58] *See* letter from Joseph Callaway, Jr., Acting Chief, Division of State Cooperation, to Wayne B. Adams, Acting State Food and Drug Commissioner, Nevada, October 14, 1943, at 3 (Attachment 3). Notably, that letter acknowledged that a number of state laws prohibited the use of sulfites in sausage at that time, even where the additive was allowed in other foods, because "it has been generally held that the use of sulfites in meat and meat products violates a provision in most food laws against the use of any substance to conceal damage or inferiority or cause the product to appear of better or greater value than it is." *Id.* at 1.

[59] *See* http://www.fsis.usda.gov/oa/news/1998/cr98-10.htm.

[60] 9 C.F.R. 424.23(a). That rule also prohibits the use of sorbates because their use "conceals damage and inferiority, i.e., the fact that the products are decaying because of bacterial action, and makes the products appear better and of greater value than they are in view of their (continued...)

characteristic of fresh meat even after the articles have begun to spoil, and thereby conceals damage or inferiority and makes them appear to be better and of greater value than they are."[61]

There is no conceivable distinction between the effect of sodium sulfite or paprika and that of carbon monoxide on fresh meat. To allow carbon monoxide in fresh meat packaging would constitute an unjustifiable departure from prior regulatory action on additives serving a virtually identical function. Carbon monoxide has similarly been shown to mask spoilage and color change due to aging by imparting an artificial red color that mimics that of fresh meat. The chemical thereby conceals damage and inferiority and makes meat appear to be of greater value than it is, within the meaning of the adulteration provisions of the FDCA and FMIA. As such, carbon monoxide in fresh meat packaging would promote consumer deception. Accordingly, FDA is prohibited by section 721(b)(6) of the FDCA from listing carbon monoxide for use in fresh meat packaging as a color additive.

This is precisely the conclusion reached by FSIS during the course of its review of the Precept GRAS notification. In a letter from the director of FSIS's Labeling and Consumer Protection Staff to FDA's Office of Food Additive Safety, FSIS explained:

> The Precept Foods MAP system stabilizes the color of the meat and, therefore, by affecting one of the sensory properties (i.e., appearance) used in assessing the quality of a meat product has the potential to mislead consumers into believing that the product they are purchasing is fresher than it actually is.
>
> . . .
>
> In summary, it is our opinion that the use of the Precept Foods MAP system described in GRAS Notice No. GRN 000143 for use with case-ready fresh cuts of meat and ground meat could potentially mislead consumers into believing that they are purchasing a product that is fresher or of greater value than it actually is and may increase the potential for masking spoilage.[62]

The FDA public record produced in response to a Freedom of Information Act ("FOIA") request is devoid of an explanation of why its Agency Response Letter to the Precept GRAS notification, issued only three months after FSIS expressed the conclusions above, states that FSIS concluded that the Precept MAP system is acceptable for packaging fresh meat.[63] In any event, whatever

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decomposing condition." 35 Fed. Reg. 15552, 15553 (October 3, 1970) (Revision Pursuant to Wholesome Meat Act).

[61] 33 Fed. Reg. 15027 (October 8, 1968) (Proposed Rule).

[62] Letter from Robert C. Post, Ph.D., Director, Labeling and Consumer Protection Staff, to Dr. Lane Highbarger, Office of Food Additive Safety, CFSAN, FDA, April 28, 2004 (Attachment 4).

[63] Agency Response Letter to GRAS Notice No. GRN 000143, at 3.

transpired during that narrow time period cannot justify a determination that the use of carbon monoxide is generally recognized as safe, as a matter of law.

ii. FDA Has Failed to Demonstrate that Carbon Monoxide in Fresh Meat Packaging Would Be Safe Under Actual Conditions of Use

A central intent of Congress in enacting the Color Additive Amendments was to ensure that such additives will be safe under actual conditions of use. The legislative history emphasizes the overarching "safe for use" principle, which is the "scientifically sound principle that we must consider conditions of use when passing on suitability and safety of a color additive."[64] FDA is required to consider actual conditions of consumer use when evaluating a color additive, and must have concrete evidence that the additive will be used safely. The House Report explains that a color additive may be listed for use only when it is *shown* that it may be safely used under the conditions prescribed by regulation.[65] Moreover, the regulatory definition of "safe" with respect to color additives "means that there is convincing evidence that establishes with reasonable certainty that no harm will result from the intended use of the color additive."[66]

Neither FDA nor FSIS have evidence establishing that carbon monoxide in fresh meat packaging is safe under the actual conditions of use. To the contrary, the evidence demonstrates that the use of carbon monoxide in anaerobic packaging systems for fresh meat poses genuine food safety risks under real-world conditions. Significantly, even FDA itself has emphasized the substantial food safety concerns that accompany foods – particularly meats – packaged with oxygen-displacing gases, such the carbon monoxide-containing modified atmospheres that are the subjects of GRN 83 and 143.[67]

FDA has devoted a portion of its Food Code to the subject of reduced oxygen packaging ("ROP"). The agency explains that an "anaerobic environment, usually created by ROP, provides the potential for growth of several important pathogens."[68] Specifically, "[i]f products in ROP are subjected to mild temperature abuse, i.e., 5°-12°C (41°-53°F), at any stage during storage or distribution, foodborne pathogens, including *Bacillus cereus, Salmonella* spp., *Staphylococcus aureus*, and *Vibrio parahaemolyticus* can grow slowly. Marginal refrigeration that does not facilitate growth may still allow *Salmonella* spp., *Campylobacter* spp., and *Brucella* spp. to survive for long periods of time."[69]

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[64] S. Report No. 86-795, at 4 (1959).

[65] House Report at 25 (emphasis added).

[66] 21 C.F.R. 70.3(i).

[67] Food and Drug Administration, Food Code 544 (2005) ("ROP [reduced oxygen packaging] which provides an environment that contains little or no oxygen . . . raises many microbiological concerns.").

[68] *Id.* at 546.

[69] *Id.* at 547.

Of particular concern in ROP are *Clostridium botulinum* and *Listeria monocytogenes*. FDA emphasizes,

> If present, *C. botulinum* could potentially grow and render toxigenic a food packaged and held in ROP because most other competing organisms are inhibited by ROP. Therefore, the food could be toxic yet appear organoleptically acceptable. This is particularly true of psychrotrophic strains of *C. botulinum* that do not produce tell-tale proteolytic enzymes. Because botulism is potentially deadly, foods held in anaerobic conditions merit regulatory concern and vigilance.[70]

Despite the agency's cautionary language in the Food Code, FDA has failed to exhibit appropriate regulatory concern and vigilance in failing to object to the proposed use of carbon monoxide in anaerobic packaging for fresh meat. No material distinction exists between fresh meats packaged in ROP at retail and fresh meat packaged pursuant to GRN 83 and GRN 143 such that FDA could reasonably ignore the safety concerns it stresses in the Food Code. Yet, there is no indication that the agency considered imposing, as a condition for safe use of carbon monoxide in anaerobic fresh meat packaging, any of the safety barriers it emphasized in the Food Code for ROP-packaged products, including meat. Most notably, FDA repeatedly expresses the need for temperature control where ROP-packaged products such as fresh meat are not treated to prevent microbial contamination.[71] The agency would mandate that all foods in ROP which rely on refrigeration as a barrier to microbial growth bear the statement, on the principal display panel in bold type on a contrasting background, "Important – Must be kept refrigerated at 5°C (41°F)."[72] Inexplicably, however, FDA imposed no such refrigeration statement as a condition of safe use of carbon monoxide in anaerobic packaging for fresh meat.

As a practical matter, however, such a refrigeration advisory would have little effect, given fact that temperature abuse, both during distribution and consumer handling of fresh meat, and related food safety concerns are well documented.[73] Such abuse is compounded for

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[70] *Id.* at 548.

[71] *Id.* ("Processors of products using ROP should be cautious if they plan to rely on refrigeration as the sole barrier that ensures product safety. This approach requires very rigorous temperature controls and monitored refrigeration equipment. If extended shelf-life is sought, a temperature of 3.3°C (38°F) or lower must be maintained at all times to prevent the outgrowth of *C. botulinum* and the subsequent production of toxin.").

[72] *Id.* at 551.

[73] *See, e.g.,* Labuza, T.P. and Fu, B., "Use of Time/Temperature Integrators, Predictive Microbiology, and Related Technologies for Assessing the Extent and Impact of Temperature Abuse on Meat and Poultry Products, 15 J. Food Safety 201-227 (1995) (Attachment 5), at 202 ("Unfortunately, the existing distribution channel is not well equipped for the optimum control of temperature during the distribution and display of refrigerated foods. Temperature abuse is common throughout the distribution and retail markets, with the temperature in 21% of household refrigerators often higher than 10°C. Recent data suggested that 33% of retail (continued...)

meats packaged in modified atmospheres with an intended longer shelf life, which provides more opportunities for the food to encounter abusive temperature variation during distribution and storage, thereby increasing the likelihood of microbial spoilage.[74] FDA acknowledges that "[t]emperature abuse is common throughout distribution and retail markets."[75] The agency cites published surveys indicating that refrigeration practices at retail need improvement, and cautioned that "[i]t must be assumed . . . for purposes of assessing risk, that occasionally temperatures of 10°C (50°F) or higher may occur for extended periods" in warehouses and transport vehicles in U.S. distribution chains.[76]

Of even greater concern are consumer handling practices. FDA observes that "[c]onsumers often cannot, or do not, maintain adequate refrigeration of potentially hazardous foods at home . . . . Under the best of circumstances, home refrigerators can be expected to range between 5° and 10°C (41°-50°F)."[77] Thus, while the need for strict temperature control has been emphasized where fresh meat is packaged with oxygen-displacing gases,[78] including

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refrigerated foods were held in display cases above 7°C and 5% were held above 13°C. Temperatures were even higher in southern market regions. Serious microbial stability problems exist because of the frequency of temperature abuse.") (citations omitted).

[74] *See, e.g.*, Farber, J.M., "Microbiological Aspects of Modified-Atmosphere Packaging Technology – A Review," 54 J. Food Protection 58-70 (January 1991) (Attachment 6), at 58 (stating that microbiological safety issues have been raised about modified-atmosphere packaged foods mainly because of "the fact that the extended shelf life of many MAP products may allow extra time for . . . pathogens to reach dangerously high levels in a food").

[75] FDA Food Code, *supra* note 68, at 547.

[76] *Id.*; *see also* Greer, G.G., *et al.*, "Evaluation of the Bacteriological Consequences of the Temperature Regimes Experienced by Fresh Chilled Meat During Retail Display," 27 Food Research Int'l 371-377 (1994) (Attachment 7) (reporting survey of commercial retail cases finding that recommended temperatures of 4°C or below cannot be maintained throughout existing retail cabinets).

[77] FDA Food Code, *supra* note 68, at 550.

[78] *See, e.g.*, Lambert, A.D., *et al.*, "Shelf Life Extension and Microbiological Safety of Fresh Meat – A Review," 8 Food Microbiology 267-297 (1991) (Attachment 8), at 272 (the data "emphasizes [sic] the need for strict temperature-control of meat packaged under modified atmospheres" because such packaging "favors the growth of potential pathogenic clostridia under temperature abuse conditions"); *see also* Farber, *supra* note 74, at Table 1 (listing among the potential disadvantages of MAP the fact that temperature control is necessary); Nissen, H., *et al.*, "Comparison Between the Growth of *Yersinia enterocolitica, Listeria monocytogenes, Escheria coli* O157:H7 and *Salmonella* spp. in Ground Beef Packed by Three Commercially Used Packaging Techniques," 59 Int'l. J. Food Microbiology 211-220 (2000) (Attachment 9), at 212 (finding that *Salmonella* strains in inoculated ground beef stored at 10°C for 5 and 7 days grew to a higher number in a high carbon dioxide/low carbon monoxide gas mixture than in a high oxygen mixture, and stating that in such systems, "[a]t abuse temperatures (>8°C) *Escherichia coli* O157:H7 and *Salmonella* spp. also may grow and increase the health risk to the consumers.").

carbon monoxide, the reality is that the necessary temperature criteria to ensure safety cannot be satisfied under actual conditions of use.

Given FDA's extreme vigilance over anaerobic packaging in other contexts, it is perplexing that the agency failed to impose strict controls on the use of carbon monoxide and other gases to displace oxygen in fresh meat packaging. With regard to low-acid and acidified canned foods, where the anaerobic environment can allow *Clostridium botulinum* spores to flourish, FDA imposes extensive regulations articulating the equipment, controls, manufacturing, processing, and packing procedures which are required to ensure the production of a safe product.[79] Yet in response to carbon monoxide-containing anaerobic packaging for fresh meat, which is known to potentially host a wide range of pathogens, including *Clostridium botulinum*, FDA has imposed no production controls whatsoever, and has failed even to require labeling concerning the need for refrigeration.

It is difficult to conceive of how the controls necessary to ensure the safe use of oxygen-displacing carbon monoxide in fresh meat packaging could be established without the promulgation of a food additive regulation, which would provide clear safety criteria to meat packagers using the technology and which would also serve as a touchstone for enforcement efforts to monitor its safe use. Given the realities of temperature abuse in current meat distribution systems, however, even criteria documented by regulation could not be satisfied under actual conditions of use.

Nor are USDA's extensive HACCP criteria sufficient to assure the safe use of carbon monoxide to displace oxygen in fresh meat packaging. USDA explains that questions to be considered in a hazard analysis include the following: "Is it likely that the food will contain pathogens and are they likely to increase during the times and conditions under which the food is normally stored before being consumed?" and "Does the method of packaging affect the multiplication of pathogenic microorganisms and/or the formation of toxins?"[80] For fresh meats packaged with oxygen-displacing gases including carbon monoxide, the answer to both questions is a resounding "yes," suggesting a potential food hazard and revealing the anaerobic packaging step to be a critical control point ("CCP"). Yet no appropriate critical limits for preventive measures associated with this CCP appear to have been established, as is required under the HACCP rule. Significantly, the microbiological performance standards for raw products under the HACCP rule involve only *Escherichia coli* and *Salmonella*,[81] which are both aerobic organisms, for the assumption underlying the establishment of those criteria appears to be that the meats will be packaged in oxygen-containing environments. Accordingly, there appear to be no process control verification criteria that test for the presence of the anaerobic pathogens of concern when meat is packaged without oxygen.

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[79] *See* 21 C.F.R. 108, 113, 114.

[80] 61 Fed. Reg. 38806, 38815 (July 25, 1996) (HACCP Final Rule).

[81] 9 C.F.R. § 310.25.

The serious food safety concerns about anaerobic packaging are substantially magnified when carbon monoxide is included among the oxygen-displacing gases. In such packaging systems, not only does the anaerobic environment inhibit aerobic spoilage organisms that provide the indications of spoilage to which consumers are accustomed, [82] but the color-imparting effect of the carbon monoxide also masks the natural color change of meat due to aging and deceptively suggests freshness well past the microbial shelf life of the meat.

It has been extensively documented that appearance – most notably, meat color – is the primary consideration of consumers in selecting meat and judging freshness.[83] By imparting a color resembling that of fresh meat, carbon monoxide in meat packaging deprives

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[82] *See* Labuza and Fu, *supra* note 73, at 203 ("A major question for chilled and/or MAP meat and poultry products is whether organoleptic spoilage due to chemical or microbial action will occur before the pathogen numbers or toxin levels become a risk when a product undergoes cycling or abuse temperatures."); *see also* Hintlian, C.B. and Hotchkiss, J.H., "The Safety of Modified Atmosphere Packaging: A Review – Do Modified Atmospheres Enhance Pathogenesis But Delay Signs of Spoilage?" 40 Food Technology 70-76 (December 1986) (Attachment 10), at 75 ("The presence of air in packaged foods supports the growth of aerobic spoilage organisms. . . . In refrigerated products, this noxious warning by spoilage organisms is a critical safety factor since it serves to alert the consumer of temperature abuse and to prevent the consumption of a product which may also contain pathogens. Because anoxic MAs can favor the growth of facultative anaerobes and/or obligate organisms, packaging of foods in oxygen-excluded MAs could result in the loss of this safety factor.").

[83] *See, e.g.,* American Meat Science Association Guidelines for Meat Color Evaluation, available at http://www.meatscience.org/Pubs/factsheets/M9110228.pdf, at 3 ("The color of muscle foods is critically appraised by consumers and often is their basis for product selection or rejection."); National Pork Board/American Meat Science Association Facts: Modified Atmosphere Packaging (MAP): Microbial Control and Quality, available at http://www.porkscience.org/ documents/Other/Q-MAP-MICROBIAL CONTandQUAL.pdf, at 3 ("Meat color is the single greatest appearance factor that determines whether or not a meat cut will be purchased") citation omitted); Kohls, L.I., *et al.*, "A Comparison of Five Different Modified Atmosphere Package Methods for Retail Display-Ready Ground Beef," 2001 Animal Sciences Research Report, Colorado State University, available at http://ansci.colostate.edu/dp/msfs/lik011.pdf, at 1 ("Consumers view color as one of the most important attributes of fresh beef when making a decision to purchase retail product. Color, therefore, determines appeal of the product in the retail case and consumer acceptability."); Jeremiah, L.E., *et al.*, "Beef Color as Related to Consumer Acceptance and Palatability," 37 Journal of Food Science 476-479 (1972) (Attachment 11), at 476 ("Consumer studies have shown that physical appearance of a retail cut in the display case is the most important factor determining retail selection of meat products. Consumers select meat cuts primarily for leanness and then for appearance and freshness, with judgments for the latter two attributes based primarily on brightness of color.") (citations omitted); Liu, Q., *et al.*, "Titration of Fresh Meat Color Stability and Malondialdehyde Development with Holstein Steers Fed Vitamin E-Supplemented Diets," J. Anim. Sci. 1996, 74:117-126 (Attachment 12), at 117 ("Meat color is the main factor affecting beef product acceptability at retail points of purchase.") (citation omitted).

consumers of color cues that would indicate spoilage, because consumers may not realize that meat has spoiled when its color remains bright red. Indeed, FDA itself has acknowledged consumers' reliance on color as a sign of freshness in expressing concerns about the use of carbon monoxide in tuna packaging, and the serious health risk posed when colorants mask the normal signs of spoilage.[84]

While odor has been suggested as an alternative indicator of spoilage of meat packaged with carbon monoxide,[85] consumers obviously cannot detect the smell of packaged meat at the point of purchase to determine freshness. Even upon opening the package, however, consumers would not be able to rely upon odor, slime, or other organoleptic indicators of spoilage, because carbon dioxide-containing anaerobic packaging systems such as those that are the subject of the Pactiv and Precept GRAS notifications suppress the growth of aerobic spoilage organisms that produce these signals, while allowing other harmful yet imperceptible pathogens to flourish.[86] Indeed, even FDA has warned of this significant safety concern accompanying the

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[84] *See* Letter from Diane E. Thompson, Associate Commissioner for Legislative Affairs, to Hon. Ray LaHood, Feb. 13, 1998 (Attachment 13), at 2 ("Consumers rely on the color of tuna to reflect its state of freshness. A process that inhibits the development of the telltale sensory changes that normally accompany decomposition or spoilage, such as the expected change in the color of the flesh, invite increased exposure to tuna products that are toxic, but not identifiable as such."). FDA ultimately issued a "no objection" letter in response to a GRAS notification for "tasteless smoke," of which carbon monoxide is a primary component, for use to "protect the taste, aroma, and color of seafood." *See* Agency Response Letter to GRAS Notice No. GRN 000015, available at http://www.cfsan.fda.gov/~rdb/opa-g015.html. However, that response has no relevance to the agency's consideration of the Pactiv and Precept GRAS notifications because section 173.350 of FDA regulations prohibits the use of carbon monoxide in the packaging of fresh meat products, due to the qualitatively distinct issues surrounding the use of colorants in fresh meat.

[85] *See, e.g.,* Sørheim, O., *et al.*, "Technological, Hygienic and Toxicological Aspects of Carbon Monoxide Used in Modified-Atmosphere Packaging of Meat," 8 Trends in Food Science & Technology 307-312 (September 1997) (Attachment 14), at 311 ("A possible negative aspect of using CO in the MAP of retail meat is concern that consumers might misjudge the quality of a product, because its true microbiological status may be masked by its stable, cherry red carboxymyoglobin color. However, consumers will be able to detect spoilage by the presence of off-odours.") (citation omitted).

[86] *See, e.g.,* Silliker, J.H. and Wolfe, S.K, "Microbiological Safety Considerations in Controlled-Atmosphere Storage of Meats," 34 Food Technology 59-63 (March 1980) (Attachment 15), at 59 (describing the fact that carbon dioxide in low-oxygen atmospheres "selectively inhibits the growth of Gram-negative bacteria, such as pseudomonads and other related psychrotrophs which grow rapidly and produce off-odors and -flavors in raw meats and poultry. . . . The organoleptic changes attended by the growth of lactic acid bacteria [in low-oxygen, elevated carbon dioxide packaging atmospheres] are less noticeable than those produced by the Gram-negative bacteria which develop upon meat in air atmospheres."); Farber, *supra* note 74, at 64 (explaining that the byproducts of the metabolism of the lactobacilli produced in anaerobic carbon dioxide-containing modified atmospheres "are inoffensive compared to the typical spoilage odors produced by the pseudomonads" that thrive in oxygenated atmospheres).

use of reduced oxygen packaging, cautioning that "the inhibition of the spoilage bacteria is significant because without these competing organisms, tell-tale signs signaling that the product is no longer fit for consumption will not occur."[87] Of particular concern is the fact that consumers would not even be aware that they need to consider freshness criteria other than color or odor, such as "use by" date labeling, because fresh meat packaged with carbon monoxide is not required to be labeled as such, nor is the carbon monoxide's coloring effect identified.[88] Accordingly, carbon monoxide in fresh meat packaging presents a serious public health risk because consumers will not be able to rely upon their accustomed indications of spoilage.[89]

The European Commission's Scientific Committee on Food squarely addressed these concerns about the likelihood that carbon monoxide will mask spoilage due to temperature abuse.[90] The Committee observed that "the inclusion of CO in MAP is controversial because the stable cherry-colour can last beyond the microbial shelf life of the meat and thus mask spoilage."[91] The extended shelf life attained by including carbon monoxide in packaging "may, therefore, under certain conditions imply increased risk of growth of pathogens."[92] The Committee concluded that carbon monoxide at levels of 0.3%-0.5% would be safe only if the temperature during storage and transport never exceeds 4°C (39°F), and observed in particular that some strains of *Salmonella* would grow at 10°C.[93] The Committee "wishes to point out that, should products be stored under inappropriate conditions, the presence of carbon monoxide may mask visual evidence of spoilage."[94] In light of the Scientific Committee's Opinion, the

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[87] FDA Food Code, *supra* note 67, at 546.

[88] *See* Labuza and Fu, *supra* note 73, at 202 (stating that the recent trend to use MAP technology, "made with 'invisible' processing methods, which are not perceived as processing by the consumer, creates a new paradigm shift for food safety control" because of the potential to mask organoleptic signs of spoilage).

[89] *See id.* at 205 ("Sensory perceptions (e.g., meat color), evidence of metabolic by-products and types and levels of microorganisms are all valuable, and together give a full picture of food quality and safety.").

[90] Opinion of the Scientific Committee on Food on the Use of Carbon Monoxide as Component of Packaging Gases in Modified Atmosphere Packaging for Fresh Meat, SCF/CS/ADD/MSAd/04 (December 18, 2001) (Attachment 16).

[91] *Id.* at 4, citing Kropf, D.H., "Effect of Retail Display Conditions on Meat Color," Proceedings of the 33rd Reciprocal Meat Conference, 15-32 (1980) (Attachment 17); *see also* Sørheim, O., *et al.*, "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) (Attachment 18), at 157 ("The inclusion of CO in MA for meat is controversial.") and 163 ("An objection raised against using CO as a small component of a MA for retail-ready meat is the possibility that the colour stability can exceed the microbial shelf life, with the risk of masking spoilage of the meat.") (citing Kropf, *supra*).

[92] *Id.*, citing Nissen, *supra* note 78.

[93] *Id.* at 7.

[94] *Id.*

European Union refused to authorize carbon monoxide in fresh meat packaging, despite petitioning by the Norwegian government, precisely because of the dangerous effects in masking spoilage and encouraging consumer deception in ways that encourage consumption of unsafe meat.[95] As a result of the EU decision, the Norwegian meat industry was required to terminate the use of carbon monoxide in fresh meat packaging by June 2004, despite the history of commercial use in Norway since 1985. The EU has also banned carbon monoxide in fresh fish on the same grounds sustaining its ban in fresh meat products,[96] as have most other countries that have addressed the issue, including Canada, Japan, and Singapore.[97]

Given FDA's recognition that home refrigerators can be expected to range between 5° and 10°C at best, in the hands of consumers, meat packaged with carbon monoxide will *never* be kept under the temperature conditions the Scientific Committee of the European Commission prescribed as necessary for safe use (at or below 4°C). Accordingly, under real world conditions, it is unavoidable that carbon monoxide in fresh meat will mask spoilage and promote consumer deception under the conditions of intended use.

The consumer safety risks from fresh meat packaged with carbon monoxide that has been exposed to temperature abuse are not ameliorated by "use by" date labeling such as that discussed in FDA's Agency Response Letter to GRN 143 and specified in FSIS Directive 7120.1 relating to use of carbon monoxide in accordance with that GRAS notification.[98] FDA has presented no consumer behavior evidence demonstrating that consumers would even consult date labeling where the color of the meat suggests freshness, and there is no means of enforcing consumer compliance with such labeling under real world conditions of use. More problematic is the fact that "use by" date labeling will likely amplify the public health risks by providing a false sense of security when the "use by" date has not passed and the meat still looks red, yet the meat has become spoiled due to microbial contamination resulting from temperature abuse. Notably, FSIS does not appear to have even considered the possibility of allowing the use of

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[95] See EFTA Surveillance Authority Annual Report at 24 (2003), available at http://www.eftasurv.int/information/annualreports/dbaFile4978.pdf (relevant pages included as Attachment 19); Europarl News Report at 3 (June 11, 2003) (Attachment 20).

[96] *See* Letter from Jane M. Davies to Directors of Public Protection in Wales (August 9, 2004) (stating that carbon monoxide "causes an irreversible colour change in the fish flesh that has the potential to mislead consumers. As the product stays red even if it deteriorates or spoils, it is considered to be a potential public health hazard.") (Attachment 21).

[97] *See, e.g.,* Julia Moskin, "Tuna's Red Glare? It Could Be Carbon Monoxide," N.Y. Times, Oct. 6, 2004 (Attachment 22); AVA Food Safety Awareness Programme Statement on Carbon Monoxide Treated Tuna, available at http://www.ava.gov.sg/JAVASCRIPT/ carbonMTuna.htm (Attachment 23); Communiqué from Canadian Food Inspection Agency, Animal Products Directorate, Fish, Seafood and Production, to All Importers of Fish, regarding Fish Treated With Carbon Monoxide, June 17, 1999, available at http://www.inspection.gc.ca/english/anima/fispoi/commun/19990617e.pdf (Attachment 24).

[98] Products are required to be coded with a "Use or Freeze by" date not to exceed 28 days after packaging for ground meat and 35 days for whole muscle cuts.

sodium sulfite or paprika with "use by" labeling to ameliorate the deceptive coloring effects of these additives.

Finally, it cannot be said that cooking the meat will kill any pathogens and thereby counter any potential safety risks due to the presence of carbon monoxide in an oxygen-displacing modified atmosphere for fresh meat. *Clostridium botulinum* and *Clostridium perfringens*, which, if present, can thrive in such anaerobic atmospheres, are uniquely dangerous in fresh meat because their toxins are not destroyed by cooking. Even the aerobic pathogen *Salmonella* remains a serious food safety concern because many consumers fail to cook meat, and particularly ground beef, to interior temperatures sufficient to destroy this and other pathogens.[99]

Given the record on consumer reliance upon meat color as an indicator of freshness, the inhibition of other organoleptic indicators of spoilage in modified atmosphere packaging, the documentation of extensive temperature abuse throughout the distribution and handling of fresh meat, and the inability of cooking to cure the harms of meat spoilage, FDA has pointed to no evidence demonstrating that no harm will result from carbon monoxide in fresh meat packaging under actual conditions of use. Without such evidence, carbon monoxide cannot be shown to be safe and suitable for use in fresh meat packaging, and therefore FDA cannot satisfy the statutory criteria at section 721(b)(1) for listing a color additive.

d. Carbon Monoxide in Fresh Meat Cannot Be Authorized Under FDCA Requirements for Food Additives and GRAS Substances

i Longstanding FDA Food Additive Regulations Prohibit Carbon Monoxide in Fresh Meat Packaging

FDA lacks authority to permit the use of carbon monoxide in fresh meat under FDCA requirements for food additives. Under well established FDA food additive regulations specifying the conditions in which carbon monoxide may be used to displace oxygen in food and beverage packaging, such use is expressly prohibited in fresh meat. Section 173.350 of FDA regulations prescribes the conditions under which "combustion product gas," including carbon monoxide gas, can be used to displace oxygen in food packaging. The regulation specifies that such food packaging gases "may be safely used" in accordance with defined conditions, including controls to insure that gases "failing to meet the specifications . . . be prevented from reaching the food being treated."[100] The rule authorizes the use of carbon monoxide gas in food packaging at levels up to 4.5 percent by volume, provided that "[i]t is used or intended for use to

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[99] While USDA actively educates consumers that the only way to ensure that meats are cooked to safety is to use a food thermometer, only 2% of consumers report doing so. *See* FSIS, "The Food Safety Educator," available at http://www.fsis.usda.gov/OA/educator/educator3-4.htm; *see also* Partnership for Food Safety Education, "Safe Cooking Fact Sheet," available at http://www.fightbac.org/cook_facts.cfm.

[100] 21 C.F.R. 173.350(a).

displace or remove oxygen in . . . the packaging of beverage products and other food, except fresh meats" and other conditions are satisfied.[101]

In view of the breadth of the regulation, section 173.350 is properly construed as a food additive regulation that encompasses and regulates the conditions of use concerning carbon monoxide in food packaging to remove or displace oxygen. Particularly since the rule authorizes the use of carbon monoxide in all "beverage and other food" packaging, other than "fresh meat" products, it is unreasonable to construe the prohibition in "fresh meat" as a limitation on the scope of the food additive regulation, rather than a prescribed condition of use within the bounds of the rule. Clearly, where conditions of use have been established for a "food additive," these conditions of use cannot at the same time be excluded from the scope of food additive regulation as "GRAS." On this ground, the conditions of use of carbon monoxide in fresh meat packaging defined in the Pactiv and Precept GRAS notifications cannot qualify as "GRAS," as a matter of law, since these have already been established as "food additive" uses that are regulated directly and explicitly prohibited by section 173.350.

In addition, even if the "fresh meat" prohibition in 173.350 were construed as a limitation on the scope of authorized uses covered by the "food additive" regulation, such a limitation could be lawfully justified only on the grounds that carbon monoxide functions as a "color additive" in fresh meat, as opposed to other meat products for which carbon monoxide use is authorized under the FDA regulation. Given the breadth of the food additive regulation, and the authorization encompassing meat and poultry products other than "fresh meat" products, there would be no reasonable alternative basis for FDA to single out "fresh meat" for separate treatment. For example, there is no evidence suggesting that there are material differences in the toxicological safety of carbon monoxide that would support its use in all food and beverage products, including meat products, except for "fresh meat."

Moreover, in view of the restrictions on color additive uses in fresh meat historically, the "fresh meat" prohibition is justified by the particular hazard carbon monoxide presents under these conditions with respect to masking spoilage and deceptively encouraging consumption of unsafe meat. Such food safety and consumer deception issues are appropriately established as food additive specifications under FDCA section 409.[102] While these same considerations bear on the status of carbon monoxide as a "color additive," as noted above, FDA is fully authorized to promulgate food additive specifications that complement the prohibited uses required under the color additive amendments.

FDA is not, however, authorized to pursue this radical departure from longstanding agency and FSIS policy prohibiting colorants in fresh meat via response to a GRAS notification. It is a well-established requirement of administrative law that where an agency

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[101] 21 C.F.R. 173.350(b), (c).

[102] 21 U.S.C. 348.

departs from its prior positions, it must offer a reasoned explanation for its change in view.[103] Such agency action may be deemed arbitrary and capricious "if its rationale does not appear in the administrative record so that its decisionmaking path may reasonably be discerned."[104] That record must demonstrate that the agency has considered all relevant factors.[105] Where FDA has drastically changed course after reviewing only the GRAS notifications of companies advocating the use of carbon monoxide in fresh meat packaging, the agency cannot demonstrate that it has met its burden of considering all relevant factors. Only after promulgating its new policy by means of notice and comment rulemaking on the public record, considering all relevant facts in its policy rationale could FDA comply with the applicable legal requirements.

ii Carbon Monoxide in Fresh Meat Cannot Satisfy FDCA Requirements for GRAS Substances

FDA lacks authority to condone the GRAS status of carbon monoxide in fresh meat packaging under the applicable FDCA requirements for GRAS substances. Under FDCA section 201(s), "GRAS" substances are distinguished from and excluded from the scope of the "food additive" definition.[106] Accordingly, under the same specified conditions of intended use, a substance cannot qualify at once as both a "GRAS" substance and a "food additive." The FDCA makes clear that these are mutually exclusive categories, and establishes entirely separate and distinct regulatory requirements for food additives and GRAS substances. As discussed above, in 1962, FDA promulgated regulations making clear that the use of carbon monoxide to displace oxygen in food and beverage packaging is not GRAS, but rather must be regulated under the food additive provisions of the Act.[107] It is clear from the broad scope of the rule, which extends to all food and beverage packaging, including meat packaging, that the prohibition against carbon monoxide use in "fresh meat" packaging constitutes a specification within the scope of the food additive regulation, rather than a limitation upon the scope of the food additive rule itself. In short, there is no "fresh meat" gap in the scope of coverage of this food additive regulation which leaves room for any use of carbon monoxide in fresh meat packaging to evade premarket clearance requirements for food additives. Moreover, as discussed above, if anything, the fresh meat prohibition in section 173.350 is best explained as a reflection of the overlapping premarket clearance requirements for color additives. Since FDA has not listed carbon monoxide in fresh meat as required by the FDCA color additive provisions, FDA reasonably codified the prohibition as a specification in the relevant food additive regulation. Notably, GRAS status provides no insulation from FDA premarket clearance requirements for a color additive. In addition, since carbon monoxide is neither safe nor suitable for fresh meat

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[103] *Department of the Navy v. FLRA*, 962 F.2d 48, 56 (D.C. Cir. 1992); *see also Hall v. McLaughlin*, 864 F.2d 868, 872 (D.C. Cir. 1989) ("[d]ivergence from agency precedent demands an explanation.").

[104] *Chamber of Argentine-Paraguayan Producers of Quebracho Extract, et al. v. Holder*, 332 F. Supp. 2d 43, 49 (D.D.C. 2004).

[105] *Id.* at 48.

[106] 21 U.S.C. 321(s).

[107] 21 C.F.R. 173.350.

packaging because it promotes consumer deception, as discussed more fully at section B.4.c. of this petition, FDA is prohibited from approving such use under both the food additive or color additive provisions of the FDCA.[108]

More fundamentally, despite the FDA responses to the Pactiv and Precept GRAS notifications, the sizable body of scientific evidence makes clear that the safety of carbon monoxide is not "generally recognized" as required by the FDCA. To the contrary, the safety of carbon monoxide in fresh meat has been widely challenged in the United States and internationally because of its capacity to mask spoilage and promote consumer deception.

Under FDA's implementing regulations, the use of a food substance may be established as GRAS either through scientific procedures or, for a substance used in food before 1958, through experience based on common use in food. Under section 170.30(b), general recognition of safety through scientific procedures requires the same quantity and quality of scientific evidence as is required to obtain approval of the substance as a food additive and ordinarily is based upon published studies, which may be corroborated by unpublished studies and other data and information.[109] Under section 170.30(c) and 170.3(f), general recognition of safety through experience based on common use in foods requires a substantial history of consumption for food use by a significant number of consumers.[110]

For a substance to qualify as GRAS, there must be evidence that the substance is safe under the conditions of its intended use. FDA has defined "safe" as a reasonable certainty in the minds of competent scientists that the substance is not harmful under its intended conditions of use.[111] FDA has emphasized that a GRAS substance is distinguished from a food additive on the basis of the common knowledge about the safety of the substance for its intended use.[112] The "common knowledge" element of the GRAS standard includes two facets: "(1) the data and information relied on to establish the technical element must be generally available; and (2) there must be a basis to conclude that there is consensus among qualified experts about the safety of the substance for its intended use."[113] FDA advises that "an ongoing scientific discussion or

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[108] 21 U.S.C. 348(c)(3) (prohibiting the approval of any food additive under conditions that "would promote deception of the consumer . . . or would otherwise result in adulteration or in misbranding of the food . . . "); 21 U.S.C. 379e(b)(6) (prohibiting the listing of any color additive under conditions that "would promote deception of the consumer . . . or would otherwise result in misbranding or adulteration of the food . . . "); 21 U.S.C. 342(b)(3)-(4) (defining adulterated food to include food in which "damage or inferiority has been concealed," and food to which "any substance has been added . . . mak[ing] it appear better or of greater value than it is.").

[109] 21 C.F.R. 170.30(b).

[110] 21 C.F.R. 170.30(c) and 170.3(f).

[111] *See* FDA's "Frequently Asked Questions About GRAS" (December 2004), available at http://www.cfsan.fda.gov/~dms/grasguid.html.

[112] 62 Fed. Reg. 18938 (April 17, 1997) (*see* proposed 170.36(c)(4)(i)(C)).

[113] *Id.* at 18942.

controversy about safety concerns raised by available data would make it difficult to provide a basis for expert consensus about the safety of a substance for its intended use."[114]

Plainly, the extensively documented controversy in the public literature about the safety of the use of carbon monoxide in fresh meat packaging belies any notion that the safety of this use is "generally recognized" among qualified experts.[115] Moreover, a claim of GRAS status for this use of carbon monoxide cannot be maintained in light of the fact that the chemical is banned for use in meat or tuna packaging across much of the globe, including by Canada, the European Union, Japan and Singapore, because of the same food safety concerns outlined in this petition.[116]

Consideration of the relevant body of evidence makes clear that carbon monoxide in fresh meat is not GRAS, and there is substantial scientific evidence substantiating the serious nature of the food safety and consumer deception risks presented.

5. The FDCA and Implementing Regulations Require Label Declaration of the Use of Carbon Monoxide in Fresh Meat Packaging as a Fact Material to the Safe Handling of the Meat

Although, as detailed in this Petition, there are no grounds upon which FDA could lawfully allow the use of carbon monoxide in fresh meat packaging, even assuming *arguendo* that FDA had such authority, the agency would be required to implement FDCA labeling provisions requiring that the presence and purpose of the carbon monoxide in the packaging system be disclosed. The inclusion of carbon monoxide in modified atmosphere packaging of fresh meat is a fact material to the safe handling of the meat, and thus must be disclosed on the label in accordance with Sections 403(a) and 201(n) of the FDCA.

Section 403(a) states that a food shall be deemed misbranded if its labeling is false or misleading in any particular.[117] Section 201(n) amplifies that provision by explaining that a food's label is also misleading if it fails to reveal facts material in light of representations made, or material with respect to consequences which may result from the use of the food under customary or usual conditions of its use.[118] The presence of carbon monoxide in fresh meat packaging is material under both prongs of section 201(n).

First, meat packaged in a carbon monoxide-containing modified atmosphere is represented as fresh and untreated. The use of carbon monoxide is a fact material in light of this representation and must be disclosed in labeling, because otherwise consumers will reasonably presume that the meat's red color is a valid indication of its freshness and microbiological safety.

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[114] *Id.*

[115] *See* discussion at section B.4.c.ii. of this petition, above, and accompanying footnotes.

[116] *See* note 97, *supra*, and accompanying text.

[117] 21 U.S.C. 343(a).

[118] 21 U.S.C. 321(n).

Notably, FDA requires label declaration of the fact that a food has been irradiated[119] – a process that produces material changes in the finished food that, in contradistinction to carbon monoxide use, serve to *increase* the safety of treated food. In the context of the food irradiation rulemaking, FDA indicated that, under sections 201(n) and 403(a), special labeling is required where a finished food is materially altered in a visually indiscernible way, and thus otherwise would be misrepresented as the traditional food.[120] In the case of irradiated food, the required labeling helps keep consumers from mistaking these foods for their traditional counterparts presenting significantly greater food safety risks. In the case of carbon monoxide-treated meats, the labeling that would be required by the FDCA would help keep consumers from mistaking these meats for traditionally packaged fresh meats, for the carbon monoxide-treated meats may give the appearance of freshness, but present significantly greater food safety risks.

The open date labeling that is a condition for use of the packaging system under GRN 143 does not obviate the materiality of the fact that carbon monoxide is present in fresh meat packaging. Consumers may disregard the "use or freeze by" date on the package if the meat still looks fresh. Even more concerning is the fact that meat may become spoiled before such date due to temperature abuse during distribution, but because the meat still looks fresh and shows no signs of spoilage and the date has not passed, consumers will reasonably assume that the meat is safe to consume.

Second, the use of carbon monoxide in fresh meat packaging is then also a fact material to the consequences that may result from the use of the meat under customary or usual conditions. Consumers accustomed to judging the freshness and safety of meat by color will likely store, prepare, and consume such meat as if it were as fresh as its color suggests, regardless of the actual age or safety of the meat. Bereft of the usual indicators that meat has spoiled, consumers could readily eat contaminated meat and suffer serious foodborne illness. Label disclosure of the presence and effect of carbon monoxide in fresh meat packaging is therefore required under sections 403(a) and 201(n), because a consumer who is not aware of the use of this chemical has no way of knowing that the appearance of the meat is not a reliable indicator that it is safe to consume.

Significantly, FDA required label declaration of the use of tasteless smoke, which includes carbon monoxide, in fresh tuna, where the smoke was used for purposes similar to that of carbon monoxide in fresh meat packaging, including to affect color.[121] While the proponents of that GRAS notification positioned the tasteless smoke as a preservative, and therefore FDA required its label declaration under sections 403(k) and 403(i)(2) of the FDCA, the food safety considerations supporting disclosure apply with equal force to both uses of carbon monoxide-containing gases – the carbon monoxide affects the appearance of the meat or tuna in a manner

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[119] 21 C.F.R. 179.26(c).

[120] *See* 21 Fed. Reg. 13376, 13388 (April 18, 1986).

[121] Letter from Janice F. Oliver, Deputy Director, CFSAN, to Martin J. Hahn, Hogan & Hartson (March 10, 2000) ("Agency Response Letter to GRAS Notice No. GRN 000015"), available at http://www.cfsan.fda.gov/~rdb/opa-g015.html.

that suggests freshness regardless of the actual age or safety of the food. Disclosure of the presence and effect of carbon monoxide, whether characterized as a chemical preservative or otherwise, is necessary to alert consumers to the fact that the appearance of the product is not a reliable indicator of its freshness or safety. It is precisely for this reason that color preservatives for use in fresh meat packaging must be identified on the label, and there is no justification for treating carbon monoxide differently.

Because the use of carbon monoxide in fresh meat packaging is a material fact in light of the representation that the meat is unprocessed and untreated and that its color is a reliable indicator of its freshness, and because of the serious food safety risks attendant to such representation, declaration of both the presence and the purpose of this use of carbon monoxide is required under sections 201(n) and 403(a) of the FDCA.

C. Environmental Impact

The action requested by this petition would result in the termination of FDA's responses to GRAS notifications and other actions preserving the status quo in conformance with well established law. The action requested is not expected to have a significant effect on the quality of the human environment, and is subject to categorical exclusion under 21 C.F.R. 25.30(h). To the best of Petitioner's knowledge, no extraordinary circumstances exist that would require an environmental assessment under 21 C.F.R. 25.21.

D. Economic Impact

Information on the economic impact of the action requested by this petition will be submitted if requested by the Commissioner.

E. Certification

The undersigned certify that, to the best of their knowledge and belief, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioners which are unfavorable to the petition.

For the foregoing reasons, this petition requests that FDA implement the actions requested to prohibit the use of carbon monoxide in fresh meat immediately.

Respectfully submitted,

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