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The Honorable John D. Dingell
Chairman
House Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, DC 20515

The Honorable Bart Stupak
Chairman
Subcommittee on Oversight and Investigations
House Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, DC 20515

Re: Response to June 26, 2007 Inquiry

Dear Chairman Dingell and Chairman Stupak:

We are writing this letter on behalf of our client, Precept Foods, LLC (Precept Foods), in response to your letter dated June 26, 2007 requesting answers to seven categories of questions regarding the generally recognized as safe (GRAS) status of carbon monoxide (CO) when used as a component in the modified atmosphere packaging (MAP) system for certain meat products. Precept Foods is a joint venture between Hormel Foods Corporation and Cargill Meat Solutions, a wholly-owned subsidiary of Cargill, Incorporated. The Precept Foods case ready pork and beef products are sold under the HORMEL® brand name. We note at the outset that we appreciate the Committee's willingness to extend the response deadline until August 10th.

By way of brief background, Precept Foods enhanced the use of CO in MAP, specifically in barrier lidstock trays, to provide an alternative and improved system for case ready meats. One of the challenges long facing the meat industry is the color change that naturally takes place with the pigments in fresh meat. The pigment in meat, myoglobin, has a purplish-red color before it is exposed to oxygen. When meat is first cut (such as a steak) or ground (such as hamburger), the meat will "bloom" and form a bright red color because the myoglobin will react with the oxygen

in the atmosphere and form oxymyoglobin. After about three days of exposure to the air, oxymyoglobin will break down into metmyoglobin, which has a brownish color.

One of the growing trends in the retail industry is the use of case ready meats. These products are cut (or ground) and packaged at a USDA-inspected facility that is operating under a Hazard Analysis Critical Control Point (HACCP) system. The USDA-inspected facility places the meat in the package that will be purchased by the consumer, eliminating the need for the retailer to handle the meat again where it would be exposed to the environment and could come in contact with physical, chemical, and microbiological contaminants. Case ready meats must be transported from the USDA-inspected facility to the retailer using a packaging technology that will minimize the formation of metmyoglobin.

Numerous packaging systems have been developed over the years to maintain a desirable natural color of packaged meats. Vacuum packaging maintains meat color by excluding oxygen and has been used for over 30 years. The meat in vacuum packages will have the purplish-red color of myoglobin. Vacuum packaged meat has a typical shelf life of about 35 days in the package and three days when removed from the package, for a total of 38 days. Another technology involves packaging meat in a high oxygen modified atmosphere. The high oxygen helps maintain the stability of the oxymyoglobin and the bright red color for up to 11 days but can result in a rancid odor and flavor due to oxidation of fat. These high oxygen and vacuum packaging systems are designed for the specific purpose of minimizing the formation of metmyoglobin and enabling the true shelf life of the meat to be realized.

The industry developed a MAP system that uses CO because it shares the strengths of the vacuum and high oxygen systems without the shortcomings. CO binds with myoglobin and forms carboxymyoglobin, which naturally has a bright red color and is relatively stable. Meat in the CO MAP system has a target shelf life of 28 days for ground beef and 35 days for whole muscle cuts, which is slightly less than the typical shelf life for vacuum packaged meat. The meat color is stabilized in the CO MAP and vacuum packaging system, but the CO MAP system maintains a bright red color rather than the purple red color in vacuum packaging. The CO MAP system does not result in an appreciable change in shelf life or color stability over the vacuum packaging systems on the market; it merely combines the shelf life benefits of the vacuum packaged product with the preferred color of the high oxygen MAP systems.

Importantly, meat color is not a reliable indicator of product safety or spoilage. Metmyoglobin can form on meat that is safe, wholesome and delicious, and meat that is bright red due to its oxymyoglobin content can be spoiled and unfit for consumption. Regardless, consumers have an aversion to meat with metmyoglobin in much the same way they avoid apples and other fruit with minor blemishes. While the blemished fruit and metmyoglobin meat may be delicious and nutritious, consumers gravitate toward products with the preferred color. The industry developed the CO MAP systems in large part to address this consumer preference for meat with a stable, bright red color.

Pactiv Corporation (Pactiv) was the first company to submit a GRAS notification for the use of CO in a modified atmosphere system for meat. Pactiv submitted its GRAS notification in September 2001 and FDA completed a favorable review of the notification in February 2002.

Two years later, in January 2004, Precept Foods filed its GRAS notification for a modified atmosphere packaging using 0.4% CO in a slightly different packaging system.

In addition to demonstrating the GRAS status of CO, the GRAS notification also contained extensive data and information establishing the technology is suitable for use in meat. These data specifically evaluated the effect of CO on meat color and whether this technology would mask signs of spoilage. While carboxymyoglobin will maintain its color after meat is spoiled, the data convincingly demonstrate the CO MAP system does not mask odor or other signs of spoilage. Moreover, each case ready product is packaged with a clear and conspicuous "use or freeze by" date. Consumer surveys establish consumers place a heavy reliance on such "use or freeze by" dates when making purchasing decisions for perishable products such as meat.

Precept Foods has taken a responsible approach regarding the implementation of the technology by making it available only to those retailers that have received training and that have passed a cold chain audit confirming the store can effectively maintain temperature control during receiving, holding and retail display. Precept Foods transports the case ready products in trailers with temperature recording devices to ensure temperature is maintained during transit. Precept Foods also has established receiving guidelines instructing the retailers to check the temperature recording devices and record the temperature of the shipped product when it arrives at the retailer. These and other programs are designed to minimize the possibility that the case ready products will be subject to temperature abuse.

In the unlikely event a package is subject to temperature abuse and the product spoils before its "use or freeze by" date, the technology does not present any issues unique to a packaged perishable product. The data convincingly establish that CO does not mask odor, one of the primary signs of spoilage used by consumers. Consumers, therefore, will have the same clues of spoilage that are present when milk, yogurt, meat packaged in vacuum packaging, and countless other packaged perishable products are subject to temperature abuse and spoil before the expiration of their "use-by" dates.

The data summarized in the GRAS notification and found in this submission convincingly establish the low level of CO found in the MAP system does not present any toxicological concerns that would present a safety issue. Indeed, there is consensus among scientific experts that there are sufficient data to support the safety of these low levels of CO. In addition, the data convincingly establish CO MAP systems are suitable for use in meat. After reviewing the information submitted, FDA, in consultation with USDA's Food Safety and Inspection Service, completed a favorable review of the GRAS notification and did not object to the Precept Foods finding that there are sufficient data to support the GRAS status of CO on the basis of scientific procedures. The agencies also found persuasive the data and information demonstrating the suitability of a MAP system containing CO in meat.

Since the agencies completed their review, there have been additional data and information further demonstrating that the technology is not used to mask decomposition and that consumers have the information they need to avoid consumption of spoiled products. After reviewing the extensive data and information in this response, we trust your Committee similarly will agree

there are sufficient data to support the GRAS status of CO and that the technology is suitable for use in packaging meat.

Below, we address each of the seven general sets of questions asked in the order presented in the June 26th letter. For your convenience, we provide background information when it is useful to place the question in the proper context and we repeat each question in its entirety before providing our response. Attached to this letter are copies of the numerous documents that support the responses to each of the questions.

A. Question 1: Scientific Evidence

1. General Background on the GRAS Process

The concept of GRAS substances is firmly embedded in the Federal Food, Drug, and Cosmetic Act (FFDCA). In 1958, the United States Congress enacted the Food Additive Amendments to the FFDCA. In essence, the 1958 amendments require that before a new additive can be used in food, its producer must demonstrate the safety of the additive to FDA. The goal of the 1958 amendments, as defined by Congress is two-fold – first, "to protect the health of consumers by requiring manufacturers of food additives and food processors to pretest any potentially unsafe substances which are to be added to food; and second, to advance food technology by permitting the use of food additives at safe levels." 1/

When enacting the 1958 amendments, Congress also recognized that many substances should not require formal premarket review to ensure their safety because their safety had been established by either scientific procedures or common use in foods prior to 1958. The 1958 amendments provide an exemption from the food additive definition (and premarket review and approval) for those substances that are generally recognized, among experts qualified by scientific training, as having been adequately shown through scientific procedures to be safe under the conditions of their intended use. 2/ Therefore, Congress specifically provided that a substance that is generally recognized as safe (GRAS) for a particular use may be marketed for that use without further FDA review and approval.

Despite the lack of mandated premarket review and approval for GRAS substances, over the years FDA has sought to assist the food industry in determining whether a given substance is GRAS for a particular use. For example, the agency's regulations in 21 C.F.R. Part 182 contain a list established by FDA shortly after the 1958 amendments identifying substances that when used for the indicated purpose are GRAS. In the 1970s, FDA undertook a systematic review of the data supporting the safety of the GRAS substances listed in Part 182. In instances when the review confirmed sufficient data support the GRAS status of the substance, FDA would affirm the GRAS status and publish the substance in Part 184. At that time, the agency also created a GRAS petition process whereby an individual could on a voluntary basis petition FDA to review

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1/ Cong. Rec. 17413 (daily ed. Aug. 13, 1958) *reprinted in* Legislative History of the Federal Food, Drug, and Cosmetic Act and Its Amendments, vol. XIV at 865.

2/ Federal Food Drug and Cosmetic Act Section 201(s).

and affirm the GRAS status of a substance though rulemaking. 3/ The petition process was "designed as a voluntary administrative process whose purpose was to provide a mechanism for official recognition of lawfully made GRAS determinations." 4/

The GRAS affirmation petition process was slow and cumbersome with some GRAS affirmation petitions taking over 20 years for the agency to review and issue an affirmation regulation in Part 184. In 1997, FDA decided to streamline the GRAS petition process and issued a proposed rule that would replace the petition process with a notification process. FDA concluded the petition process, due to the resource intensive rulemaking component, "deter[red] many persons from petitioning the agency to affirm their independent GRAS determinations." 5/ In the preamble to the proposed rule creating the notification process, FDA explained that the notification process would "provide an incentive for manufacturers to inform FDA of their GRAS determinations. This would result in increased agency awareness of the composition of the food supply and the cumulative dietary exposure to GRAS substances." 6/ The GRAS notification process, therefore, replaced one voluntary process with another – one designed to provide greater transparency to independent GRAS determinations.

While FDA has not yet finalized the GRAS proposed rule, the agency has been accepting and successfully reviewing GRAS notifications since shortly after publishing the proposed rule. FDA received its first GRAS notification on November 2, 1998 7/ and as of the date of this letter has received 227 GRAS notifications. 8/ The notification process has successfully resulted in the review of these GRAS notifications, reviews that would have been less likely to occur under the old GRAS affirmation petition process.

When proposing the notification procedure, FDA set forth the required contents of a GRAS notification and clarified the criteria for a GRAS determination. FDA stated that as a general matter, "a determination that a particular use of a substance is GRAS requires both technical evidence of safety and a basis to conclude that this technical evidence of safety is generally known and accepted." 9/ FDA has defined "safe" as "a reasonable certainty in the minds of competent scientists that the substance is not harmful under the intended conditions of use." 10/ Establishing general knowledge and acceptance of safety has two components: (1) the data and information relied upon to establish safety 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. 11/ FDA has explained that "consensus does not require

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3/ 62 Fed. Reg. 18937, 18940 (April 17, 1997).
4/ *Id.* at 18941.
5/ *Id.*
6/ *Id.*
7/ GRN 000001, copy accessed on Aug. 6, 2007 at http://www.cfsan.fda.gov/~rdb/opa-g001.html.
8/ GRN 000227, copy accessed on Aug. 10, 2007 at http://www.cfsan.fda.gov/~rdb/opa-grsn.html.
9/ 62 Fed. Reg. at 18940.
10/ 21 C.F.R. § 170.3(i).
11/ 62 Fed. Reg. at 18940.

unanimity among qualified experts." 12/ Thus, although the existence of "a severe conflict among experts regarding the safety of the use of a substance precludes a finding of general recognition, . . . mere conflict" will not. 13/

2. The Precept Foods GRAS Determination

Almost two years before Precept Foods filed its GRAS notification, FDA had completed a favorable review of a GRAS notification filed by Pactiv Corporation for the use of CO in a MAP system. 14/ The Pactiv GRAS notification, GRN 000083 (hereinafter GRN 83), involved the use of a modified atmosphere containing 0.4% CO, 30% carbon dioxide and 69.6% nitrogen. The technology involves the packaging of case ready meats in a larger package or "mother bag" that would contain the modified atmosphere. When the "mother bag" arrives at the retailer, the case ready meats are removed from the MAP system and placed on the retail shelf. The Pactiv system involves the use of permeable packaging film surrounding the trayed meat, which allows the CO, carbon dioxide and nitrogen in the atmosphere surrounding the meat in the mother bag to dissipate over time. Prior to the Pactiv GRAS notification, FDA also completed a favorable review of a GRAS notification for tasteless smoke, which contains CO, to protect the taste, aroma and color of seafood. 15/ FDA and FSIS, therefore, had a familiarity with the underlying data supporting the GRAS status of CO containing systems in the processing of foods.

The Precept Foods technology involved a similar application of CO as the Pactiv system with an atmosphere of 0.4% CO, with the balance being approximately 35% CO_2 and 65% N_2. The Precept Foods system differed from the Pactiv system in that the modified atmosphere containing CO remains in contact with the meat until the package is opened by the consumer. The technology also differs in that Precept Foods, rather than the retailer, applies the "use or freeze by" date. Given the similarities with the GRAS notification submitted by Pactiv, Precept Foods initially thought its packaging system would be covered by GRN 83. Relying upon the scientific data summarized in GRN 83 and its own corroborating studies, Precept Foods contacted FSIS and asked the agency to recognize the safety and suitability of its new low oxygen system with CO. 16/ FSIS decided the slight differences in the technology warranted the filing of a separate GRAS notification by Precept Foods. 17/

12/ *Id.* at 18941.
13/ *Id.*
14/ GRN 83, Document 100568-100829.
15/ GRN 000013, Letter to Martin J. Hahn from Ms. Janice F. Oliver, Deputy Director, CFSAN, FDA (March 10, 2000) (copy accessed Aug. 9, 2007 at http://www.cfsan.fda.gov/~rdb/opa-g015.html).
16/ Letter to Robert Post, Labeling and Consumer Protection Staff, FSIS, USDA, from Gary Kushner and Ann Boeckman, Hogan & Hartson LLP (July 2, 2003), Document 10001-100061.
17/ Letter to Robert Post, Labeling and Consumer Protection Staff, FSIS, USDA, from Lane A. Highbarger, Division of Biotechnology and GRAS Notice Review, CFSAN, FDA (Sept. 11, 2003), Document 100062-100064.

Precept Foods filed a GRAS notification with FDA on January 6, 2004 providing the data and information supporting the GRAS status of CO when used as a component in a MAP system. 18/ Given the similarities between the Precept Foods and Pactiv systems, the Precept Foods GRAS notification incorporated by reference all of the data submitted by Pactiv in GRN 83. Stated differently, Precept Foods did not resubmit data and information that already had been covered in GRN 83. Precept Foods also used the same approach to assess the safety of its MAP system containing CO as other modified atmosphere systems. Precept Foods compared CO intake estimated to result from the specific modified atmosphere of interest to national health-based standards for acceptable exposure to CO in ambient air. 19/ Based on national, health-based standards for CO exposure, Precept Foods concluded that the use of CO at 0.4% in a MAP system for fresh meats poses no health or safety concern and is not reasonably expected to result in any measurable levels of carboxymyoglobin in the blood of those who consume treated meat or who are nearby when one or more packages of case ready meat are opened. This conclusion is consistent with the conclusion of Sorheim, et al. (1997) in the published literature that "it is highly improbable that CO exposure from meat packaged in an atmosphere containing up to 0.5% will represent a toxic threat to consumers through the formation of COHb [carboxyhemoglobin]." 20/

Precept Foods concluded that the intended use of CO is GRAS on the basis of scientific procedures at the trace concentrations used in the MAP system on the basis of the published data, including toxicology studies evaluating the safety of CO. As the basis for its GRAS determination, Precept Foods relied on conclusions in the published literature and generally accepted scientific data, and incorporated by reference GRN 83, including the finding of the panel of experts convened by Pactiv that issued an opinion supporting the GRAS status of CO. Moreover, the use of CO in retail packages has an established safety record in Norway. A system widely and safely used for nearly twenty years in a country such as Norway clearly meets the "reasonable certainty of no harm" standard.

In addition to demonstrating there are no toxicological concerns under the intended conditions of use and the proposed use of CO is GRAS, Precept Foods also submitted information addressing the suitability of using a CO MAP system in meat products. As part of any GRAS notification for use on meat or poultry products, FSIS consistently asks companies to submit information demonstrating the suitability of the substances intended for use in meat products or processing.

18/ GRN 143, Document 100081-100110.

19/ In its GRAS notification, Precept Foods estimated that exposure to CO would be 0.054 mg CO per meal of cooked meat, assuming meat absorbs 30% of the CO in the package, an 85% reduction in CO exposure due to cooking of the meat, and 100% absorption by the consumer. Alternatively, if 100% of the CO in the package were absorbed and 100% of the CO is consumed, Precept Foods estimated that a consumer would be exposed to 1.2 mg of CO. Further, if the consumer were exposed to 100% of the CO in the package, the consumer would only be exposed to 2.18 mg of CO. These exposure amounts are well below the safety limits set by the Environmental Protection Agency (EPA) and OSHA. EPA's National Ambient Air Quality Standard is 9 ppm CO in air, resulting in the inhalation of 52 mg of CO in 8 hours. The OSHA Permissible Exposure Limit is 50 ppm in air, resulting in the inhalation of 290 mg CO in 8 hours.

20/ Sorheim, et al., (1997), Document 100845-100850.

The suitability analysis relates to the effectiveness of the GRAS substance in performing the intended purpose of use and assurance that the conditions of use will not result in an adulterated product or one that misleads consumers. 21/ For purposes of its suitability analysis, FSIS asked for data demonstrating that CO does not significantly change key meat characteristics and does not mask spoilage.

Precept Foods commissioned three studies to substantiate the suitability of the planned MAP system. The first study evaluated the effects of temperature abuse on ground beef stored in different atmospheres and concluded that meat stored in a CO atmosphere (0.4%) does spoil and emanate a noticeable odor. 22/ The second study examined shelf life, bloom, and cooked color of ground beef packaged in varying levels of CO. 23/ The third study examined the shelf life of boneless beef strip steaks and top round steaks packaged in a barrier lid stock back-flushed with 0.4% CO, 35% CO_2, and the balance as N_2. In this study samples were found to maintain acceptable quality for at least 42 days. Microbiological, chemistry, color, odor, and cooked evaluations showed no signs of spoilage over this period of time. 24/

These studies confirmed that the use of CO in the Precept Foods system will not mask spoilage and will perform in a manner comparable to similar systems, including other CO packaging systems that FDA and FSIS previously deemed acceptable. Specifically, a CO-containing environment will allow meat to maintain a desirable color but will neither inhibit microbial growth nor affect the characteristic odor or other indicators (e.g., gas or slime formation) of meat spoilage. The ability of meat packaged in CO to spoil and to emanate off-odors has been reported in the published literature (Sorheim et al., 1999). 25/

Thus, the data submitted to FDA and FSIS convincingly established that the proposed use of CO in a MAP system is GRAS and does not present any unique toxicological or safety concerns. The extensive published information on the safety of CO establish there is general recognition among experts qualified by scientific training and experience to evaluate safety and that the proposed use of CO presents a "reasonable certainty of no harm," which is the safety standard required for GRAS substances. The data also demonstrated the suitability of CO in the MAP system. Perhaps most important, the scientific experts reviewing the GRAS notification within FDA, in consultation with the individuals at FSIS with extensive expertise on reviewing the

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21/ Letter to Dr. Lane Highbarger, Office of Food Additive Safety, CFSAN, FDA, from Dr. Robert Post, Labeling and Consumer Protection Staff, FSIS, USDA (Apr. 28, 2004), Document 100114-100116.

22/ John, Wilborn and Catano, Excel Report: "Ground beef abuse study in peelable, low oxygen and carbon monoxide lid stock tray," (May 13, 2003), Document 100012-100015.

23/ Rathje and Catano, Excel Report: "Use of Carbon Monoxide in Lid Stock on Ground Beef. Project #23034" (Feb. 14, 2003), Document 100016-100024.

24/ Ruzek, Hormel Report: "Precept Foods/MAP Packaging, R&D Project #PF002.00," (June 6, 2003), Document 100025-100061.

25/ Sorheim, et al., (1999), Document 100851-100858.

suitability of substances for use in meat and poultry, completed a favorable review of the Precept Foods GRAS notification. 26/

3. Response to Questions

Question 1(a): Does Precept consider these reports [referring to three internal studies conducted by Precept] submitted to FDA and FSIS, to meet standards for publication in a reputable, peer-reviewed scientific journal?

Precept Foods used methodologically valid practices and conducted the studies in a manner that would meet the standards for a reputable peer-reviewed journal. The quality of research done within the research and development departments of individual companies is often of the same quality as that done by universities, but industry research is generally not published because it usually contains sensitive and proprietary information that is used to develop and differentiate products within a very competitive marketplace. Precept Foods did not conduct these studies with the intent of seeking publication in peer-reviewed journals. Nor is Precept Foods required to do so under the applicable GRAS standard.

It is well recognized that GRAS notifications can be corroborated by unpublished data. The FDA position is clear. The safety of GRAS substances must be established through "generally available and accepted scientific data, information, methods, or principles which ordinarily are published and may be corroborated by unpublished scientific data, information, or methods." 27/ The Precept Foods GRAS notification satisfied this requirement. GRN 143 and GRN 83 summarize the extensive published safety data supporting the GRAS status of CO in MAP systems. The Precept Foods notification established that the use of CO in MAP systems met the reasonable certainty of no harm standard by demonstrating, using established scientific principles and data, that the use of CO at 0.4% in a MAP system for fresh meats poses no health or safety concern and is not reasonably expected to result in any measurable levels of carboxymyoglobin in the blood of those who consume treated meat or who are nearby when one or more packages of case ready meat are opened. A similar conclusion is reached in GRN 83 and by the published literature.

The three studies mentioned by the Committee corroborated information in the published literature regarding the suitability of CO-containing systems by evaluating the effect of such systems on color. One of the studies specifically focused on whether the CO-containing system would mask spoilage under abusive conditions. These three studies established the effective concentration of CO in a modified atmosphere, establish a suitable shelf life, and confirm that the systems will not adversely affect meat characteristics, including the signs of spoilage. Precept Foods designed the studies primarily to address issues that could be raised by FSIS as it conducted its suitability analysis. After reviewing the data submitted in the GRAS notification, FSIS concluded the proposed use of CO was suitable for application on meat products.

26/ Letter to Gary Jay Kushner and Anne M. Boeckman from Laura Tarantino, Director, Office of Food Additive Safety, CFSAN, FDA (July 29, 2004), Document 100148-100150.

27/ Proposed 21 C.F.R. § 170.30(b); 62 Fed. Reg. at 18960.

Question 1(b): Does Precept intend to publish these reports? If not, why not?

No. As explained above and in GRN 143, the published literature supports the GRAS determination that CO is safe for the intended conditions of use, raises no material questions about the safety of CO and reflects no significant conflict of expert opinion regarding key safety factors.

Question 1(c): How does Precept respond to the allegation that some of the above reports fail to include all data, report only mean values – without a measure of variability, fail to include replicate results, or fail to support conclusions with data?

Precept Foods used methodologically valid practices and procedures when developing and conducting the studies. Precept Foods shared with FSIS and FDA the information the agencies needed to evaluate the suitability of the MAP system containing 0.4% CO. The studies supported the proposed shelf life for products in CO MAP systems and confirmed conclusions in the published literature that meat packaged in a CO containing environment will produce noticeable signs of spoilage.

Although the studies primarily reported Mean values, these values were statistically analyzed to include Standard Error, Median, Standard Deviation, Sample Variance and Range. The Hormel study also involved replications of the primals. 28/ Dr. Bruce Paterson and Dr. Forrest Dryden helped design the Hormel test protocol and interpret the data. Moreover, the study results are consistent with earlier exploratory studies conducted by Hormel R&D and Cargill and discussed in response to question 4(a), below, and with studies reported in the Precept Foods patent application, which included a statistical analysis of the odor scores. 29/ These studies further corroborate the data submitted to FSIS establishing that the Precept Foods MAP system will perform in a manner comparable to similar systems deemed safe and suitable.

Any potential concern regarding the reporting of only mean values was addressed in a follow-up submission to FSIS. In a May 12, 2004 letter to Dr. Robert Post, Director of the FSIS Labeling and Consumer Protection Staff, Precept Foods submitted additional studies supporting the

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28/ The rigor that went into designing this test, as outlined in Table 1 attached to the study, is further emphasized. Two different beef sub-primals (strip loins and top rounds (were evaluated – each one was replicated six times (six different strip loins, six different top rounds). A total of 252 packaged samples (tests and control) were manufactured and analyzed. The test was designed to evaluate the samples after spending a specified period of time in storage and in the display case. As shown in table 1, C1-10-13 means this control sample was held in boxed storage for 10 days and then placed in the display case for 3 days before being sent to the lab for micro/chem. analysis (day 13). T1-20-38 means this test sample was held in boxed storage for 20 days prior to being placed in the display case and was then held in the display case for 18 days before being sent to the lab (day 38); See *infra* note 79 for study and data, Document 400015-400412.

29/ Patent Application, "A Method of Using Lactate and Carbon Monoxide to Improve the Quality of Fresh Meat," Document 100833-100844.

conclusions drawn from these initial suitability studies. 30/ Specifically, Precept Foods provided FSIS with a revised copy of the ground beef study (Use of Carbon Monoxide in Lid Stock on Ground Beef; Project #23034). Precept Foods expanded this revised study to include additional data points collected through 27 days in support of a shelf life of 28 days for ground beef products packaged in the Precept Foods system. In addition, Precept Foods provided FSIS with information regarding the relationship between subjective color assessments and "a* values" used in the ground beef study. 31/

Precept Foods designed the studies for purposes of assessing the suitability of CO in the MAP system using standard protocols that typically are conducted for these type of studies. The final reports contained the data and information that FSIS needed to complete its analysis. Regardless of the accuracy of the Committee's characterization of the "issues" with the submitted data, FSIS – the agency with extensive expertise in reviewing the suitability of substances in meat and poultry products – found the studies sufficiently designed and the information appropriately robust to support the agency's suitability analysis.

Question 1(d): Were other studies provided to FDA or FSIS in support of GRN 000143 to address these issues?

Precept Foods provided FSIS with additional information confirming that spoilage occurs in untreated meats packaged in the Precept Foods system. In particular, Precept Foods provided a study that sought to compare the effects of different combinations of injection treatments (including untreated controls) and atmosphere on the shelf life of strip steaks packaged in barrier lid stock trays. 32/ The study confirmed that untreated steaks packaged in the planned MAP system do not have significantly different spoilage patterns from steaks treated with antimicrobial agents in the time periods examined (26, 30, and 41 days). The results further confirmed that untreated products packaged in a modified atmosphere containing 0.4% CO, 35% CO_2, and 65% N_2 have an acceptable microbiological profile and may reasonably be expected to be sound and wholesome throughout a 35-day shelf life. Precept Foods also provided FSIS with information explaining the criteria used in this study to determine that the products were acceptable and that spoilage had not occurred. Specifically, Precept Foods provided FSIS with the range of the typical count of psychotropic bacteria found after 41 days. 33/

Furthermore, Precept Foods met with FSIS and FDA in September 2006 and discussed two additional studies regarding the impact of CO on the microbiological quality and safety of ground beef. 34/ These studies showed that the spoilage characteristics of meat packaged in

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30/ Letter to Robert Post, Labeling and Consumer Protection Staff, FSIS, USDA, from Gary Kushner and Ann Boeckman, Hogan & Hartson LLP (May 12, 2004), Document 100117-100133.

31/ Letter to Robert Post, Labeling and Consumer Protection Staff, FSIS, USDA, from Gary Kushner and Ann Boeckman, Hogan & Hartson LLP (May 28, 2004), Document 100135-100141.

32/ See *supra* note 30.

33/ See *supra* note 31.

34/ Power Point Presentation by Mindy Brashears, Ph.D., Texas Tech University (Sept. 29, 2006), Document 100527-100560; See, Brooks, C. et al., Reciprocal Meat Conf. Proceedings (2006), Document 200062-200069.

different atmospheres (traditional overwrap, high-oxygen, and CO) are similar when factors such as age, temperature and source are controlled.

Precept Foods also referenced or submitted the studies, below, in its correspondence with FDA and FSIS regarding GRN 143.

> O. Sørheim et al., *Technological, hygienic, and toxicological aspects of carbon monoxide used in modified-atmosphere packaging of meat*, 8 Trends in Food Sc. & Tech. 307, 311 (1997). 35/
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> O. Sørheim et al., *The storage life of beef and pork packaged in an atmosphere with low carbon monoxide and high carbon dioxide*, 52 Meat Sci. 157-164 (1999). 36/
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> D.H. Kropf, *Effect of Retail Display Conditions on Meat Color*, 33 Reciprocal Meat Conf. Proceedings 15, 29 (1980). 37/
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> Gamage, S. D., J. B. Luchansky and S. C. Ingham, *Pulsed-field gel electrophoresis typing of Hafnia alvei isolated from chub-packed and retail ground beef*, Letters in Appl. Microbiol. 26 (1998). 38/
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> H. Nissen, et al., *Comparison between the growth of Yersinia enterocolitica, Listeria monocytogenes, Escherichia coli O157:H7 and Salmonella spp. in ground beef packed by three commercially used packaging techniques*, Int. J. Food Micro., Vol. 59, 211-220 (2000). 39/
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> J.H. Silliker and S.K. Wolfe, *Microbiological Safety Considerations in Controlled-Atmosphere Storage of Meats*, Food Tech. 59-63 (Mar. 1980). 40/
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> Watts, D.A. et al., 1978. *Fate of [^{14}C] Carbon monoxide in Cooked or Stored Ground Beef Samples. J. Agric.* Food Chem. 26, 210-214. 41/

Finally, the Precept Foods GRAS notification incorporated by reference GRN 83 and thereby all studies provided in association with that GRAS notification were also provided to FDA in support of the Precept Foods GRAS notification.

> *Question 1(e): We were told that the food industry practice for firms seeking a GRAS determination by FDA is to generally convene an independent GRAS panel and submit the panel's report as part of their GRAS notification. Apparently*

35/ Document 100845-100850.
36/ Document 100851-100858.
37/ Document 100859-100876.
38/ Document 100887-100891.
39/ Document 100877-100886.
40/ Document 100892-100896.
41/ Document 100897-100903.

Pactiv Corporation convened a GRAS panel to support its GRAS notification for the use of carbon monoxide in its fresh meat packaging system. Did Hormel and/or Cargill convene an independent GRAS panel? If not, why not?

A GRAS panel is not a requirement for a GRAS determination – the requirement is expert consensus regarding safety. There is no genuine scientific dispute regarding the underlying toxicological and other studies supporting the safety of a 0.4% concentration of CO in a MAP system for fresh meat under the intended conditions of use. Moreover, at least two expert panels have reviewed the data on CO and issued opinions supporting its GRAS status. As recognized by this Committee, Pactiv convened an expert panel for its GRAS notification, which Precept Foods incorporated by reference. Dr. Sørheim, Dr. Hunt, and Dr. Cornforth are the three experts on the Pactiv Expert Panel, all of whom support the safety of CO in retail packages. 42/ A GRAS notification for CO submitted by Tysons Foods, which is currently under consideration by FDA and FSIS as GRN 000188, also contains the findings of an expert panel recognizing the GRAS status of the CO in that system. 43/

In addition, several experts have publicly stated their conclusion that low oxygen systems with CO are safe. For example, in a perspective published in *Food Technology,* Professors Joseph Sebranek, Melvin Hunt, Daren Cornforth, and Susan Brewer stated that –

> The claim that CO packaging will result in unsafe products is not scientifically sound. There is no greater risk of pathogenic bacteria associated with CO packaging than with any other packaging system currently used for fresh meat. In fact, a valid argument can be made that CO packaging creates opportunities to increase safety. It is important to realize that the presence or absence of bacteria of public health significance on meat is independent of meat color. 44/

Finally, Dr. Hunt, Dr. Brashears, and Dr. Sørheim have submitted letters to FDA supporting the use of CO in the Precept Foods system. 45/ In addition, other competent and reliable scientific

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42/ See *supra* note 14, Document 100773-100829.

43/ GRAS Notification No. GRN 000188, GRAS Claim for the Use of Carbon Monoxide in Modified Atmosphere Packaging for Red Meat Products 20 (Dec. 22, 2005), Document 101163-101184.

44/ J.G. Sebranek, M.C. Hunt, D.P. Cornforth, and M.S. Brewer, *Carbon Monoxide Packaging of Fresh Meat,* 60 J. Food Tech., No. 5, 184 (May 2006), Document 100904.

45/ Letter to Dr. Laura Tarantino, Office of Food Additive Safety, CFSAN, FDA from Dr. Melvin Hunt, Professor of Meat Science (Jul. 26, 2006), Document 100905-100907; Letter to Dr. Laura Tarantino, Office of Food Additive Safety, CFSAN, FDA from Dr. Mindy Brashears, Texas Tech University (Aug. 23, 2006), (accessed on Aug. 10, 2007 at http://www.fda.gov/ohrms/dockets/dockets/05p0459/05p-0459-c000009-01-vol2.pdf), Document 101191-101215; Letter to Dr. Laura Tarantino, Office of Food Additive Safety, CFSAN, FDA from Dr. Oddvin Sørheim (Sept. 6, 2006) (accessed Aug, 10, 2007 at http://www.fda.gov/ohrms/dockets/dockets/05p0459/05p-0459-c000011-01-vol7.pdf), Document 101216-101218.

experts, such as those in 1(g), below, have expressed their support for the safety of CO-systems. Clearly there is a firm basis for finding consensus among qualified experts regarding the safety of CO packaging in the Precept Foods system.

Question 1(f): Please provide CV for the authors of the reports listed above

A copy of the CV for each of the following authors is attached.

- Graciel R. Catano 46/
- Liza John 47/
- Nancy M. Rathje 48/
- David C. Ruzek 49/
- Barney S. Wilborn 50/

Question 1(g): Please provide names and CV of any experts Precept consulted, and copies of any reports supplied.

The individuals identified below have been instrumental in the development of the data and information supporting the GRAS status and suitability of CO in a MAP system. Some of these individuals are employees of Precept Foods, Cargill or Hormel while others are outside experts. In instances when the individual has prepared an expert report or opinion, we are attaching copies of such reports. The CVs for these individuals also are attached, if available.

- April A. Archer, Cargill, study investigator (CV provided) 51/
- Dr. Alden M. Booren, Michigan State University, food science researcher (opinion regarding CO MAP systems provided) 52/
- Dr. Mindy Brashears, Texas Tech University, food science researcher (CV and various presentations to FDA and USDA regarding CO MAP systems provided) 53/
- Dr. Daren P. Cornforth, Utah State University, food science researcher (CVs and opinion and presentation regarding CO MAP systems provided) 54/

46/ Document 100911.
47/ Document 100912.
48/ Document 100913-100914.
49/ Document 100915.
50/ Document 100916-100917.
51/ Document 100918-100919.
52/ Document 100920-100921.
53/ Document 100922-100989.
54/ Document 100990-101018.

- Dr. Forrest Dryden, former Vice President, Research and Development, Hormel (Retired, CV not provided)
- Curtis J. Cundith, Cargill, research and development (CV provided) 55/
- Dr. Scott J. Eilert, Cargill, research and development (CV provided) 56/
- Dr. Vasilios H. Frankos, ENVIRON Corporation (currently at FDA), (CV and opinion regarding CO MAP systems provided) 57/
- Dr. Melvin C. Hunt, Kansas State University, food science researcher (CV and opinions and presentation regarding CO MAP systems provided) 58/
- Dr. Bruce Paterson, Development Leader, Hormel Foods Corp. (now with Schwan's) (CV not provided)
- Dr. Oddvin Sørheim, MATFORSK – Norwegian Food Research Institute, food science researcher (CVs and opinions and presentations regarding CO MAP systems and presentation 59/

We also are providing the Committee with scientific publications, presentations, and other information in the Precept Foods files that are supportive of the GRAS status of CO.

- T. Aune, *Fresh meat in consumer packaging – a toxicological evaluation of the use of up to 0.5% CO in a gas mixture*, (reference not identified). 60/
- R. Huffman, American Meat Institute Foundation, "Current Events in Case ready Packaging: The Challenge of Managing Meat Color," presented at Meat Industry Research Conference, Hollywood, FL (Oct. 3, 2006). 61/
- H. Nissen et al., *Packaging of ground beef in an atmosphere with low carbon monoxide and high carbon dioxide restrains growth of Escherichia coli O157:H7, Listeria monocytogenes, Yersinia enterocolitica and Salmonella diarizone*, in Food Microbiol. and Food Safety Into the Next Millennium: Proceedings of the 17th Int'l Comm. on Food Microbiol. and Hygiene, Veldhoven, The Netherlands (13-17 Sept. 1999). 62/

55/ Document 101019.
56/ Document 101185-101190.
57/ Document 101020-101035.
58/ Document 101036-101083.
59/ Document 101084-101101.
60/ Document 101102-101106.
61/ Document 101107-101141.
62/ Document 101142-101144.

- R. Solheim, "Consumer purchase probability of beef and pork packaged in different atmospheres," English summary of report O-7224 for MATFORSK, Norwegian Food Research Institute (11 July 1996). 63/
- O. Sørheim, "Discoloration of meat as an indicator of leakages in packages containing a CO gas mixture," English summary of report O-7224.col for MATFORSK, Norwegian Food Research Institute (28 Nov. 1996). 64/

Question 1(h): Please provide copies of all reports submitted by Precept to FDA or FSIS related to GRN 000143.

We are attaching a copy of all reports and correspondence submitted by Precept Foods to FDA or FSIS relating to GRN 143 as Documents 100000-100567.

B. Question 2: Consumer Reliance on Meat Color as an Indicator of Freshness and Safety

1. Background on Spoilage

Meat spoilage has been defined as "any single symptom or group of symptoms of overt microbial activity, manifested by changes in meat odor, flavor or appearance." 65/ Spoilage is highly dependent on the specific type of bacteria present and determining an exact numerical enumeration for spoilage is not absolute. Generally, products will exhibit signs of spoilage with total plate counts in the range of 10^7 to 10^8. Depending on the bacteria present, however, there could be evidence of spoilage with significantly lower plate counts such as 10^4 or with significantly higher plate counts reaching 10^9. 66/ The total plate count by itself, therefore, is not a particularly reliable indicator of spoilage.

In an anaerobic environment such as that in the CO MAP system, lactic acid bacteria will predominate, displacing pseudomonads and other aerobic bacteria. 67/ Although lactic acid bacteria typically produce fewer malodorous compounds than the more aerobic bacteria, this does not mean that spoilage is "masked;" it simply means that good quality shelf life is extended because off-odors may not develop as rapidly. In addition to lactic acid bacteria, low oxygen

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63/ Document 101145-101157.
64/ Document 101158-101162.
65/ Gill, C.O. The control of microbial spoilage in fresh meats. *In* Advances in Meat Research, vol. 2, Meat and Poultry Microbiology. Pp. 49-88 A.M. Pearson and T. R. Dutson (Eds.) AVI Publishing Company Inc: Westport, CT. (1986), Document 200011-200032.
66/ Lund, BM, Baird-Parker, TC, Gould, GW, "The Microbiological safety and Quality of Food," Aspen Publishers, Inc., Gaithersburg, MD (2000), pg 376, Document 200000-2000001; Doyle, PD, Beuchat, LR, Montville, TJ, "Food Microbiology Fundamentals and Frontiers," ASM Press, Washington DC, pg 95, Document 200002-200004; Jay, MJ, "Modern Food Microbiology" (6^{th} Ed), Aspen Publishers, Inc., Gaithersburg, MD (2000), pg 71-75; Document 200005-200010.
67/ Gill (1986) at 283-84, 286, 288-89, Document 200011-200052.

environments with CO may contain facultative anaerobes such as *Hafnia alvei* and *Serratia liquefaciens*. These microorganisms produce putrescine and cadaverine, which are very malodorous compounds. *Heterofermentative lactics* and *enterics* can also produce copious amounts of gas, causing swelled packages. 68/ At the end of shelf life or after extended temperature abuse, spoilage odors and gassy packages will develop in product packaged in a low oxygen CO-containing atmosphere. Sørheim et al. (1997) noted that "consumers will be able to detect spoilage by the presence of off-odours." 69/

Microbial shelf life will continue to be determined, as it always has been, on such considerations as anticipated microbial growth, product composition, and distribution conditions, including storage temperatures. Product shelf life is not a static issue that is addressed with one or two studies and then forgotten. Responsible companies, such as Precept Foods, maintain aggressive quality control programs in which product shelf life is continually monitored at the retail level and adjusted on a case-by-case basis. As discussed in detail below, the data and information submitted as part of GRN 143 supported a targeted shelf life of 28 days for ground beef and 35 days for whole muscle meats. At present, Precept Foods is currently using more conservative dates, such as 24 days for most whole muscle cuts of beef and pork.

Shelf life determinations are based primarily on quality factors. The safety of any meat product is based on an absence of pathogens, the control of spoilage organisms, and adequate handling, including cooking. CO is not reasonably expected to stimulate or otherwise affect pathogen growth. CO does not affect the ability of a MAP system to slow the growth of microorganisms, nor does it affect the characteristic odor of meat spoilage. The only impact of CO is stabilization of the product color. While consumers do consider the color of meat in assessing product quality, it is only one – and not necessarily the primary one – of many factors.

2. Response to Questions

"2(a)" We are interested in any special labeling or educational means that Precept employs to inform the consumer that meat has been treated with carbon monoxide to make it appear red indefinitely, and that its color should not be used to judge freshness or safety, since the packaged meat can appear to be edible well beyond the point of microbial spoilage.

The label on all Precept Foods case ready meats has a clear and prominent "use or freeze by" date. The attached pictures show the prominence of the date code statement and its placement on both the top and bottom of the meat package. 70/ While FSIS does not require the "use or freeze by" dates on fresh meat, Precept Foods includes a prominent date on each of its packages. As

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68/ Gamage, S. D., J. B. Luchansky and S. C. Ingham, *Pulsed-field gel electrophoresis typing of Hafnia alvei isolated from chub-packed and retail ground beef*, Letters in Appl. Microbiol. 26 (1998), Document 100887-100891.

69/ O. Sørheim, et al., *Technological, hygienic, and toxicological aspects of carbon monoxide used in modified atmosphere packaging of meat*, 8 Trends in Food Sci. & Tech. 307, 311 (1997), Document 100845-100850.

70/ Product shots showing date codes and labeling generally. Documents 200033-200038.

discussed in more detail below, the data establish that consumers rely on such "use or freeze by" dates when making decisions about whether to purchase or consume a product. Data in the literature as well as that generated by Precept Foods show that CO does not mask spoilage and in the unlikely event of abuse, signs of spoilage (e.g., odor, bulging packages, slime) will be present. Importantly, this scenario is the same with other foods that can spoil when in packaged form such as vacuum-packaged meats and other packaged perishable foods such as milk and yogurt. For most perishable foods, including fresh meat, consumers have a long history of relying upon open code dates along with odor and other signs that the product may not be suitable for consumption.

> *"2(b)" Has Precept conducted studies that demonstrate consumers are able to recognize meat that is aged, spoiled, or temperature abused in the face of contradictory visual cues that they have historically relied upon? Please provide to the Committee any studies or other documents Precept has prepared or relied upon relating to the ability of consumers to detect spoilage where meat appears red and fresh looking.*

Aside from the acknowledged long history of consumers relying upon open code dating and other signs of spoilage, several studies have been conducted on the ability of consumers to detect spoiled meat products through odor and/or bulging packages when the color of the meat is otherwise acceptable.

A study by Excel Corporation, which was submitted as Attachment A of Precept's submission to FSIS, examined the effects of temperature abuse on ground beef stored in different atmospheres. 71/ Three MAP treatments were studied: a CO system with "peelable" trays (containing 0.4% CO, 35% CO_2, and 64.6% N2), a CO lid stock system (containing 0.4% CO, 35% CO_2, and 64.6% N2), and a low oxygen system (containing 35% CO_2 and 65% N2). All trays were stored initially at 35°F for 5 days. After 5 days, trays were stored at 50°F under dark conditions; on day 7, the film on the "peelable" tray was removed and all trays were stored at 50°F under lighted conditions. Microbial analysis, odor analysis, and color scores were performed. Spoilage characteristics were found to be similar for all three atmospheres. On day 7, all trays displayed increased microbial counts but did not have a detectable odor. On day 9, however, the film on all trays was bulging, all samples had a detectable odor, and elevated microbial counts were measured for all treatments. It was concluded that meat stored in a CO atmosphere (0.4%) does spoil and emanate a noticeable odor.

Research conducted by Texas Tech University and presented at the 2006 Reciprocal Meat Conference further confirmed CO did not mask signs of spoilage. 72/ Trained panelists and

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71/ John, L., B. Wilborn, and G. Catano, (May 13, 2003) "Ground beef abuse study in peelable, low oxygen and carbon monoxide lid stock tray," Excel Corp., Document 100012-100015.

72/ J.C. Brooks, M.M. Brashears, M.F. Miller, A.R. Hoyle, J.D. Kellermeier, and J.M. Mehaffey. 2006. "New Developments and Future Needs in Fresh Meat Packaging: The Spoilage Characteristics of Ground Beef Packaged in High-Oxygen and Low-Oxygen Modified

consumers evaluated the interaction of color change, odor scores, and microbial counts in ground beef patties packaged in a variety of MAP systems. The study evaluated five treatments: traditional foam tray with film over-wrap, high oxygen (80% O_2 and 20% CO_2), high oxygen with rosemary extract, low oxygen carbon monoxide (0.4% CO, 30% CO_2, and 69.6% N_2), and low oxygen carbon monoxide with rosemary extract. The trained and consumer panelists evaluated the beef patties for changes in color and odor through 21 days of simulated retail display conditions, including continuous fluorescent lighting. The trained panelists evaluated color and odor on scales of 1-5. Consumer panelists were asked if the patties were of good color, how likely they would be to purchase the product based on color, if the meat smelled fresh, and how likely they were to consume the meat based upon odor. Microbial loads, consisting of total aerobic plate counts (APC), Lactobacilli, and psychrophilic aerobes, were determined using standardized methods.

A majority of trained and consumer panelists detected off odors in ground beef packaged in a low oxygen atmosphere with CO after approximately 14 days of storage, which corresponded to a substantial increase in microbial loads. Though such products are not actually "spoiled" unless the off odors are sufficient to cause product rejection, the results do confirm that anaerobic packaging systems with carbon dioxide will not suppress the formation of off-odors. It should be noted that the conditions of this test kept the product in a display case for the duration of the shelf life, conditions not reflective of normal fresh meat distribution.

Consumer research commissioned by the American Meat Institute supports the favorable experience to date with CO MAP systems. 73/ The research, conducted by the Opinion Dynamics Corporation, asked primary grocery shoppers about willingness to purchase and prepare meat based on appearance and odor. When asked about willingness to purchase meat that appeared bright red but was in packaging that appeared to be excessively bulging, most consumers (88%) said that they would be very unlikely (75%) or somewhat unlikely (13%) to purchase such a product. In terms of willingness to prepare and consume meat products, almost all consumers (95%) said they would be very unlikely (90%) or somewhat unlikely (5%) to prepare and consume a product that was bright red but past its use-by date and accompanied by a detectable odor.

These results comport with portions of the survey recently commissioned by the Consumer Federation of America, in which consumers rated qualities used in purchasing meat. 74/ Overall, consumers identified the "use-or-sell-by date" as the single most important factor in evaluating meat to purchase (with 60% reporting to give it a "great deal" or "a lot" of weight). In comparison, 57% gave smell a "great deal" or "a lot" of weight; 52% gave color a "great deal" or "a lot" of weight; 43% gave price a "great deal" or "a lot" of weight; and 30% gave texture a

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Atmosphere Packages." Proceedings of the Reciprocal Meat Conference, University of Illinois at Urbana-Champaign, pp 61-65, Document 200062-200069.

73/ Memorandum dated Nov. 16, 2006, from Larry Shiman, ODC, to Janet Riley, AMI, entitled "Omnibus Questions on Packaging and Color," Document 200070-200071.

74/ Letter to Laura Tarantino, Ph.D., Director, Office of Food Additive Safety, CFSAN, FDA from Chris Waldrop, Deputy Director, Food Policy Institute, Consumer Federation of America (Oct. 3, 2006), Document 200039-200061.

"great deal" or "a lot" of weight. These results show unambiguously that consumers rely on numerous factors in deciding whether to purchase, prepare, and consume fresh meat products, and that open code dating is of particular importance. Other parts of that survey, however, are of limited use in evaluating consumer perceptions regarding low oxygen systems with CO. Significantly, questions relating to consumer perceptions about the use of CO were asked without adequate context. For instance, the questions did not explain why the CO technology is used, that it has been favorably reviewed by both FDA and USDA, that it offers distinct benefits, that it has a history of favorable use in Norway and this country, or how it compares to other packaging systems that have long been used.

The prominent "use or freeze by" dates on the product label, the development of off odors in spoiled product and the consumer surveys summarized above demonstrating the importance of such "use or freeze by" dates when making purchasing and consumption decisions, establish the ability of consumers to recognize meat that has been spoiled. 75/

C. Question 3: Odor and Package Bulging as Purported Indicators of Spoilage

3. Does Precept allege that consumers can adequately detect spoilage in red, fresh-looking carbon-monoxide treated meat by aroma or by the presence of a bulging package?

Consumers are well versed at detecting spoilage in perishable foods, including that of fresh meat. As discussed in the response to Question 2, above, odor is one of the primary means of spoilage detection, while other signs, such as gas (e.g., bulging packages) and slime formation also are used.

3(a) Please explain how the consumer can detect off-odors in hermetically sealed packages at the point of purchase – the point at which consumer deception occurs.

Consumers cannot detect off-odors in hermetically sealed packages of foods of any type at the point of purchase, regardless of whether it is meat, dairy, produce or other perishable foods in such packaging. There is hardly a regular consumer of milk who has not purchased the product in a sealed container only to discover upon opening that it has soured or "turned." Singling out the point of purchase as the purported point at which consumer deception occurs, however, makes little sense for perishable products in sealed containers. Consumers who discover a spoiled product upon its opening can receive a refund by returning it to the store.

75/ The Committee also asked for focus group testing evaluating consumer acceptance of meat whose color is treated with carbon monoxide. We are attaching the results from focus group testing demonstrating consumer acceptance of raw and cooked meat products that are packaged in CO MAP systems. Levin, Nora, "Report of Meat Preparation Focus Groups and In-Home Qualitative" (Nov/Dec 2002), Document 200072-200111; Sorensen Associates Final Report, "T-Bone Steak Beef Durability HVT," (March 2004), Document 200112-200156.

3(b) Has Precept done any studies on what percentage of the population may have difficulty detecting the spoilage odors associated with carbon monoxide-packaged meat?

Precept has not investigated what percentage of the population may have difficulty detecting spoilage odors of meat packaged in low oxygen atmospheres containing CO. The research conducted by Texas Tech University and discussed in 2(b), above, showed consumers can indeed detect the spoilage of meat packaged in a CO MAP system. Moreover, as discussed previously, the odors associated with spoilage of meat in low oxygen atmospheres containing CO have been found to be similar to those associated with meat spoilage in other MAP systems.

To the extent there is a subset of the population that will be unable to detect spoilage odors, these consumers will have difficulty detecting spoilage in any packaged perishable product such as meat packaged in chub packs, meat in vacuum packaging, milk, and many others. Because color is not a reliable indicator of spoilage, there is no reason to single out low oxygen atmospheres containing CO for this type of evaluation.

3(c) Did Precept discuss with FDA the special risks facing anosmic individuals, especially the elderly, who are also at high risk for food-borne illness? If not, why not?

Precept Foods did not discuss with FDA the purported "special risks" facing anosmic individuals. To the best of our knowledge, neither FDA nor FSIS has required studies of such a unique population of consumers for any perishable foods regardless of the type of packaging employed. The anosmic individual will have difficulty detecting spoilage of any packaged perishable product. Because low oxygen atmospheres containing CO do not mask spoilage in fresh meats, they present no unique risks. Moreover, unlike dairy products and fresh produce that are consumed without further processing, raw meat will be subjected to thermal processing, further mitigating any potential food safety issues.

3(d) Does Precept have data describing the percentage of packages that bulge as a result of over-filling during manufacture, changes in elevation during transport, changes in weather or any factors that would tend to make sealed packages bulge? If not, why not?

Precept Foods controls the volume of gas put into the lid stock packages – and, consequently, the amount of bulge in these products – by measuring the dome height of packages immediately following the sealing step. A written and visual description of the dome appearance on ground beef packages is attached. 76/ The optimal amount of gas, as measured from lip of the tray to the top of the dome using a T-bar rule or plastic cut-out templates for pre-determined tray heights, creates a slight (1/8 to 1/4 inch) dome in the retail case, which aids in wicking any condensation to the corners of the package. Too much gas (anything exceeding 1/2 inch) deforms the package, gives it an hourglass or football shape, and prevents the specified number of packages from

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76/ Cargill Meat Solutions, "REDiFresh™ Ground Beef" (undated), Document 300000-300001.

fitting into a shipping container. Overfilled packages are not purposely distributed to customers, and, therefore, the percentage of such packages has not been measured.

Changes in elevation will affect the degree to which a sealed food container will bulge. This bulging is commonly observed in a variety of food products, including potato chips, grated cheese, processed meats, and low oxygen systems containing CO. Customers living in high altitude areas are well accustomed and familiar with the increased bulge resulting from the differences in atmospheric pressure. Spoiled products will still exhibit off odors and/or slime formation allowing consumers in high altitude areas to detect spoiled product. As a result, the percentage of bulging packages resulting from changes in elevation has not been measured.

D. Question 4: Labeled Shelf Life

1. Background on Date Codes

Date codes are not required on meat products. As explained by FSIS in its consumer guidance on product dating, "Use-by" dates are calendar dates provided by the manufacturer to indicate "the last date recommended for the use of the product while at peak quality." 77/ FSIS has recognized and reiterated for consumers that "'Use-by' dates usually refer to best quality and are not safety dates. But even if the date expires during home storage, a product should be safe, wholesome and of good quality – if handled properly and kept at 40°F or below."

All products packed in the Precept Foods CO MAP system display an open date code or "use or freeze by" date. Application of a validated and controlled "use or freeze by" date addresses a major drawback of traditional meat packaging – lack of consistent code dating because the point at which a product will be prepared and displayed for sale is unknown. Reliance on a centrally applied open date code offers a far more objective means of assessing product age and quality than highly subjective measures such as color.

"Use or freeze by" dates are applied by a centralized packing facility and will not vary depending upon the timing of retail display. The use of a centralized packing facility for the finished retail package eliminates all retailer discretion in the process, adding the consumer benefit of an open dating system that is scientifically established, validated, and controlled. In addition to minimizing any risk of cross contamination that can occur in a retail establishment, the use of such a system substantially reduces any risk that the shelf life will be manipulated inappropriately at the retail level. It also provides some assurance that product labels will not be altered following application of the mark of inspection.

As shown in the studies conducted by Opinion Dynamics Corporation and the Consumer Federation of America discussed in question 2(b) above, consumers rely on date codes when making purchasing decisions for fresh meat. Consumer reliance on date codes is further documented in the annual report of U.S. Grocery Shopper Trends, published by the Food

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77/ FSIS Fact Sheet, "Food Labeling, Food Product Dating;" (copy accessed Aug. 8, 2007 at http://www.fsis.usda.gov/fact_sheets/Food_Product_Dating/index.asp), Document 400000-400004.

Marketing Institute. 78/ According to the Trends report, virtually all consumers (99%) are aware of date codes, with 83% of consumers participating in that survey reporting use of date codes with respect to fresh meat and poultry specifically. When asked about the frequency with which date codes are used, 92% of consumers responded that they checked date codes "every time" or "fairly often" and 77% reported discarding foods past the use-by date "every time" or "fairly often." Most participating consumers tied date codes to some degree of health risk: 25% felt eating a food past the code date would present a "serious" health risk; 37% felt it would present "some" health risk; and 30% felt a "slight" health risk would be presented. Though such views may not be appropriate because codes typically are quality- rather than safety-based, the apparent view of date codes as relevant to health further suggests consumers take date codes seriously.

Consumers rely on code dates in numerous contexts, including hot dogs, deli meats, and dairy products. Fresh meat products such as whole muscle cuts and ground beef are no different. "Use or freeze by" dates are important features of many perishable foods, but are only one aspect of product quality. As with milk, yogurt, hot dogs, luncheon meats, retail chub packs, and numerous other products, a "use-by" date is interpreted in light of other factors, such as signs of spoilage.

2. Responses to Question 4

Question 4(a): Please provide the data upon which Precept Foods proposed the 28 and 35 day shelf lives.

Precept Foods submitted to FSIS and FDA two specific studies in support of the company's request for a 28 day maximum shelf life for ground beef and a 35 day maximum shelf life for whole muscle cuts. The shelf life conditions in GRN 143 are guidelines that reflect potential shelf life. Precept Foods selects the "use or freeze by" dates (not to exceed 28 or 35 days, as applicable) most achievable for any particular product in light of the specific conditions of that particular product. The studies submitted with GRN 143 represent only part of the shelf life picture. Precept Foods collected then, and continues to collect today, data to ensure that product of the highest quality is sold to consumers.

As noted above, two studies were submitted with GRN 143 in support of the Precept Foods request for shelf life as a condition of use for the proposed CO packaging system. In the first study, Hormel Foods examined the shelf life of boneless beef strip steaks and top round steaks packaged in a barrier lid stock back-flushed with 0.4% CO, 35% CO_2, and the balance as N_2. 79/ A treatment simulating the Pactiv master bag concept described in GRN 83 was used as a control. Samples were stored in a 38°F cooler prior to display and placed in a 38-40°F simulated retail display case at designated intervals. Control samples were removed from the master bag prior to display. After 3-5 days in the display case, samples were photographed, opened for odor

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78/ Food Marketing Institute, U.S. Grocery Shopper Trends 68-69, 115, 117, 121 (2006), Document 400005-4000014.

79/ David Ruzek, Precept Foods/ MAP Packaging (R&D Project #PF002.00) (June 6, 2003), Document 400015-400412.

evaluation, and sent to the lab for microbiological and chemistry analysis. Some samples were also cooked and evaluated for flavor.

Overall, both test and control samples were found to maintain acceptable quality at least 42 days. Microbiological, chemistry, color, odor, and cooked evaluations showed no signs of spoilage over this period of time. Although total Mesophilic and Psychrophilic bacteria counts increased throughout the study, the counts were deemed acceptable and not indicative of spoilage. The pH and TBA values remained constant, suggesting that no significant microbial spoilage or oxidative rancidity, respectively, had taken place. All samples were judged to be acceptable for odor, and no cooked samples exhibited unacceptable flavors.

Because the steaks in this first study were injected with an antimicrobial solution, Precept Foods submitted additional information to FSIS confirming the spoilage pattern associated with untreated meats packaged in the same modified atmosphere. 80/ The study sought to compare the effects of different combinations of injection treatments (including untreated controls) and found that the untreated steaks did not have significantly different spoilage patterns from those that were treated with antimicrobial agents. After 41 days, the microbial, odor, and chemistry results justified a 35 day shelf life for both untreated and treated steaks packed in a MAP with 0.4% CO.

An additional study provided with GRN 143, conducted by Excel, examined shelf life, bloom, and cooked color of ground beef packaged in varying levels of CO. 81/ Four treatments were studied: three CO treatments at 0.2%, 0.3%, and 0.4% (with 35% as CO_2 and the balance as N_2) in a plastic tray with a barrier film, and one CO treatment at 0.4% in a peelable film tray. Trays were stored in a cooler at 35° F and removed and placed under conditions simulating retail display at designated intervals. Microbial sampling was conducted "pre-display" and "post display," objective and subjective colors were read daily, residual oxygen levels and product off-odors were analyzed daily, cooked color and sensory evaluations were performed, and bloom was assessed. Based on microbial sampling throughout the test, it was concluded that there were no major differences in microbial counts between treatments. On day 20, a greater increase in aerobic plate count was noted for the peelable treatment than the lid stock treatments. This was described as a "trend" and attributed to removal of the product from a high CO_2 environment.

Color was deemed acceptable on the 0.3% CO and 0.4% CO lid stock treatments throughout the test. The 0.2% CO treatment received a lower color score. The peelable treatment received a higher color score than the 0.2% treatment, but a lower score than other CO treatments. Evaluations of cooked colors on days 9 and 16 showed normal cooked colors in all

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80/ Summary of Hormel Foods Research Report, in Letter to Dr. Robert Post, Food Safety and Inspection Service, from Gary Kushner and Ann Boeckman, Hogan & Hartson, LLP (May 12, 2004), Document 100117-100133.

81/ Nancy Rathje and Graciel Catano, Use of Carbon Monoxide in Lid Stock on Ground Beef (Project #23034) (Feb. 14, 2003), Document 400413-400427, 400438-400461; Color photographs for this and studies conducted on Feb. 6, 2003, *infra* note 86, and Feb. 13, 2003, *infra* note 87, are attached in Documents 400553-400602.

concentrations of CO with no pinking at 145°F or 170°F. No off or spoiled odors or flavors were noted for any treatments through day 16.

A revised summary of this study, also submitted to FSIS, provided additional information regarding the microbial count for the ground beef. After 27 days in storage the ground beef had a microbial count of slightly more than 7-log, depending upon whether the product was tested on day 27 or after 3 days of display. Thus, the authors concluded that "on the basis of these data, measured to a total shelf life of 30 days (27 days plus 3 days display), a shelf life of 28 days for ground beef packaged in this format is justified." 82/

In addition to the studies submitted with GRN 143, Hormel Foods conducted for Precept Foods a number of exploratory shelf life studies on intact muscle cuts. Excel/Cargill similarly conducted exploratory shelf life studies examining the shelf life potentially achievable under the Precept Foods packaging system. The following studies were conducted prior to the submission of GRN 143:

- Heidi Edwards, Hormel Foods Research Report R&D Project # PF002.00; Sensory Study #3653; "Always Tender Beef - New York Strip Steak – Various Pump Levels (Sept. 27, 2002). 83/

- Hormel Foods Research Report R&D Project # PF002.00; Sensory Study #3655; Oct. 8, 2002 "Always Tender Beef – Chuck Steak– Various Pump Levels. 84/

- Heidi Edwards, Hormel Foods Research Report R&D Project # PF002.00; Sensory Study #3656; Oct. 9, 2002 "Always Tender Beef – Top Round Steak – Various Pump Levels. 85/

- Nancy Rathje and Graciel Catano, Use of Carbon Monoxide in Lid Stock on Beef Cuts and Grind (Project # 23034) (Feb. 6, 2003). Strip steaks were stored for 3, 10, 17, 24, and 31 days and then were displayed for 5 days. At 22 days (17 days storage and 5 display days) microbial counts for product treated with 0.4% CO were less than log 5 for aerobic plate counts, anaerobic counts, and LAB counts. In addition there were no off or spoiled odors or flavors on any of the product through day 24. This study is significant

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82/ Nancy Rathje and Graciel Catano, Use of Carbon Monoxide in Lid Stock on Ground Beef (Project #23034) (Feb. 14, 2003, Revised May 12, 2004) in Letter to Dr. Robert Post, Food Safety and Inspection Service, from Gary Kushner and Ann Boeckman, Hogan & Hartson, LLP (May 12, 2004), Document 100119-100128.

83/ Document 400428-400437.

84/ Document 400462-400471.

85/ Document 400472-400481.

because it shows the packaging system can achieve acceptable microbial, odor, and flavor profiles throughout the stated shelf life for these products. 86/

- Nancy Rathje and Graciel Catano, Use of Carbon Monoxide in Lid Stock on Beef Cuts (Project # 23034) (Feb. 13, 2003). Inside round steaks were stored for 3, 10, 17, and 24 days and then were displayed for 4 days. At 28 days (24 days storage and 4 days display) microbial counts for product treated with 0.4% CO were less than log 6 for aerobic plate counts, anaerobic counts, and LAB counts. In addition there were no off or spoiled odors or flavors on any of the product through day 27. 87/

- Barney Wilborn, Impact of Tray Footprint on Beef in CO in Barrier Lid stock (Oct. 13, 2003). This study examined the effect of the tray size on the performance of beef packaged in a CO MAP system. The study found that product performed well in the display case from day 7 to day 43; however, off odors did begin to develop at day 35. Microbial counts were found to be acceptable for all cuts throughout the 43 day test and similar to vacuum packaged product approximately the same age. This study shows packaged product can be acceptable past the shelf life established in the GRAS notification. The study also demonstrates microbial load is not the only indicator of spoilage, as odor developed before unacceptable microbial levels were reached. 88/

- Barney Wilborn, Shelf Life Performance of Enhanced Beef, Enhanced Pork and Ground Beef in Various Tray Depths of CO in Lid stock (Oct. 31, 2003). Although the objective of this study was to examine the appropriate tray depth for product in a MAP system containing CO, microbial analysis was also conducted. After 29 days (26 days storage and 3 display days) all microbial cuts for beef counts were approximately log 6 or lower. Microbial counts for pork cuts were approximately log 5 or lower after 35 days (32 days storage and 3 days display). Ground beef samples revealed microbial counts of around log 7.5 after 16 and 20 days. This study does not have associated odor and other sensory data but indicates microbial levels were acceptable for beef and pork cuts. The ground beef microbial levels are in the range typically associated with spoilage, but spoilage cannot be confirmed without odor and other sensory data. 89/

- Dave Ruzek, Hormel Foods Research Report; Precept Foods/MAP Packaging (Dec. 6, 2003). This study examined the shelf life of T-bone steaks cut from different aged raw materials – 7 and 14 day old beef short loins. The steaks were packaged in a MAP system with .35% carbon monoxide. The author of the report concluded that a code date

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86/ Document 400482-400520; Color photographs for this and studies conducted on Feb. 13, 2003, *infra* note 87, and Feb. 14, 2003, *supra* note 81, are attached in Documents 400553-400602.

87/ Document 400521-400552; Color photographs for this and studies conducted on Feb. 6, 2003, *supra* note 86, and Feb. 14, 2003, *supra* note 81, are attached in Documents 400553-400602.

88/ Documents 400603-400681.

89/ Documents 400682-400742.

of 28 days could be recommended for bone-in product packaged in such a system with 0.35% CO. 90/

- Graciel Catano, Enhanced vs. Nonenhanced in CO Lidstock (PRP 23270) (Sept. 19, 2003). This study was conducted to evaluate the impact enhancement may have on the performance of lidstock product packaged in CO. Enhanced product performed as well as non-enhanced in overall color and outperformed in lower microbial counts over 31 days of observation. 91/

Finally, the companies gained a wealth of knowledge through shelf life testing conducted using the Pactiv system described in GRN 83. This system served as the foundation for the Precept Foods system. Notably, the Pactiv system produces a comparable shelf life to that proposed by Precept Foods in GRN 143. Pactiv commissioned a study where meats were packaged in the Pactiv system, then stored at 35°F or 43°F for up to 35 days. In discussing the study results, the authors stated that "this suggests that quality products that have been handled in a sanitary fashion can be stored in the MAP system up to 35 days without compromising microbial quality. 92/ Thus, there is ample evidence that a shelf life of 28 or 35 days can be achieved for most products packaged in a CO MAP system.

> *Question 4(b): Were these periods of shelf life established under ideal laboratory conditions or under conditions reflecting the actual conditions of distribution, storage, and retail and consumer handling that the treated meat is likely to encounter? If these periods were established based upon ideal laboratory conditions, please explain why actual conditions were not considered when Precept Foods originally submitted its GRAS notification to FDA.*

Precept Foods carefully designed the shelf life studies to simulate conditions of centralized production, distribution, and display of retail beef and pork. In other words, most of the Precept Foods shelf-life studies were conducted under laboratory conditions designed to simulate average distribution and retail display case conditions. Specifically, initial or preliminary shelf life studies are conducted using product processed in a pilot plant under conditions similar to those in production facilities. Product is stored at temperatures typically found in retail storage facilities and then displayed in retail display cases that mimic the typical temperature, lighting, and defrost cycle conditions in grocery store display cases.

Thus, the conditions used in the studies submitted with GRN 143 did reflect typical retail temperature controls. This is consistent with the design of shelf life studies in the industry where a *potential* shelf life is established. Moreover, the application of appropriate temperature controls is a fundamental good manufacturing practice (GMP) requirement for all perishable foods. The intended conditions of use on which a GRAS assessment is based necessarily assume GMP compliance. Temperature abuse, therefore, is not part of the intended conditions of use of a GRAS substance.

90/ Documents 400743-400883.
91/ Document 400884-400909.
92/ GRAS Notification No. 83 (attachment 4) at 168, Document 100729-100760.

Nonetheless, to address the potential for temperature fluctuations, Precept Foods tested the performance of the CO MAP system under abusive conditions and confirmed that the system would not mask spoilage. 93/ Precept Foods included this study, which has been discussed previously, as part of its GRAS notification. In addition, GRN 143 also pointed to practical experience with other modified atmosphere packaging systems that present nearly identical issues, as well as almost twenty years of experience in Norway. 94/ This information is direct evidence of actual distribution, retail conditions, and consumer behavior and was included in the Precept Foods GRAS determination.

Finally, in addition to initial or preliminary shelf life determination studies, Precept Foods also conducts routine shelf life verification studies. These studies either adopt or simulate normal production practices. For those studies that adopt normal production practices, product is produced in case ready facilities under normal production, stored in the plant's finished goods cooler, shipped by truck to the product distribution center, and stored in the raw material/ finished goods cooler until the specified display period. Product display and evaluation is then conducted based on the specific protocol for the particular study. Through these shelf life verification studies, as well as through ongoing monitoring, including monitoring of temperature control in retail settings, Precept Foods sets shelf life on a case-by-case basis. Thus, Precept Foods continually takes into consideration actual or simulated conditions of distribution, storage, and retail display when determining the shelf life for its products.

> *Question 4(c): Was Precept Foods aware of the EC opinion prior to the submission of GRN 000143? If so, why was this opinion not provided to FDA as part of the GRAS notification – consistent with FDA's requirement that GRAS notifications must include a "comprehensive discussion of any reports of investigations or other information that may appear inconsistent with the GRAS determination?*

Precept Foods was aware of the Opinion of the European Commission's Scientific Committee on Food prior to the submission of GRN 143. It was unnecessary to specifically address the Scientific Committee on Food opinion in GRN 143 because this opinion views the intended use of CO in a favorable light. Specifically, the Committee reviewed toxicological and microbial aspects of CO, and concluded as follows: "[T]here is no health concern associated with the use of 0.3%-0.5% CO in a gas mixture with CO_2 and N_2 as a modified atmosphere packaging gas for fresh meat provided the temperature during storage and transport does not exceed 4°C." 95/ Precept Foods views the temperature requirement as consistent with the GRAS determination because cold chain management is important for any perishable food, not simply fresh meats marketed in MAP systems.

93/ Liza John, Barney Wilborn, and Graciel Catano, Ground Beef Abuse Study in Peelable, Low Oxygen Carbon Monoxide Lid stock Tray, May 13, 2003, Document 400910-400930.

94/ Scott Eilert, What I learned in Norway ... A Trip Report, July 16, 2002, Document 400931-400938.

95/ Opinion of the Scientific Committee on Food on the use of carbon monoxide as a component of packaging gases in modified atmosphere packaging for fresh meat, SCF/CS/ADD/MSAd/204 Final (18 Dec. 2001), Document 400939-400947.

Equally important is that the legal status of a material in the European Union or any other political system has no bearing on a GRAS assessment in the United States. There are numerous instances in which substances and technologies are deemed safe in the United States but not Europe (and vice-versa), as evidenced by the longstanding disputes over beef hormones, regulation of modern biotechnology, and the so-called "precautionary principle." What matters from the perspective of the "common knowledge" element of a GRAS determination is not the policy of any particular government; the issue is whether qualified experts consider the substance to be "safe" for its intended conditions of use. Governments may reject an additive for reasons other than safety, or they may choose a more conservative position than the scientific evidence would suggest is necessary. In Europe, for example, a food additive may be rejected if a technological need for the additive is not demonstrated. 96/

A letter from the European Commission Health & Consumer Protection Directorate-General provides insight into the distinctive policy approaches taken in the United States and Europe. In addressing whether to recommend changes to the existing authorizations for nisin, a GRAS antimicrobial in the United States, the letter stated that the "Commission agrees with the principle that anti-microbial agents should not be used in the food production chain." Though the Commission was actually contemplating an exception for nisin, the fact remains that such a principle is obviously at odds with U.S. law and policy. U.S. agencies are no more bound to accept EU policy on CO than on antimicrobials, biotechnology, or any other matters in which different points of view are evident.

> *Question 4(d): How does Precept Foods reconcile the substantial difference between the shelf lives of 11 and 14 days (for ground beef and beef loin steaks, respectively) reported in the EC Opinion and the 28- and 35-day self lives proposed by Precept Foods? Was this difference discussed with FDA? If not, why not?*

The Scientific Committee on Food based its shelf life recommendation on the publication by Sorheim (1999), which was cited and discussed in the Norwegian Meat Cooperative and the Norwegian Independent Meat Association application for the assessment of carbon monoxide. 97/ It was not a recommendation on the commercial shelf life for all meat stored in low oxygen atmospheres with CO. The Sorheim study was cited in GRN 143 and in GRN 83. Beyond these references, this difference was not discussed with FDA or FSIS because it was not relevant to the Precept Foods GRAS determination. The focus of a GRAS determination is whether there are sufficient data in the public domain to support the GRAS status of CO on the basis of scientific procedures.

96/ Indeed, the treatment of CO by the European Commission, Health & Consumer Protection Directorate-General appears to have been driven by concerns other than safety – namely, the issue of whether CO misleads the consumer with respect to product freshness. Letter from Robert J. Coleman, European Commission, to Mrs. Caroline F. Jackson, European Parliament, Document 400948-400951.

97/ Application for Assessment of the Food Additive Carbon Monoxide (CO) Prior To Its Authorization, Document 400952-400990.

As a practical matter, the shelf life results obtained by Sorheim (1999) cannot be used to determine the shelf life for product processed and packaged by Precept Foods. The specifics of shelf life are determined on a case-by-case basis, taking into account such factors as raw material quality, the type of meat product, distribution needs, likely temperature variations, and similar conditions. Shelf-life for a particular product is determined by a number of factors. As noted in the Scientific Committee Opinion, "[e]nd-product characteristics affecting the shelf life depend among others on type of product, initial contamination, atmosphere, storage temperature, packaging material and design." 98/ Shelf life can also be influenced by the age of the raw materials, conditions at slaughter, and conditions in the processing facility. In addition, acceptable shelf life is not a universally defined standard. It is based on microbial count, flavors, and odors, and other acceptability factors (such as appearance and purge level) and there is variability within each of these factors. For example, depending upon the type of bacteria present, different microbial counts may be deemed acceptable. Obvious signs of spoilage can occur at 10^4 if certain types of microorganisms predominate, while ground beef that contains 10^7 per gram can be organoleptically acceptable if the predominant flora consists of homofermentative lactic acid bacteria. Because the Sorheim (1999) study was conducted under different conditions from those in the studies conducted by Precept Foods, it is not surprising that different shelf lives were obtained.

Finally, we note that the shelf lives requested by Precept Foods are consistent with modified atmosphere packaging systems in general that extend the shelf life of products. For example, vacuum packaged primals can be stored for 36 days before being ground in a retail facility and put on display. 99/ Vacuum packaged case ready ground beef typically has a shelf life of 23 days and case ready meats in high oxygen systems typically have a shelf life of 11 to 14 days. 100/ Beef and pork that is exported to Asia typically have a shelf life of 45-55 days. Using the Pactiv system described in GRN 83, Precept Foods used a display-by date of approximately 25 days and a recommended display life in the retail case of 3 days, for a total shelf life of 28 days. 101/ Moreover, the National Beef Tenderness Survey found that the average age of raw materials the cold storage facilities of retail stores was 23 days. 102/ Finally, Precept Foods is aware of at least one meat processing company in Norway (a country with considerable experience in CO MAP packaging) that achieved approximately 20-22 days shelf

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98/ Opinion of the Scientific Committee on Food on the use of carbon monoxide as a component of packaging gases in modified atmosphere packaging for fresh meat (adopted on 13 December 2001) at 3. *Supra* note 95.

99/ AMI Foundation, "Ground Beef Shelf Life (Days)," Document 401002.01-401002.02.

100/ *Id.*

101/ Letter to Dr. Robert Post, Food Safety and Inspection Service, from Gary Kushner and Ann Boeckman, Hogan & Hartson LLP (July 2, 2003), Document 100001-100061.

102/ J.W. Savell et al., National Beef Tenderness Survey – 2006, Proceedings of the 59th American Meat Science Association Reciprocal Meat Conference 43, 44 (2006), Document 401021-401029.

life for its consumer-ready meat despite a cold chain management system that is not as rigorous as those used by companies in the United States. 103/

> *Question 4(e): We are aware that Precept Foods has stated that, in light of "actual conditions," Precept Foods is using "more conservative dates" reflecting a shorter shelf life. What labeled shelf life is Precept Foods currently using on its carbon monoxide treated meat? Please explain the "actual conditions" that prompted this change. Please provide all tests and/or other documents that were used to establish the "more conservative dates" Precept Foods has said it currently uses.*

There has been no "change" in the Precept Foods shelf life determinations. Shelf-life determinations do not and should not always be the same as the periods used for "use or freeze by" dates. Significantly, the 28- and 35-day limits for ground products and whole muscle cuts, which are supported by the shelf life studies, serve as guidelines, these values were never intended to apply to all products. Precept Foods is currently using shelf life limits that are more conservative than these targets, to allow for tolerance and temperature variations as well as age of the raw material. For example, Precept Foods currently uses a shelf life of approximately 24 days for most whole muscle cuts. Any reputable company will take the same approach, as a brand cannot survive continual sales of products that spoilage before the expiration of the "use or freeze by" date.

Numerous shelf life studies, which are summarized briefly below and attached to this submission, have been conducted as part of the ongoing shelf life verification program.

- Barney Wilborn, Impact of Residual Oxygen on Meat Packaged in CO in Lidstock (Jan. 29, 2004). This study found residual oxygen in CO lid stock packages as high as 0.5% does not appear to impact visual color, microbial growth or cooked color of ground beef or pork chops. Visual color scores were acceptable for all packages throughout the 27 day shelf life evaluation, although some packages did possess off odors at the end of 27 days. In addition, both the pork chops and the ground beef had microbial counts within acceptable levels throughout most of the study period. At the end of the 27 day study period, log 7 microbial counts were observed and, combined with the development of off odors, resulted in a shortening of the prescribed shelf life. 104/

- Always Tender Barrier Lid stock Test I (Mar./April 2004). This project evaluated the effect of various injection treatments on subjective odor scores of beef strips packaged in the CO MAP system, stored up to 41 days. 105/

- Always Tender Barrier Lid stock Test II (Jun./Jul. 2004). This project evaluated the effect of various injection treatments on subjective odor scores of beef strips packaged in

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103/ Scott Eilert, What I learned in Norway ... A Trip Report, July 16, 2002, Document 400931-400938.
104/ Document 401030-401097.
105/ Document 401098-401179.

the CO MAP system, stored up to 45 days. Microbial data was also collected, summarized and showed a psychrophilic count of less than 10^7 after 45 days (38 days storage and 7 days display). 106/

- Always Tender Barrier Lid stock Test III (Aug./Sept. 2004). This project evaluated the effect of various injection treatments on subjective odor scores of beef strips packaged in the CO MAP system stored up to 47 days. In addition to odor, color, gas, microbial and chemistry data were collected. After 35 days (30 days storage, 5 days display) total plate count was less than log 5 and the psychrophilic count was less than log 6. Similar microbial counts were found after 47 days. The few samples examined for flavor evaluation, however, produced a livery flavor at 35 days. 107/

- Hormel CO Barrier Headspace Test PF 006.02 (Sept. 16, 2004). This study was an exploratory study conducted to evaluate two different tray depths (hence headspace) and compare their respective effect on the color of top round steaks that were cut to two different thicknesses. Psychrophilic bacteria counts also were collected, and the counts were acceptable (less than log 7) at 21 days but reflected some signs of spoilage (greater than log 7) at 40 days. 108/

- Hormel "Gas Mixture Shelf Life Testing" (Oct. 19, 2004). This study was conducted to evaluate the effect of higher levels of CO_2 in the CO MAP system. The study was terminated because the higher levels of CO_2 caused the lidded film to be drawn down onto the meat surface. Microbial analysis was performed, and the psychrophilic counts were found to be less than log 7 at 26 days. No formal study report was written because there was no practical value in increasing CO_2 levels in the barrier lidstock package. 109/

- Carolina Realini and April Archer, Raw Material Age Requirement of Beef Packaged in CO Lid stock (Oct. 2004). As an example of the numerous factors that can influence shelf life, this study examined the effect of raw material age on shelf life. This study found odor for strip steaks, chuck roasts, or inside round steaks can be acceptable through 28 days of finished product shelf life when using 7 or 14 day old raw material but not when using 21 day old raw material. Microbial counts were found to be less than log 7 for strip steaks, chuck roasts, and inside round steaks when using 7, 14, or 21 day old raw material to produce up to 28 day old finished product. 110/

- Hormel Foods Report; PF # 002.30 Enhance vs. Non-Enhance Strip Steaks in CO Lid stock (Nov. 9, 2004). This study examined the effect of enhancement on strip steak performance in CO lid stock packaging. Steaks were examined for color, odor, wetness,

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106/ Document 401180-401288.
107/ Document 401289-401517.
108/ Document 401518-401549.
109/ Document 401550-401583.
110/ Document 401584-401609.

and microbial counts after 14, 21, and 28 days. Enhanced steaks had lower microbial counts. 111/

- April Archer, Raw Material Age Requirement of Pork Packaged in CO Lid stock (Jan. 2005). This study examined the effect of raw material age on shelf life for pork. Study results show the odor scores and the microbial counts for various cuts of pork after certain periods of time by raw material age. Microbial results for pork butt steaks, boneless chops, and bone-in chops were less than log 7 for 7, 14, 21, and 28 day old finished products when using 7, 14, or 21 day old raw material. Odor was acceptable for boneless and bone-in butt steaks for 28 day and 21 day finished products when using 7 day old and 14 day old raw material, respectively. Using 21 day old raw material can result in acceptable odor through 14 days for boneless chops and bone-in butt steaks. For bone-in chops, 7 day old and 14 day old raw material will result in acceptable odor through 21 day and 14 day finished products, respectively. Odor was not acceptable for bone-in chops using 21 day raw material. 112/

- Hormel: Modified Atmosphere Gas Comparison Effects on TBA Values for Beef Top Round Steak and Beef Top Sirloin Butt Steaks (March 15, 2005). This study, which was conducted for a marketing presentation, examined the oxidative rancidity for two cuts of beef packaged in two different MAP systems (low O_2/CO v. high O_2) at 11, 14, 17, 25 and 31 days. The study found that meat packaged in a low O_2/CO containing atmosphere has less oxidative rancidity over time than the high O_2 atmosphere. In addition to TBA scores, the study also collected microbial data. 113/

- Hormel: Residual O2 Top Round Evaluation PF 006.002 (Mar. 21, 2005). This study involved a rudimentary test designed to evaluate the effects of varying levels of residual oxygen in the barrier lidstock tray. The study evaluated only one top round, which was at least 14 days old prior to being cut into steaks. This study did show some correlation between the high psychrophilic counts and a sour odor. However, because of its very limited size, no formal study report was written. 114/

- Hormel: Top Round and Top Butt Headspace Evaluation (Mar. 31, 2005). This was another exploratory study conducted to investigate the effect of headspace on the color life of top round and top butt steaks. Product was evaluated after at 1, 5, 9, 19, 20 days for color. Microbial data were collected after 20 days, and it was noted that the psychrophilic bacteria counts were less than log 6. No formal study report was written. 115/

- Dave Ruzek, Headspace vs. Residual O2 in CO Barrier Lid stock Tray (May 12, 2005). This study examined whether there is a correlation between headspace and the level of

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111/ Document 401610-401612.
112/ Document 401613-401672.
113/ Document 401673-401763.
114/ Document 401764-401777.
115/ Document 401778-401825.

residual oxygen on the performance of various cuts of beef packaged in CO containing MAP. This study demonstrates that the overall performance of products over time is dependent upon specific primals and individual muscles. Most samples were evaluated for color acceptability at 3, 14, 21 and 27 days. Some samples were also tested for pH and TBA value after 14 and 27 days. Results showed that, based on a small sampling size (three pieces per primal), headspace and levels of residual oxygen did have short term and long term effects on the performance (depending on the primal) of steaks cut from top rounds, top butts, chuck rolls or strip loins and packaged in CO barrier lidstock trays. 116/

- Hormel: CR Pork Chops/ Barrier Lid High Ox vs. CO (July 14, 2005). This study was conducted primarily to generate TBA values for a marketing presentation. It compared TBA values for products packaged in high O_2 barrier lidstock to those packaged in low O_2/CO barrier lidstock. The high O_2 packages produced significantly higher TBA values. The psychrophilic counts were generally less than log 6. 117/

- April Archer, #23895 Laura's Lean Whole Muscle Shelf Life Verification (Feb. 17, 2006). In this first study, microbial analysis was acceptable through the 21 day shelf life and 5 day display period (26 total days), but odor evaluations indicated that the product would be unacceptable before the end of the 21 day shelf life. Thus, subsequent studies were conducted to validate a 15 day shelf life and 5 day display period (21 total days). 118/

- David Ruzek, Always Tender Case Ready Pork Shelf-Life Studies (Feb. 28, 2006). The objective of this study was to determine if the shelf-life code date could be extended from 24 to 28 days for assorted pork chops, boneless pork sirloin chops, and pork blade steaks packaged primarily in lidstock based on odor, color, TBA, and microbial counts. Although the code date could be increased for certain items, it became apparent that the amount of time the product spends in the display case has a major effect on its shelf life. Due to off odors and microbial counts exceeding log 7, it was concluded that most, if not all, case ready pork items should be rotated out of the display case after 5-7 days to ensure acceptable quality and performance of the product. 119/

- April Archer, #23895 Laura's Lean Whole Muscle Shelf Life Verification II (April 2006). As evidence as to how different cuts of meat can perform differently, in this study strip steaks and stew meat remained acceptable through a 16 day shelf life and 5 day display period (21 total days), according to odor and microbial analysis. Eye of Round steak did not perform through 21 total days; therefore, the study authors recommended both additional testing and a shorter shelf for this cut. This validation study and the one preceding it demonstrate how shelf life is determined and adjusted according to spoilage

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116/ Document 401826-402087.
117/ Document 402088-402136.
118/ Document 402137-402173.
119/ Document 402174-402182.

indicators even though a longer allowable shelf life was established in the GRAS notification. 120/

- Cargill Meat Solutions, #24092 New Laura's Lean Offerings-Shelf Life (Sept. 2006). As part of the shelf life verification program, this study was conducted to validate the shelf life for top blade and cubed steaks. Top blade steaks performed acceptably through 21 total days, but cubed beef did not. Product was stored for 14, 18, and 21 days and then displayed for 3 days. Cubed steaks had aerobic plate count of 7-log at 14 days storage plus 3 days display (17 total days). 121/

E. Question 5: Legibility and Effectiveness of Date Labeling

Question 5(a): Does precept use any special labeling to assure that consumers can read the "use or freeze by" dates on the packages?

Federal regulations do not require the use of date codes on case ready meats. Precept Foods included date codes as a condition of use in its original GRAS submission. These date codes are featured prominently on the package in at least one location. The attached pictures show the prominence of the date code statement and its placement on both the top and bottom of the meat package. 122/

Date codes are commonly used on many food products. In addition to meat packages, these codes routinely appear on perishable commodities such as milk, yogurt, cheese, and bagged vegetables. The studies discussed above establish consumers are aware of and comfortable with date codes such as the Precept Foods "use or freeze by" dates. The consumer of meat is no different than the consumer of these other commodities. Accordingly, there is no reason to believe that date codes on meat packages should be considered any differently than date codes on other food.

Question 5(b): Has Precept gathered data regarding the prominence of the "use or freeze by" date labeling required to allow persons with compromised vision – particularly the elderly, who have a long history of relying on color as their primary indicator of meat quality, and who may have difficulty smelling the odors associated with spoiled meat – to be able to read the "use or freeze by" date on the package? If not, why not?

As evident from the attached photographs, the date codes on the Precept Foods packages are clear and prominent – far more prominent than the codes on many other food packages. The prominence makes it easier for anyone with compromised vision to read the date code.

120/ Document 402183-402218.

121/ Document 402219-402244.

122/ Product Shots, Document 200033-200038. See also, "Hormel Case Ready Pork and Beef Meat Case to Cook Product Shots," Document 500000-500014; "Pork Lidstock," Document 500015-500023; Beef Lidstock Line," Document 500024-500034; "Pork Line," Document 500035-500047.

Individuals with compromised vision and smell will have difficulty reading the date codes on any perishable product and detecting spoilage due to odor. The issues presented by this subset of the population, therefore, are not unique to meat packaged in a CO MAP system.

> *Question 5(c): If meat has been temperature abused during manufacture, distribution, at retail or in the possession of the consumer, the "use or freeze by" date becomes worthless as an indicator of meat quality and questionable with regard to food safety. Under temperature abuse conditions, neither the color of carbon monoxide-treated meat nor "use or freeze by" date labeling provide consumers with accurate information as to the product's fitness for consumption.*

"Use or freeze by" dates are important features of many perishable food packages, but are only one aspect of product quality. As with milk, yogurt, and bagged spinach packages, a "use-by" date is interpreted in light of other factors, such as signs of spoilage. A product that has been temperature abused has not been handled in accordance with the Food Code and with other regulatory requirements. As recognized by FDA in the 2005 Food Code, the fresh meat case has a relatively good record of temperature control as compared to other areas. 123/

The same issues raised by the Committee with temperature abuse are presented by other perishable food products. Milk that has been temperature abused can spoil before its "use-by" date and the consumer will have no indication the milk is spoiled at the point of purchase. The nature of the spoiled product will be evident, however, when the consumer opens the milk and can smell the off odors. The same holds true for meat that has been shipped in vacuum packaged bags, subjected to temperature abuse resulting in spoilage and then ground into hamburger or cut into steaks. These products will exhibit the bright cherry red color and the consumer likely would not discover the product is spoiled until he or she takes the product home and opens the package. Simply stated, when temperature abuse occurs, the consumer frequently will not realize the product is spoiled until the packaged is opened at home. The issues raised by the Committee, therefore, are not unique to meat packaged in a MAP system involving CO. Fortunately, we have one of the most sophisticated retail food systems in the world that will minimize the likelihood for temperature abuse. And in the unlikely event temperature abuse takes place, there will be evidence of spoilage other than color alerting the consumer that the product should not be consumed.

Moreover, the issues raised by the Committee are at odds with the consumer acceptance of case ready meats. The attached graph tracks consumer satisfaction ratings from case ready and primal cuts of fresh pork and beef. 124/ The graph shows that over 99.999% of consumers are satisfied with these products, as measured by the absence of consumer complaints. Case ready meats have out-performed primal cuts by generating fewer consumer complaints in every year of the analysis, which started in 2003.

123/ FDA, 2005 Food Code 547 (Annex 6), (copy accessed Aug. 9, 2007 at http://www.cfsan.fda.gov/~acrobat/fc05-a6.pdf).

124/ Hormel Fresh Pork & Beef Consumer Satisfaction," Document 500048.

Question 5(d): Has Precept taken any steps to inform the customer of these facts, through product labeling or other means? If not, why not?

As discussed above, there is no reason for consumers to treat differently the date codes on the Precept Foods packages than the codes on other food products. As such, there is no reason to believe that the "use or freeze by" dates on meat packages warrant special explanation. In fact, the Precept Foods "use or freeze by" dates are larger and more prominent than the date codes provided on the packages of many other perishable foods.

The efficacy of the date codes on meat packages is further enhanced by FSIS consumer education guidance, which is made available on the FSIS website. 125/ This guidance addresses the importance of good handling practices and signs of spoilage, such as bad odor and a "sticky" feeling on the outside. In its guidance, FSIS says, "even if the date expires during home storage, a product should be safe, wholesome and of good quality – if handled properly and kept at 40°F or below." FSIS goes on to emphasize, "Foods can develop an off odor, flavor or appearance due to spoilage bacteria. If a food has developed such characteristics, you should not use it for quality reasons. If foods are mishandled, however, food borne bacteria can grow and cause food borne illness – before or after the date on the package."

Precept Foods takes great efforts to educate its own customers about its products and their "use or freeze by" dates by providing them with training materials. For example, Precept Foods developed a DVD, which is discussed in 6(b), below, that educates the retail customer about the placement, prominence, and purpose of the "use or freeze by" date and explains that such dates should be used to answer customer questions about when to use the product.

F. Question 6: Temperature Abuse Concerns

1. Background

The risk of temperature abuse, especially any alleged threat of deliberate mishandling in the distribution chain, is speculative and certainly of limited relevance to the intended or likely conditions of use for CO in fresh meat packaging. Indeed, similar allegations could be made with respect to other perishable foods (e.g., milk, eggs, processed and cured meats, fresh-cut fruits and vegetables, and even fresh meat and poultry packaged in high oxygen environments), any of which could theoretically be subject to temperature abuse sufficient to promote spoilage or the growth of pathogens (if any) without a noticeable change in product color. For most perishable foods, including fresh meat, consumers have a long history of relying upon open code dates along with odor and other signs that the product may not be suitable for consumption (e.g., slime).

In the merchandising of any perishable commodity, great care needs to be employed to ensure proper storage and handling that will minimize the potential for spoilage. This discipline, commonly referred to as "cold chain management," is practiced on all meat products today. The application of appropriate temperature controls is a fundamental good manufacturing practice

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125/ FSIS Fact Sheet, *supra* note 77, Document 400000-400004.

(GMP) requirement for all perishable foods. The intended conditions of use on which a GRAS assessment is based necessarily assumes GMP compliance. Temperature abuse, therefore, is not part of the intended conditions of use of a GRAS substance.

2. Responses to Question 6.

Question 6(a): Since the color of carbon monoxide-treated meat is completely insensitive to temperature abuse, what contracted conditions or other additional controls has Precept put in place to insure adequate temperature control during manufacture, storage and distribution?

Case ready packaged meats can be prepared in a central facility under continuous FSIS inspection and in compliance with applicable FSIS requirements. Among these are requirements for Hazard Analysis Critical Control Point (HACCP) 126/ plans for raw meat products, Sanitary Standards Operating Procedures (SSOPs), and Good Manufacturing Practices (GMPs). These HACCP plans, SSOPs, and GMPs all emphasize the importance of temperature control. In addition, use of a central facility eliminates any handling of meat and poultry products after USDA applies its mark of inspection. The Food Code recognizes that post-production handling can present a risk of cross-contamination:

> Even if foods . . . receive adequate thermal processing, a particular concern is present at retail when employees open manufactured products and repackage them. This operation presents the potential for post-processing contamination by pathogens. 127/

In addition to preventing cross-contamination, preparation in a central location also enhances food security by reducing the risk of product tampering.

Temperature control is managed from receiving through shipment and delivery. 128/ Briefly, the product arrives at the establishment typically as a sub-primal of beef, pork, trim, or ground package. The sub-primal is processed into steaks, chops, roasts, ground beef, sausage and other products and then tray packaged and shipped. As described below, control points for

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126/ HACCP involves the systematic identification and management of risks associated with the manufacture and distribution of meat and poultry by identifying potential hazards in the system, monitoring critical control points, and implementing corrective actions when necessary. The HACCP regulations are promulgated at 9 C.F.R. Part 417.

127/ FDA, 2005 Food Code 547 (Annex 6) (copy accessed Aug. 9, 2007 at http://www.cfsan.fda.gov/~acrobat/fc05-a6.pdf).

128/ "Product Category Description" and accompanying documents containing the HACCP and temperature control plans for the Precept Foods seasoned steaks manufactured at its Austin facility, Documents 600000-600017.

temperature occur throughout the process with different temperatures tailored to meet different processes and products. 129/

- Receipt of raw materials: Temperature controls identify the maximum temperature that is acceptable when receiving raw material at the facility (e.g., 40 or 41°F, depending on the product). Measurements typically are taken when the trailer arrives at the facility from the refrigeration unit settings of the trailer, temperature recorders on the trailer during transit, and product temperature at receiving. Temperatures in excess of the specified parameters will cause the load to be rejected and the product will not be processed.

- Holding Cooler: The temperature of the holding coolers will be monitored to ensure they are maintained at an acceptable level. A typical temperature would be between 32-35°F.

- Production Room: Production room temperature is maintained at a specified temperature, such as less than 40°F. The temperature of product throughout the process (saws, injectors, portioning equipment) also can be monitored and maintained at a specified level.

- Finished Product/Box Cooler: Finished product will be stored in a cooler that may have automated temperature recorders. Depending on the nature of the product that is processed, the specified temperature can vary with 32-36°F considered appropriate for some processes and 22-24°F for others.

- Shipping/Trailer temperatures: Trailer temperatures will be specified with 28°F considered typical for many shipments. This temperature can be written on the Bill of Ladings and verified before the trailer leaves the plant. Temperature recorders are placed on each load to ensure ambient air temperature of shipment.

In addition, Precept Foods has established receiving guidelines for customers receiving case ready meats. 130/ The guidelines instruct customers to record the surface temperature of product in each shipment by placing a calibrated, probe-style thermometer between the packages. If the surface temperature is between 28.0 to 40.0°F, the product is acceptable and no further action is necessary. When the surface temperature exceeds 40.1°F, the customer is instructed to obtain one internal temperature and 10 additional surface temperatures. If the internal temperature exceeds 40.0°F, a single surface temperature exceeds 45.0°F, or the average surface temperature exceeds 40.0°F, the customer is instructed to contact Precept Foods for assistance in determining the disposition of the product.

129/ "Temperature Control of Seasoned Steaks" and accompanying documents, Documents 600018-600047; "Product Receiving Log" and accompanying documents, Documents 600048-600050.

130/ "Precept Case Ready Meats Receiving Guidelines," Document 600051.

Precept Foods also uses temperature tracking devices in each shipment of case ready products. If the temperature of the tracking device is between 40.1-50.0°F for less than six hours and the product surface temperature averages less than 40.0°F, the product is considered acceptable. If the temperature of the trailer exceeds 50.0°F or exceeded 40.0°F for more than 6 hours, the retailer is instructed to contact Precept Foods for assistance in determining the disposition of the product.

The temperature controls used by Precept Foods in receiving, processing and shipping the product are designed to ensure the integrity of the cold-chain system and eliminate the potential for temperature abuse.

> *Question 6(b): What steps has Precept taken to educate meat retailers about the different way this meat product will behave when temperature abused?*

Precept Foods has made extensive efforts to educate its retail customers about the importance of cold chain management. Precept Foods conducts an extensive education and audit program before it will allow retailers to carry case ready meats in CO MAP systems. Precept Foods used the process described below, when qualifying the first retailer for use of the CO MAP system. 131/

> Phase I – In the first phase of product roll-out, Precept Foods personnel held meetings with the top four management people for each store in the retailer's distribution regions. These meetings included a detailed presentation. These store managers were also each given reference pocket cards containing information about the case ready system.
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> Phase II(a) – Before the case ready product was to be rolled out to each store, Precept Foods personnel held a pre-meeting with the stores' meat managers regarding the logistics of testing temperature controls and setting store displays. The information provided in these meetings generally followed the same format as the presentations conducted in Phase I, except Precept Foods conducted live demonstrations in the store rather than a Power Point presentation. Precept Foods also provided each store with a video of the demonstrations for future reference and for the training of new employees. 132/
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> Phase II(b) – The first step in rolling out case ready product in each store was a cold chain audit. Precept Foods personnel conducted cold chain audits and inspections of each store and distribution facility. These audits and inspections included a comprehensive inspection of distribution, storage, and display facilities to ensure the case ready product would be maintained at proper temperatures throughout the distribution and retail systems. Until a store was able to pass the cold chain audit successfully, it did not receive case ready product.

131/ The attached cold chain audit documents outline the detailed process used for qualifying the retailer, Documents 600052-600278.

132/ "Blue Ribbon Beef Production Overview DVD," Document 600279-600280.

Phase III – Once a store demonstrated that proper temperature control would be provided to the product in its cold chain audit, Precept Foods personnel set each store. Store setting included emptying, cleaning and sanitizing store shelving, ensuring proper air flow and temperature, and setting up store displays and point-of-sale materials. At this time, Precept Foods personnel also met with all the employees in the store's meat department to explain the case ready program and, again, to give the live product demonstration that had been given to the store's meat department management in Phase II(a). Each employee was also given a pocket reference card that explains the case ready program.

Phase IV – After each store was set with case ready product, Precept Foods personnel visited within a week. During these visits, Precept Foods personnel monitored temperature and other product display and storage conditions and answered questions from store employees.

Ongoing – On an ongoing basis, the Precept Foods retail operations teams visit each store on a regular basis and continues to monitor and approve storage and display conditions and educate store employees.

Precept Foods followed a similar approach when rolling out a new case ready product for this same retail customer. 133/ As part of this roll-out, the Precept Foods personnel again went through the entire Phase II and Phase IV steps, including conducting audits of the store's storage and display conditions and interviewing each store's meat manager concerning questions, concerns, education, criteria, and other issues of concern.

In 2005, Precept Foods worked with another retailer to launch that store's case ready product system. The launched paralleled that explained, above, except the roll-out was simultaneous throughout all stores. In addition, the retailer produced their own training materials, based on the Precept Foods information, and conducted mandatory training of all meat department employees and management. 134/

G. Question 7: Retail Practices

Question 7(a): What is average loss to spoilage of ground meat, and other cuts that have been prepackaged in atmosphere containing carbon monoxide? Please provide the related documentation.

Precept Foods does not track the loss that is due to spoilage of its products. Retail stores have historically purchased meat and have been responsible for managing their inventory. When the store-packaged meat turns an unacceptable color, the store can re-cut the meat exposing a "fresh surface" that will again bloom into a bright red color, grind the whole muscle meat into hamburger, process the product and sell it as a prepared food in the deli, or destroy it. Any

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133/ "Roll-Out Schedule," Document 600281-600288.
134/ "Receiving Food Products Safely" and accompanying documents, Document 600289-600357.

information regarding the average loss due to spoilage would be considered confidential information by the retailer.

The case ready meats do allow the retail store to maintain better control over their meat inventory. The savings due to better inventory management are not unique to the use of CO containing MAP systems but to the nature of case ready meats. Case ready meats have a validated shelf life providing the retailer with a high degree of assurance that the product will be of an acceptable quality and color. Product that is packaged in the store may be prone to color changes well before the product has "spoiled" and is unacceptable for consumption. The case ready meats also allow the retailer and the processor to track more efficiently how quickly a particular product is selling at the store. Through increased tracking, the retailer can better manage inventory and can minimize the likelihood of stocking meat that will not be sold before its "use or freeze by" date. Confidential information from a retailer and shared with Cargill Meat Solutions demonstrates case ready meats have helped at least one retailer better manage its meat inventory and decrease loss. 135/ The retailer tracked loss due to "shrink," which is a measure of whether a product has to be marked down or removed from the retail meat display. These products, which may be perfectly wholesome and suitable for consumption, are marked down or removed due to their color.

The ability to better manage meat inventory, consumer convenience, and other factors have led to the continued growth of the case ready meat market. According to the 2006 National Meat Case Study published by Jerry Kelly of Cryovac Food Packaging Division, case ready meats now represent 60% of the total self serve meat case packages, which represents an 11% growth since 2002. 136/ The study notes case ready meats experienced a greater in stock position than store wrapped products with over 71% of case ready meats available throughout the day while compared to only 51% for store wrapped products. These findings provide further evidence that it is easier for retailers to manage meat inventory with case ready meats.

We are aware of reports in the literature that the CO MAP systems are saving the meat industry over $1 billion dollars per year. We believe this number is based on a 1995 publication that evaluated the use of vitamin E supplementation of beef cattle for the purpose of improving the color of beef. 137/ These authors report that the supplementation of beef cattle with vitamin E could extend the display life of fresh, ground and frozen beef because the increased levels of vitamin E in the meat blocked the oxidation of myoglobin to metmyoglobin. The authors designed the study to evaluate a scientific, rather than economic, effect of the technology. The

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135/ Cargill Meat Solutions PowerPoint Presentation, "Current Business Environment, What is your ability to manage...." (showing a decrease in average shrink for 93% grind, ground round, and ground chuck since switching to case ready meats of about 4, 5, and 9%, respectively), Document 700034-700046.

136/ Kelly, Jerry, "National Meat Case Study," Published in the Proceedings of the American Meat Science Association 59th Reciprocal Meat Conference, University of Illinois at Urbana-Champaign (June 18-21, 2006). Document 700000-700005.

137/ Liu, Q., Lanari, M.C., Schaefer, D.M., "A Review of Dietary Vitamin E Supplementation for Improvement of Beef Quality," J. Animal Sci 73:3131-3140 (1995), Document 700006-700015.

authors, nonetheless, estimated the technology would save retailers $792 million per year. The authors arrived at this number by identifying the total beef market as $22 billion and "extrapolating that retailers could improve their receipts by 3.6%." The authors do not identify the basis for the 3.6% extrapolation and we are unaware of any data indicating that retailers lose 3.6% of beef each year due to shelf life.

> *Question 7(b): How does this loss compare to meat that is not treated with carbon monoxide? Please provide the related documentation.*

We are aware of reports that the category of case ready meats allows the retailer to better manage inventory and will translate into less loss due to "shrink" as discussed, above. The information, however, does not compare the CO MAP systems with other MAP systems such as vacuum packaging or high oxygen MAP systems.

> *Question 7(c): When such losses occur at the retail level, does the retailer absorb the loss or does Precept reimburse the retail stores for spoiled meat?*

The retailer generally is responsible for managing the meat inventory and will absorb the loss for meat that is not sold before the expiration of its "use or freeze by" date.

> *Question 7(d): Do the same commercial terms apply to carbon monoxide-treated meat and meat that has not been so treated?*

The terms under which a retailer and a manufacturer do business are governed by contract and are unique and confidential between the customer and the manufacturer. The terms under which CO-treated and untreated meat are sold, however, are identical and are governed by the same terms and conditions. A standard Precept Foods invoice, reflecting these standard terms and conditions is provided. 138/

> *Question 7(e): Does Precept have any systems in place that are capable of documenting customer complaints relating to carbon monoxide-treated meat? If so, please describe these systems.*

Precept Foods has a system for receiving and tracking consumer complaints that is able to track complaints on specific products. The system is used for all products and is not limited to those packaged in CO MAP systems.

Consumer complaints are received through the 800 number, e-mail or regular mail. An 800 number appears on each of the Precept Food packages making it easy for consumers to contact the company. All contacts are entered into the Consumer Response System and the following minimum information is collected: reason, product, and initial comment. 139/ We are attaching a print out of the computer screen showing the field codes that are used to collect information on consumer complaints. Category codes also have been established to help track the nature of the

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138/ Standard Invoice, Document 700016-700018.

139/ "Consumer Complaint Display Screens," Document 700019-700026.

complaints. 140/ Examples of the general category codes include consumer inquiries about the formula, labeling, recycling, the appearance, flavor, foreign objects, ingredients, packaging, compliments, and many others. These general categories are then further broken into more specific subcategories. By way of example, the general category of "Off condition" is broken into subcategories such as bad color, freezer burned, off odor, rancid condition, slimy and spoiled. The detailed nature of the system allows for the collection and coding of consumer complaints for the various products marketed by Precept Foods.

H. Conclusion

The information contained in this letter and the extensive documents attached to this submission establish there are sufficient data to support the GRAS status of CO MAP systems and the suitability of these systems for in use in packaged meat. The data in this submission detail the extensive testing that has gone into the development and continued monitoring of the shelf life of these products. These studies form the foundation for the "use or freeze by" dates appearing prominently on the label. The numerous consumer studies referenced in this submission establish consumers rely heavily on "use of freeze by" dates when making purchasing decisions.

We understand the Committee also has expressed concern with potential issues that could be developed when product in the CO MAP system is subject to abusive temperatures. The information in this submission establishes the numerous controls that are in place to ensure the product is manufactured, held, transported, received and displayed at proper refrigerated temperatures. The integrity of the system is further maintained by the detailed training and cold chain audits that take place before a retailer is allowed to receive the case ready products. The comprehensive nature of the program minimizes the possibility that product will be subject to temperature abuse. In those rare instances when temperature abuse does occur and the product spoils before the expiration of its "use or freeze by" date, there will be evidence of spoilage through off odors, bulging packages, and/or the formation of slime. The consumer, therefore, will have the same tools that are available to detect spoiled perishable products such as milk, yogurt, or vacuum packaged meats.

We trust the Committee will concur with our assessment that the data and information submitted to FDA and FSIS and developed since the agencies completed their review of the GRAS notification support the GRAS status of CO and the suitable use of the CO MAP system in meat.

We would like to discuss briefly the documents that we included in this response. For purposes of our response, we focused primarily on those responsive documents that are in the files of the joint venture, Precept Foods. In instances when the questions could not be answered by the documents solely in the files of Precept Foods, Hormel and Cargill have supplemented the response with documents falling outside of the joint venture. The documents attached to this request are representative of the documents that are responsive to each of the seven sets of questions raised by this Committee. Many of the attached documents contain proprietary business information and are marked "confidential." We ask that this Committee respect the proprietary nature of these documents and take the necessary precautions to protect their

140/ "Consumer Complaint Category Codes," Document 700027-700033.

confidentiality. Finally, we were unable to provide the documents in a searchable electronic format. We received hard copies of many of these documents and they could not be converted easily into an electronic form that is readily searchable.

If you have any questions or comments, please contact us.

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Counsel to Precept Foods

MJH/jgw

Attachments

Volume 1, Documents 100000-100567
Volume 2, Documents 100568-100829
Volume 3, Documents 100833-101218
Volume 4, Documents 200000-300001
Volume 5, Documents 400000-400412
Volume 6, Documents 400413-400938
Volume 7, Documents 400939-401517
Volume 8, Documents 401518-402087
Volume 9, Documents 402088-402244
Volume 10, Documents 500000-600357
Volume 11, Documents 700000-700045