ONE HUNDRED TENTH CONGRESS

U.S. House of Representatives
Committee on Energy and Commerce
Washington, DC 20515–6115

JOHN D. DINGELL, MICHIGAN
CHAIRMAN

June 26, 2007

Mr. Jeffrey M. Ettinger
Chairman, President, and CEO
Hormel Foods Corporation
1 Hormel Place
Austin, MN 55912

Mr. Warren R. Staley
Chairman and CEO
Cargill, Incorporated
15407 McGinty Road West
Wayzata, MN 55391

Dear Messrs. Ettinger and Staley:

Under Rules X and XI of the Rules of the United States House of Representatives, the Committee on Energy and Commerce and the Subcommittee on Oversight and Investigations are investigating the adequacy of the efforts of the Food and Drug Administration (FDA) and the U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS) to protect Americans from contaminated or otherwise unsafe food. It is our understanding that Precept Foods, LLC (Precept), a joint venture between Hormel Foods Corporation and Excel Corporation (a wholly-owned subsidiary of Cargill, Incorporated), markets fresh meat that is packaged in an atmosphere containing carbon monoxide, designed to alter the color of the meat indefinitely. For the purposes of this letter, the use of "Precept" refers to the joint venture and to each of your firms individually, as well as any subsidiaries of your firms.

Beyond any consumer deception that may be involved, the Committee has concerns about the public health consequences of this packaging and the *ex parte* decisions by FDA and FSIS that made such packaging lawful. We have questions regarding the conditions under which these rulings have come about, as well as how Precept chooses to market prepackaged fresh meats that appear to have been deceptively colored. Accordingly, we request responses to the following inquiries and make the following record requests:

1. **Scientific Evidence:** We are interested in the scope and quality of the studies Precept submitted to FDA and FSIS to support its GRAS (Generally Recognized As Safe) notification (GRN 000143) for the use of carbon monoxide in meat packaged in which carbon monoxide remains in contact with the meat until the package is opened by the consumer. We are aware of three studies that were submitted by Precept in support of its GRAS notification. These are:

- Excel Report: Use of Carbon Monoxide in Lid Stock on Ground Beef. Project # 23034, February 14, 2003, Authors: Nancy Rathje and Graciel Catano;

- Excel Report: Ground beef abuse study in peelable, low oxygen and carbon monoxide lidstock tray, May 13, 2003, Authors: Liza John, Barney Wilborn and Graciel Catano; and

- Hormel Report: Precept Foods / MAP Packaging, R&D Project # PF002.00, June 6, 2003, Author: Dave Ruzek

(a) Does Precept consider these reports, as submitted to FDA and FSIS, to meet standards for publication in a reputable, peer-reviewed scientific journal?

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

(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?

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

(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, 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?

Please provide the following:

(f) Curricula vitae for the authors of the reports listed above;

(g) Names and curricula vitae of any experts Precept consulted, and copies of any reports they supplied; and

(h) Copies of all reports submitted by Precept to FDA or FSIS related to GRN 000143.

2. **Consumer Reliance on Meat Color as an Indicator of Freshness and Safety:** It is apparently well documented in published scientific and industry literature that consumers rely heavily upon meat color in selecting fresh meat for purchase and consumption. By reacting with the meat to create a red color that simulates the look of fresh meat—regardless of the age of the meat or whether it has been temperature abused—carbon monoxide can mask signs of microbial spoilage, aging, and deterioration. 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.

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.

3. **Odor and Package Bulging as Purported Indicators of Spoilage:** 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?

   (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.

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

   (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?

   (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 other factors that would tend to make sealed packages bulge? If not, why not?

   Please provide all documents relating to your responses to the questions listed above.

4. Labeled Shelf Life: We understand that Precept proposed, and FDA and FSIS accepted, "use or freeze by" dates on packages of carbon monoxide-treated meat of up to 28 days from packaging for ground beef and up to 35 days for whole muscle cuts. We are informed that the Opinion of the European Commission's Scientific Committee on Food (EC Opinion) on the use of carbon monoxide as component of packaging gases in modified atmosphere packaging for fresh meat, adopted 13 December 2001, determined that the shelf life of the treated meat was 11 days for ground beef and 14 days for beef loin steaks (at 4° C or 39.2° F). The EC Opinion also states that raising the temperature to 8° C (46.4° F) reduced the shelf life of carbon monoxide-treated ground beef by about one half. According to published scientific reports, 21 percent of the refrigerators in the U.S. operate at temperatures around 50° F and temperature abuse in other parts of the chill chain is well documented.

   (a) Please provide the data upon which Precept proposed the 28- and 35-day shelf lives noted above.

(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 originally submitted its GRAS notification to FDA.

(c) Was Precept 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 to be inconsistent with the GRAS determination?"

(d) How does Precept 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 shelf lives proposed by Precept? Was this difference discussed with FDA? If not, why not?

(e) We are aware that Precept has stated that, in light of "actual conditions," Precept is using "more conservative dates" reflecting a shorter shelf life. What labeled shelf life is Precept 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 has said it currently uses.

5. Legibility and Effectiveness of Date Labeling:

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

(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?

(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.

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

Please provide any data or other information Precept has generated or relied upon relating to the effectiveness of "use or freeze by" date labeling to positively affect consumer purchasing practices.

6. Temperature Abuse Concerns: The discoloration of meat packaged in air or in high oxygen modified atmospheres that occurs as a result of temperature abuse is an enormous financial incentive driving meat production and transportation activities to maintain rigorous and proper control of temperature. If the temperature is not controlled, the meat turns brown and becomes unsaleable.

   (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?

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

   Please provide all documents relating the responses to questions listed above.

7. Retail Practices:

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

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

   (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?

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

   (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.

The Committee hereby requests all records relating to Precept's decision to market fresh meat products treated with carbon monoxide. This request includes, but is not limited to, all studies that Precept—including its component firms as noted earlier—has commissioned or performed in-house regarding the use of carbon monoxide in the packaging of fresh meat, the due diligence that Precept performs on such fresh meat products regarding temperature controls in the processing and transport of these products, any studies or focus groups regarding the criteria for consumer selection of fresh meat products, consumer acceptance of meat whose color is

preserved by carbon monoxide, consumer ability to smell or otherwise detect spoiling meat, and the ability and actual experience of consumers reading "use or freeze by" dates on packages.

Please provide Precept's responses and the requested records to the Committee offices in room 316 Ford House Office Building no later than 30 days from the date of this letter. Please provide all records requested in an electronic sortable format. The words "records" and "relating to" are defined in an attachment to this letter. If this request is interpreted to require production of documents that would constitute an unreasonable burden, it may be modified upon agreement with Committee staff. If you have any questions regarding this request, please contact us or have your staff contact David Nelson, Kevin Barstow, or John Arlington of the Committee staff at (202) 226-2424.

Sincerely,

John D. Dingell
Chairman

Bart Stupak
Chairman
Subcommittee on Oversight and Investigations

Attachment

cc: The Honorable Joe Barton, Ranking Member
Committee on Energy and Commerce

The Honorable Ed Whitfield, Ranking Member
Subcommittee on Oversight and Investigations

ATTACHMENT

1. The term "records" is to be construed in the broadest sense and shall mean any written or graphic material, however produced or reproduced, of any kind or description, consisting of the original and any non-identical copy (whether different from the original because of notes made on or attached to such copy or otherwise) and drafts and both sides thereof, whether printed or recorded electronically or magnetically or stored in any type of data bank, including, but not limited to, the following: correspondence, memoranda, records, summaries of personal conversations or interviews, minutes or records of meetings or conferences, opinions or reports of consultants, projections, statistical statements, drafts, contracts, agreements, purchase orders, invoices, confirmations, telegraphs, telexes, agendas, books, notes, pamphlets, periodicals, reports, studies, evaluations, opinions, logs, diaries, desk calendars, appointment books, tape recordings, video recordings, e-mails, voice mails, computer tapes, or other computer stored matter, magnetic tapes, microfilm, microfiche, punch cards, all other records kept by electronic, photographic, or mechanical means, charts, photographs, notebooks, drawings, plans, inter-office communications, intra-office and intra-departmental communications, transcripts, checks and canceled checks, bank statements, ledgers, books, records or statements of accounts, and papers and things similar to any of the foregoing, however denominated.

2. The terms "relating," or "relate" as to any given subject means anything that constitutes, contains, embodies, identifies, deals with, or is in any manner whatsoever pertinent to that subject, including but not limited to records concerning the preparation of other records.