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June 9, 2008



Honorable John D. Dingell
United States House of Representatives
Chairman, Committee on Energy and Commerce
Washington, D.C. 20515-6115

Honorable Bart Stupak
United States House of Representatives
Chairman, Subcommittee on Oversight and Investigation
Washington, D.C. 20515-6115

Dear Chairman Dingell and Chairman Stupak:

Thank you for this opportunity to provide a follow up to the response of Brenda Barnes, Chairman and Chief Executive Officer of Sara Lee Corporation, for your recent request for information. This letter was prepared to allow for public posting. Information in response to Questions 2 and 3 has been separated from the body of the letter and is now located in appendices following the letter.

Sara Lee Corporation conducts business under the regulatory oversight of both the U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS) and the Food and Drug Administration (FDA). Sara Lee Corporation operates 57 manufacturing facilities in the United States regulated by FDA and 12 manufacturing facilities under the regulatory oversight of FSIS. The Corporation is located in Illinois and our plants and distributions centers are located in 44 states. In addition to these domestic facilities, we have numerous food manufacturing plants worldwide with limited import into the U.S.

At Sara Lee Corporation our entire organization is committed to providing safe and wholesome foods that are innovative and delight consumers. Sara Lee Corporation has long supported science-based regulation that is transparent to all stakeholders. We support USDA, FDA, state, and local regulatory authorities in their science-based efforts to improve the safety of our nation's food supply and the safety of imported products. Each request and response is listed below based on our facility records.

- 1. A list of all food recalls and food safety alerts issued by your company. For each recall or safety alert, please provide the date of the recall or alert, the product and brand affected, and the reason for the recall or alert. If the food was affected by microbial or chemical contamination, please identify the contaminant.*

We have comprehensive food safety policies and procedures to test our products, our manufacturing facilities, and our ingredients to assure safe products for our consumers. We have initiated voluntary recalls to minimize any potential health risks to the public. Prior to and during our voluntary recalls we have ALWAYS notified either FDA or USDA, depending on jurisdiction. Furthermore, to our knowledge we have supplied the relevant agencies with all requested information.

To our knowledge we have listed below all the voluntary recalls Sara Lee Corporation has conducted since January 1, 2000 working in collaboration with FDA or USDA. We have sold and bought several companies since January 1, 2000, but we believe we have listed all Sara Lee Corporation products recalled during that time period. Sara Lee took these voluntary actions to protect our consumers.

On July 26, 2007, we issued a voluntary recall for Sara Lee branded and private label bread produced in Meridian, MS after we discovered foreign material from a flour sifter screen. On October 30, 2006, we issued a voluntary recall for Sara Lee Hamburger Buns produced in Valdese, NC after we discovered milk not listed in the ingredient statement. On June 30, 2006, we issued a voluntary recall for private label chocolate chip cookie dough produced in Carrollton, TX after we discovered pecan not listed in the ingredient statement.

On December 13, 2005 we issued a voluntary recall for Jimmy Dean, State Fair and Rudy's Farm mini cheeseburgers and chicken biscuits produced in Florence, AL and comanufactured in Itasca, IL. This recall for *Listeria monocytogenes* was due to supplier notification of a possible positive on the cheese supplied to Sara Lee. This cheese had been received and used in finished goods entered into commerce prior to notification by the supplier. After this discovery, we took proactive steps to voluntarily recall and notify FDA.

On September 14, 2005, we issued a voluntary recall for Sara Lee and multiple private label breads and bagels produced in Vernon, CA after we discovered foreign material from a tape measure. On February 1, 2005, we issued a voluntary recall for multiple private label customers crescent roll dough produced in Forest Park, GA after we discovered foreign material from an employee's eyewear. On November 12, 2004, we issued a voluntary recall on Bryan Corn Dogs produced in Haltom City, TX after we discovered egg not listed in the ingredient statement. On April 20, 2004, we issued a voluntary recall on Country Farms Old Fashioned Wheat Bread produced in Phoenix, AZ after we discovered buttermilk not listed in the ingredient statement. On September 19, 2003, we issued a voluntary recall for private label chocolate chip cookie dough produced in Carrollton, TX after we discovered milk not listed in the ingredient statement. On March 28, 2003, we issued a voluntary recall for Sara Lee Butter Streusel Coffee Cake produced in Tarboro, NC after we discovered pecan not listed in the ingredient statement. On December 23, 2002, we issued a voluntary recall for Sara Lee Fruits of the Forest Pie produced in Traverse City, MI after we discovered walnut not listed in the ingredient statement. On June 17, 2002 we issued a voluntary recall for Earth Grain Onion Buns in multiple Sara Lee plants after an inspector in Sioux Falls, SD found egg not listed in the ingredient statement. On June 17, 2002, we issued a voluntary recall for Earth Grains Onion Buns in multiple Sara Lee plants after an FDA inspector found egg not listed in the ingredient statement in Sioux Falls, SD. On January 24, 2002, we issued a voluntary recall for Jimmy Dean Maple Link Sausage produced in Newbern, TN after we discovered monosodium glutamate not listed in the ingredient statement. On December 27, 2001, we issued a voluntary recall for April Hill Frozen Cookie Dough produced in Grand Rapids, MI after we discovered egg not listed in the ingredient statement.

On July 18, 2001, we issued a voluntary recall for Sara Lee Cajun Style Beef, Brown Sugar Ham, and Roast Beef produced in Cincinnati, OH due to *Salmonella*. This recall was the result of one consumer complaint sample. The sample was taken from a package already opened by the consumer which tested positive for *Salmonella*. All subsequent testing of product and the facility did not find *Salmonella*.

On May 17, 2001, we issued a voluntary recall for Little Bucket Parfait Lemon Cream produced in Traverse City, MI after we discovered Yellow #5 not listed in the ingredient statement. On April 19, 2001, we issued a voluntary recall for Ball Park Beef Franks produced in West Point, MS after we discovered pork and turkey not listed in the ingredient statement. On February 22, 2001, we issued a voluntary recall for Bistro Collection Pecan Tarts comanufactured in Torrance, CA after we discovered egg and cottonseed oil not listed in the ingredient statement. On August 16, 2000 a voluntary recall was issued for Earth Grains Potato Bread produced in Stockton, CA after we discovered whey and nonfat dry milk not listed in the ingredient statement. On March 24, 2000, we issued a voluntary recall for Ball Park Franks produced in Philadelphia, PA due to a customer test of the product that found it to be positive for *Listeria monocytogenes*.

Sara Lee Corporation initiated these voluntary recalls to protect our consumers and assure safe, high quality product in the marketplace. The volume of product that we voluntarily recalled represented 0.01 percent of our total pounds sold.

2. *For each brand or kind of product, please list all instances when internal microbiological testing was found to be positive for the presence of E. coli, Salmonella, Cyclospora cayetanensis, Cryptosporidium, hepatitis A, Clostridium botulinum, or Listeria in excess of the highest limit acceptable to the Food and Drug Administration (FDA) or any State regulatory authority.*

For microbiological testing, we use a world-renowned independent third-party laboratory that is accredited by an independent international certification body (ISO/IEC 17025) to verify that they conduct high quality, accurate and precise results. We believe that this independent testing of our products, our manufacturing environment, and our ingredients provides an unbiased reliable confirmation that our internal policies and procedures are effective to produce safe product. Sara Lee invests in strong, proactive microbiological testing programs in order to protect our consumers.

Since January 1, 2000 to our knowledge, we have NEVER shipped any ready-to-eat product to our customers or consumers that was known or suspected at the time to be positive for the microbiological pathogens that were listed.

We have a policy that requires the manufacturing plant to hold product (not ship to customers or consumers) pending receipt, in writing, of microbiological test results for pathogens on finished product. Furthermore, Sara Lee policy prohibits release of finished product when a microbiological pathogen is found to be present in excess of regulatory limits, even if subsequent investigational test results indicate the pathogen is not present. If our independent third party laboratory determined that the finished product was positive for any of these pathogens, then the product would be destroyed. In addition, we would immediately implement corrective actions and preventive measures to address the issue at the facility.

Due to our comprehensive food safety programs, on the rare occasion where we have found product that did not meet regulatory or our own food safety standards, we have destroyed and disposed of that product. Since January 1, 2000 we have had five instances where we destroyed product as listed in Appendix 1.

In all of these instances product was NOT introduced into commerce (NOT sold to customers or consumers). We protect our consumers and properly dispose of any products that do not meet our stringent food safety and quality requirements.

3. *For each brand or kind of product, please list the instances when internal testing was found to be positive for the presence of a chemical contaminant at levels in excess of the highest limit acceptable to FDA or any State regulatory authority.*

We have a policy that requires the manufacturing plant to hold product (not ship to customers or consumers) pending receipt, in writing, of chemical contaminant test results for finished product. If our independent third party laboratory determined that any chemical contaminant is present in the finished product in excess of regulatory limits, then the product would be destroyed in accordance with applicable state and federal regulations. Furthermore, Sara Lee policy prohibits release of finished product when a chemical contaminant is found to be present in excess of regulatory limits, even if subsequent investigational test results indicate the chemical contaminant is not present. In addition we would immediately implement corrective actions and preventive measures to address the issue at the facility.

Due to our comprehensive food safety programs, on rare occasions we find product that does not meet regulatory or our own food safety standards and we destroy and dispose of that product. To the best of our knowledge, since January 1, 2000, Sara Lee has detected only one chemical contaminant. See Appendix 2. The product was NOT introduced into commerce (NOT sold to customers or consumers). We protect our consumers and properly dispose of any products that do not meet our stringent food safety and quality requirements.

Since January 1, 2000 to our knowledge, we have NEVER shipped any ready-to-eat product to our customers or consumers that was known or suspected at the time to be positive for chemical contaminants.

4. *For products imported into the United States for handling or processing by any facility operated by your firm, please list the instances when internal or outside laboratory testing was positive for the presence of either a chemical or microbiological contaminant in excess of FDA or State regulatory limits.*

To our knowledge, by internal or third party testing we have not found any microbiological pathogens or chemical contaminants in excess of regulatory limits upon importing ingredients or importing finished products.

Per the Committee's expressed concern, we would take action on the initial positive microbiological or chemical contaminant. Sara Lee policy prohibits release of finished product when a microbiological pathogen or chemical contaminant is found to be present in excess of regulatory limits, even if subsequent investigational test results indicate the pathogen or chemical contaminant is not present.

5. *For each of the above items, please specify whether FDA was notified, and if not, why not.*

Either the district FDA office or USDA Recall Center (depending on jurisdiction) was notified prior to implementing all voluntary recalls.

Pursuant to the Federal Meat Inspection Act, the Federal Poultry Products Inspection Acts, 9 CFR § 320, 9 CFR § 416 and 9 CFR § 417, we promptly informed the local FSIS Inspector and the FSIS

District Office of the above reported microbiological pathogen positives, as well as our plans for destruction of the product, our corrective actions, and our preventive measures.

We are unaware of any requirement under the Federal Food, Drug and Cosmetic Act to notify FDA regarding internal positive microbiological pathogen results or chemical contaminant results. To the best of our knowledge, Sara Lee has complied with all FDA notification requirements.

6. *Please supply a list of all instances where FDA or any State regulatory authority was denied entrance to any facility, foreign or domestic, or denied access to any records regarding microbiological or chemical testing performed on products processed at the facility. This request encompasses denials of initial requests for entry or any such testing record regardless of whether the plant or its records were to be made available for inspection at a later date.*

To the best of our knowledge, Sara Lee has complied with all regulatory entrance and access requirements. Given the different regulatory requirements for our USDA and FDA regulated facilities, we elaborate below.

Our FDA regulated facilities are inspected by FDA inspectors, state inspectors, and on occasion local health inspectors. To our knowledge, we have never denied entrance to our FDA regulated facilities to an FDA, state, or local inspector. On occasion, we have told an inspector that we do not allow cameras in the food processing environment. If an FDA inspector requests access to microbiological pathogen or chemical contaminant test results, the plants are directed to ask the inspector to submit their request in writing to our Legal Department. To the best of our knowledge, Sara Lee has not received a request in writing from FDA to access microbiological pathogens or chemical contaminants records.

Our USDA regulated facilities have USDA inspectors present during operations. The USDA inspectors have access to all microbiological and chemical contaminant test results conducted on behalf of our facilities. To our knowledge, we have never denied entrance to our USDA regulated facilities to a USDA inspector. On occasion, we have told an inspector that we do not allow cameras in the food processing environment. To our knowledge, we have never denied a USDA inspector access to microbiological pathogen or chemical contaminant testing records.

Sara Lee Corporation is pleased to cooperate with your investigation. Food safety is a top priority at Sara Lee Corporation and we take great pride in our commitment to work cooperatively with FDA and USDA in overseeing that all our manufacturing facilities surpass all regulatory requirements and produce safe high quality products. We trust you will find this response, based on review of our facilities' records and the knowledge of senior personnel, satisfactory. We regard the information found in the attached appendices, concerning testing procedures and results as confidential commercial information, which we respectfully request the Committee handle accordingly. I would be pleased to address any further questions you might have.

Respectfully,

