



**Gregory R. Page**  
Chairman and  
Chief Executive Officer

PO Box 5724  
Minneapolis, MN 55440-5724

June 10, 2008

Honorable John Dingell  
Chairman, Committee on Energy and Commerce  
U.S. House of Representatives  
Washington, DC 20515-6115

Honorable Bart Stupak  
Chairman, Subcommittee on Investigations and Oversight  
U.S. House of Representatives  
Washington, DC 20515-6115

Dear Chairman Dingell and Chairman Stupak:

This is our initial response to the Committee's May 19, 2008 letter relating to food safety recalls, testing data and government inspections between January 1, 2000 and May 19, 2008.

Cargill<sup>1</sup> is an international provider of food, agricultural and risk management products and services, with operations in 66 countries. Of Cargill's 77 business units, 53 are covered by the Committee's request. Many of these businesses are located outside the U.S., and we appreciate the Committee's understanding that the collection of data from international facilities will take additional time. We are supplying the data requested by the Committee as completely as possible at this time, and, as discussed with Committee staff, some of the data will be delivered separately from this initial response. We are committed to providing this additional data in a timely fashion.

We address the questions presented in your letter in the text below and in separate attachments. Information and data that support our response, but are confidential, are submitted as attachments, and marked with the word "Confidential." We request that this information be kept confidential. We also request that you provide us with 72 hours advance notice should the Committee determine that it needs to release any portion of our confidential information or data to the public.

Although information relating to food recalls and published food safety alerts is in the public domain, testing results are not. We would urge the committee not to disclose internal testing data which, because of its complexity, may be easily misunderstood or misinterpreted, and may have the undesirable effect of discouraging companies from conducting robust voluntary internal testing.

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<sup>1</sup> For purposes of this letter, Cargill means Cargill, Incorporated, a Delaware corporation, and its majority owned subsidiaries and joint ventures.

Cargill believes that no responsibility is more important than ensuring the safety of its food products. Among our most significant commitments to leadership in food safety:

#### HACCP

In 1991 we initiated the adoption of a modernized food safety preventive control system based on Hazard Analysis and Critical Control Points (HACCP), in all our food production operations around the world, including those regulated in the U.S. by the Food and Drug Administration (FDA). We have taken this step even though HACCP is not required in the U.S. for FDA regulated foods other than seafood and juice. HACCP became mandatory across our company globally in 2004. Cargill has been very active in promoting HACCP around the world as a logical, prevention-based food safety system. While HACCP is at the top of Cargill's food safety pyramid, the base is made up of a host of prerequisite programs including the complete set of CODEX Good Hygiene Principles (GHP) and an additional nine Cargill-specific programs including adulterant testing, allergen control, product development, laboratory functions, and internal audits.

Physical, chemical and biological contaminants are all addressed in our HACCP programs. HACCP allows us to assess these hazards, and directs us to establish control systems that focus on preventive measures rather than relying solely on finished product testing.

#### Technology

We have been an industry leader in researching, developing and sharing technology and practices that benefit public health, including: steam pasteurization of beef carcasses; on-line spectroscopic detection of organic material; cattle carcass sanitation systems; in-package pasteurization; anti-listerial product formulations and brine chilling systems; rapid detection methods for *E. coli* O157:H7, *Salmonella* and *Listeria*; and vaccines, antimicrobials and probiotic interventions for use on the farm.

#### Operational Risk Protection

Cargill has implemented a number of prevention and testing programs to eliminate or minimize microbiological contamination of our products by *E. coli* O157:H7, *Listeria monocytogenes* (*Lm*) and *Salmonella*.

- With regard to *E. coli* O157:H7 we have a testing system<sup>2</sup> focused on both beef components as well as ground beef. Our industry-leading, scientifically validated approach and methodology greatly enhances our ability to find and eliminate this pathogen. Product testing serves as a final verification of our HACCP and prerequisite programs.
- Cargill relies on the most effective methods of *Lm* and *Salmonella* protection, relying on effective implementation of HACCP and prerequisite programs, including: environmental monitoring, sanitary design of facilities and equipment, and personal hygiene practices.

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<sup>2</sup> Our program utilizes the industry best practice N=60 protocol. Under this protocol, beef trimmings are tested at a rate of about 2000-2500 per week, using a composite of material from 120,000-150,000 individual samples. In addition, we currently test our ground beef at a rate of about 900 times per week depending on production volume. USDA manages its own independent testing program.

### Education and Partnership

Cargill, together with several other large ready-to-eat meat and poultry products companies, has participated in the development of, and presentation of training *Lm* workshops, assisting smaller food manufacturers with the establishment of their control programs. We have also provided training for the USDA.

Cargill is currently leading an industry initiative to create a repository of industry best practices to assist in the control of *Salmonella* in dry food products. The company also participated in a training workshop for industry (especially in support of small plants) relating to the prevention and control of *E. coli* O157:H7.

### **Scope**

The information provided below is for Cargill products sold or intended-to-be-sold in the United States for human consumption. We have included information on Cargill's domestic production and as much information as we have currently in hand concerning production outside the U.S. intended for sale within the U.S. Although the Committee's letter refers to the FDA several times, our meat and poultry and some of our egg products are regulated by the United States Department of Agriculture, and thus we are providing information on those products as well.

Please note that for facilities or businesses acquired by Cargill since January 1, 2000, information is provided as of the date of acquisition, through May 19, 2008. Information relating to facilities or businesses divested or closed since January 1, 2000 is not included. We will supplement this letter with additional information concerning overseas production as well as our response to question 4 as quickly as possible. It is the Company's normal document retention practice to maintain these types of records only for the longer of three years, or the period required by applicable law. We have, however, instructed relevant Cargill personnel to review all available information contained in our existing files, or known to such personnel to be responsive to your request.

### **Responses to Questions**

The Committee has asked us to answer five questions relating to our food safety performance and a sixth question relating to government inspections. Our answers are presented in summary format below, as well as additional detail on the attachments to this letter.

#### **Question 1.**

[Please] list all food recalls and food safety alerts issued by your company [between January 1, 2000 and May 19, 2008]. 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.

#### ***Response to Question 1***

Attachment I summarizes recalls conducted by Cargill during the relevant time period. We had twelve recalls relating to USDA regulated products during the relevant time period.

We had no recalls of FDA-regulated products during this time period. We have not issued any food safety alerts independent of product recalls. Recall information is in the public domain, and so is not marked as "Confidential."

## **Question 2.**

For each brand or kind of product, please list all instances [between January 1, 2000 and May 19, 2008] when internal microbiological testing was found to be positive for the presence of *E. coli*, *Salmonella*, *Cyclospora cayentanensis*, *Cryptosporidium*, hepatitis A, *Clostridium botulinum*, or *Listeria* in excess of the highest limit acceptable to the Food and Drug Administration (FDA), [USDA] or any State regulatory authority.

## **Response to Question 2**

*Under Cargill's adulterant testing policy, no lot of food that has been tested for a microbiological contaminant can be released from Cargill's direct control until the test results are known and reflect that the product is in compliance with applicable law. Any test result that reveals the presence of a microbiological contaminant above applicable legal limits renders the entire lot unfit for consumption unless a scientifically validated and legally approved process for microbiological contaminant removal, destruction or inactivation is performed. And, since microbiological contaminant may not be uniformly distributed in foods, Cargill policy prohibits the use of further negative test results to negate an original positive unless it can be definitively determined that a laboratory error or contamination during or after sample collection occurred to produce the original positive result.*

### *E. coli* O157:H7

We have applied this question to our testing program for *E. coli* O157:H7, because this is the pathogenic serotype of *E. coli* that is the greatest food borne public health concern. The main pathway for the contamination of beef products is cross contamination from the hide of the animal to the carcass during the harvesting process. By regulation, USDA observes a zero tolerance standard for the presence of *E. coli* O157:H7 in ground beef, non-intact beef, and non-intact products intended-to-be-manufactured into ground beef. No other limits for *E. coli* O157:H7 in food products has been set by the USDA. The FDA applies a zero tolerance for this pathogen for ready-to-eat products.

Results of our *E. coli* O157:H7 testing program accompany this document as Attachment II-A, which is marked "Confidential".

### *Listeria*

We have applied the Committee's question to mean *Listeria monocytogenes* (*Lm*) because this is the species of *Listeria* that is the greatest food borne public health concern. Both FDA and USDA observe a zero tolerance standard for the presence of *Lm* in fully cooked, ready-to-eat food products. FDA and USDA have not set a limit for *Lm* in raw non-ready-to-eat food products. As a result of our multiple intervention approach, which is described above, we rarely find positive test results. This approach has proven very effective, and is the industry best practice, as demonstrated in our results.

Results of our *Lm* testing programs accompany this document as Attachment II-B, which is marked "Confidential."

*Salmonella*

Both FDA and USDA have adopted a zero tolerance policy for *Salmonella* in ready-to-eat products. Cargill's approach to meeting this standard is to ensure our multiple intervention systems are working effectively.

As the Committee may be aware, *Salmonella* is not considered an adulterant in raw meat and poultry, or in non-ready-to-eat products such as wheat flour. These products go through an additional lethality treatment step prior to consumption. *Salmonella* monitoring is however used by USDA as a process indicator for raw meat and poultry. Individual positive results are not actionable, as outlined in the 1996 USDA Pathogen Reduction/HACCP regulation, and therefore are not reported in this submission.

Results of our *Salmonella* testing programs accompany this document as Attachment II-C, which is marked "Confidential."

*Cryptosporidium*

This protozoan parasite has caused illness outbreaks associated with contaminated water supplies. Our product mix and production practices, such as our prerequisite programs mandating the use of safe and appropriate water supplies, make this organism a hazard not likely to occur in our products, and thus we do not test for *Cryptosporidium*.

*Clostridium botulinum*

Typically this organism is a concern in canned products. A thorough hazard analysis of our production practices and product mix indicates this organism does not present a biological hazard likely to occur in Cargill's food products, and therefore we do not test for this organism.

*Cyclospora cayetanensis*

*Cyclospora* has been associated with illness linked to contaminated fresh produce. Cargill does not manufacture or import products for which *Cyclospora* may be a concern, and therefore we have no testing data to report.

Hepatitis A

Hepatitis A is a virus associated with food handler contamination of ready-to-eat products. Analysis of our production practices and product mix shows that this hazard is not likely to occur; therefore we have no test data to report.

**Question 3.**

For each brand or kind of product, please list the instances [between January 1, 2000 and May 19, 2008] 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, [USDA] or any State regulatory authority.

***Response to Question 3***

Under Cargill's Adulterant Testing policy, no lot of food that has been tested for a chemical contaminant can be released from Cargill's direct control until the test results are known and reflect that the product is in compliance with applicable law. Any test result that reveals the presence of a chemical contaminant above applicable legal limits renders the entire lot unfit for consumption unless a scientifically validated and legally approved process for removal, destruction or inactivation of the chemical contaminant is performed. And, since chemical contaminants may not be uniformly distributed in foods, Cargill policy prohibits the use of further negative test results to negate an original positive unless it can be definitively determined that a laboratory error or contamination during or after sample collection occurred to produce the original positive result.

The specific data in response to question three is included as Attachment III and is marked "Confidential."

**Question 4.**

For products imported into the United States for handling or processing by any facility operated by your firm, please list the instances [between January 1, 2000 and May 19, 2008] when internal or outside laboratory testing was positive for the presence of either a chemical or microbiological contaminant in excess of FDA, [USDA] or State regulatory limits.

***Response to Question 4***

Most of this information will be submitted in our follow-up response relating to imported foods. Our attachments do contain some information relating to meat products our company produces in Canadian facilities and imports into the U.S. Canadian regulatory standards are essentially identical to USDA requirements.

**Question 5.**

For each of the above items, please specify whether FDA [or USDA] was notified, and if not, why not.

***Response to Question 5***

All recalls of USDA-regulated foods are executed in partnership with FSIS.

FSIS inspectors have the authority to review, among other records, microbiological and chemical testing data compiled in compliance with regulations. In the event of a test that shows a positive result for a particular pathogenic requirement, in accordance with USDA policy, the FSIS is notified. It is also an express requirement that we employ the provisions of our HACCP programs to institute reviews and corrective actions. USDA has reviewed, and is well informed of the provisions of our HACCP programs.

As noted above, we had no FDA-regulated product recalls during the relevant time period. With respect to testing of FDA-regulated products, Cargill's policy is to notify FDA in the event of any test result that may represent a threat to public health. We do not notify FDA of positive test findings under our "test and hold" policy, as those products never enter commerce for distribution to consumers.

**Question 6.**

Please supply a list of all instances [between January 1, 2000 and May 19, 2008] where FDA [USDA] 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.

***Response to Question 6***

With respect to FDA-regulated facilities, our policy is to provide FDA and State regulatory authorities access to our facilities, and we believe that such access is regularly provided. To the best of our knowledge, at no time has Cargill denied FDA or state inspectors entrance to any of our facilities, so long as they present appropriate credentials. We do not generally provide routine open access to microbial and chemical testing records, as such access is not required by law or regulation, but we do provide FDA access to necessary records on a case-by-case basis.

With regard to our USDA-regulated products, the FSIS maintains a presence in all our plants, thus we are under continuous inspection. As stated above, we run our operations in a very transparent, open manner with the regulator. It is critical that the FSIS understands our food safety systems so that we can be effective partners in consumer health protection. USDA has the right to see any records related to the execution of our HACCP or prerequisite programs.

This information is presented as completely as possible as of this date. We will shortly deliver a second letter containing the additional information relating to imported foods. As we further review records, we will provide the committee with any additional information that is responsive to the Committee's request. Should committee staff require additional information or clarification of any of the material we have submitted, please contact Mike Mullins (202-530-8162), in our Washington, DC government affairs office.

Sincerely,



Gregory R. Page  
Chairman and Chief Executive Officer

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

The Honorable John M. Shimkus  
Ranking Member, Subcommittee on Oversight and Investigations