

September 2, 2010

Mary Porretta, Petitions Manager
Office of Policy and Program Development
USDA-Food Safety and Inspection Service
1400 Independence Avenue, SW
Room 350-E Jamie Whitten Building
Washington, DC 20250

RE: Petition Number 09-03: Petition for an Interpretive Rule Declaring all enterohemorrhagic Shiga Toxin-producing Serotypes of *Escherichia coli* (*E. coli*), including Non-O157 Serotypes, to be Adulterants Within the Meaning of 21 U.S.C. § 601(m)(1)

Dear Ms. Porretta:

Enclosed please find the second supplemental statement of additional grounds for petition number 09-03 for the issuance of an interpretive rule, submitted on behalf of Marler Clark LLP, PS, Outbreak, Inc., the family of June Dunning, Megan Richards, and Shiloh Johnson. Also enclosed are supporting documents in the form of Exhibits No. 1 and 2.

Thank you.

Very truly yours,



William Marler, Esq., on behalf of:

Marler Clark LLP, PS
Outbreak, Inc.
The Family of June Dunning
Megan Richards
Shiloh Johnson

cc: Mary Porretta

UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE

Petition for an Interpretive Rule)	Docket No. 09-03
Declaring all enterohemorrhagic Shiga)	
Toxin-producing Serotypes of <i>Escherichia</i>)	
<i>coli</i> (<i>E. coli</i>), Including Non-O157 Serotypes,)	<u>SECOND</u>
to be Adulterants Within the Meaning)	<u>SUPPLEMENTAL STATEMENT</u>
of 21 U.S.C. § 601(m)(1))	<u>OF ADDITIONAL GROUNDS</u>
_____)		

CITIZEN PETITION

Submitted by:

Marler Clark LLP, PS

Outbreak, Inc.

The Family of June Dunning

Megan Richards

Shiloh Johnson

September 2, 2010

Philip Derfler, Assistant Administrator
Office of Policy and Program Development
USDA-Food Safety and Inspection Service
1400 Independence Avenue, SW
Room 350-E Jamie Whitten Building
Washington, DC 20250

I. INTRODUCTION

A petition was filed on October 5, 2009 that requested FSIS to issue an interpretive rule declaring all enterohemorrhagic (EHEC) Shiga Toxin-producing serotypes of *Escherichia coli* (*E. coli*), including non-O157 serotypes, to be adulterants within the meaning of the Federal Meat Inspection Act (FMIA). This petition was subsequently given further support by the filing of a Supplemental Statement of Additional Grounds, which was dated May 7, 2010. In light of the recently-documented outbreak of illnesses that the USDA and CDC has attributed to ground beef contaminated with *E. coli* O26, we are now filing this Second Supplemental Statement of Additional Grounds in support of our petition. We also ask that we be informed within the next twenty days when, or whether, the USDA intends to reach a final decision on the petition, which as you will recall was granted expedited review.

II. STATEMENT OF ADDITIONAL GROUNDS

On May 21, 2010, the CDC published, through Patricia M. Griffin, MD, a memorandum titled “Non-O157 Shiga toxin-producing *E. coli* (STEC) outbreaks, United States.” Speaking of the recent *E. coli* O145 outbreak linked to romaine lettuce, Dr. Griffin explained to a reporter for the Washington Post that:

it is likely that *E. coli* O145 has caused previous food poisonings but has gone undetected because only about 5 percent of clinical laboratories are able to detect it. "The fact that we found it now doesn't mean it wasn't there before," she said. "The ability to look for the organism in ill people and in outbreaks and food has been increasing. We're gradually finding more of these organisms."

We have attached the CDC Memorandum as Exhibit No. 1.

In addition to the CDC Memorandum on Non-O157 Shiga toxin-producing *E. coli* , you will find attached a copy of the FSIS Recall Release, issued on August 28, 2010, Exhibit No. 2.

III. CONCLUSION

The USDA previously granted our petition expedited review. According to the regulation found at 9 CFR § 392.8(a), this means that

the requested action is intended to enhance the public health by removing or reducing foodborne pathogens or other potential food safety hazards that might be present in or on meat, poultry, or egg products.

Given the recent outbreak of illness attributed to ground beef contaminated with *E. coli* O26, we believe that the USDA has no justification for further delay in acting on our petition. We thus ask that we be informed within twenty days when the required action will take place.

Very truly yours,



William Marler, Esq., on behalf of:

Marler Clark LLP, PS
Outbreak, Inc.
The Family of June Dunning
Megan Richards
Shiloh Johnson

Enclosures



Public Health Service
DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Disease Control and Prevention (CDC)

Memorandum

Date: May 21, 2010

From: Ruth E. Luna, MPH
Rajal Mody, MD, MPH
Enteric Diseases Epidemiology Branch (EDEB)
Division of Foodborne, Waterborne, and Environmental Diseases (DFWED)
(proposed)
National Center for Emerging and Zoonotic Infectious Diseases (NCEZID)
(proposed)

Thru: Patricia M. Griffin, MD
EDEB, DFWED, NCEZID

Subject: Non-O157 Shiga toxin-producing *E. coli* (STEC) outbreaks, United States

To: The Record

We summarized non-O157 Shiga toxin-producing *E. coli* (STEC) outbreaks in the United States through 2008. Outbreaks of foodborne and waterborne diseases have been reported to CDC since the 1970s. In 2009, CDC's National Outbreak Reporting System (NORS), which collects these reports, also began collecting reports of outbreaks of enteric infections caused by exposure to animals or by person-to-person spread.

The preliminary data in the table included in this memo were obtained primarily from reports voluntarily made by state health departments to CDC. In 2010, we supplemented NORS data on non-O157 STEC outbreaks by contacting state and federal health agencies, by reviewing the scientific literature, and by other methods. Our contacts with agencies that reported data to NORS resulted in some modifications to the NORS data that have not yet been made in the NORS database. We found 27 outbreaks through 2008 that involved at least one serogroup of non-O157 STEC. Only one death has been associated with a non-O157 STEC outbreak, an outbreak of *E. coli* O111 infections in 2008 in Oklahoma.

Outbreaks of non-O157 Shiga toxin-producing *E. coli* (STEC) infections, United States, through 2008 (preliminary data compiled by CDC, subject to change)

Year	Month	State	<i>E. coli</i> Serogroup	Other pathogens	Setting	Vehicle (confirmed or suspected)	Associated with ill food worker(s) ^a	Total ill ^b	Reported hospitalizations ^c	HUS reported
1990	Apr	Ohio	O111		Home/family outbreak	Unknown	Unknown	5	1	Yes
1994	Feb	Montana	O104		Home	Pasteurized milk	No	18	4	No
1998	Oct	Montana	O121		Camp	Unknown	Unknown	8	0	No
1999	Jun	Texas	O111		Camp	Salad bar; ice from barrel	No	55	2	Yes
1999	Jul	Connecticut	O121		Community	Recreational lake water	No	11	3	Yes
1999	Dec	Minnesota	O145		Daycare	Person-to-person	No	2	0	No
2000	Jun	Minnesota	O111	<i>Cryptosporidium</i> , <i>Campylobacter</i> , <i>Salmonella</i>	Camp	Animal contact (calves)	No	59	1	No
2000	Jul	Washington	O103		Banquet hall	Water-based punch	No	18	2	Yes
2000	Aug	Utah	O111	<i>Campylobacter</i> , <i>E. coli</i> O157:H7	Camp	Irrigation water	No	102	0	No
2001	Jun	Minnesota	O111 and O51	<i>Cryptosporidium</i> , <i>E. coli</i> O157:H7	Camp	Animal contact (calves)	No	25	2	No
2001	Aug	Minnesota	O26		Swimming beach	Recreational lake water	No	4	0	No
2001	Sept	South Dakota	O111		Daycare	Person-to-person	No	3	0	No
2004	Sept	New York	O111	<i>Cryptosporidium</i>	Community	Unpasteurized apple cider	No	212	14	No
2005	Unknown	Nevada	O26		Daycare	Person-to-person	No	4	0	No
2005	May	Oregon	O145	<i>E. coli</i> O157:H7, <i>Campylobacter</i>	Camp	Drinking water	No	60	0	No
2005	Aug	New York	O45		Correctional facility	Ill food worker(s)	Yes	52	3	No
2006	Apr	North Carolina	O45		Family farm	Animal contact (goats)	No	11	0	No
2006	Jun	Nebraska	O121		Daycare	Person-to-person	No	5	5	Yes
2006	Jul	Utah	O121		Catered event	Lettuce	No	42	3	Yes
2006	Jul	Massachusetts	O26		Community	Strawberries, or blueberries, or both	No	5	1	No
2007	Mar	Maine	O111	<i>Cryptosporidium</i>	Daycare	Person-to-person	No	8	0	No

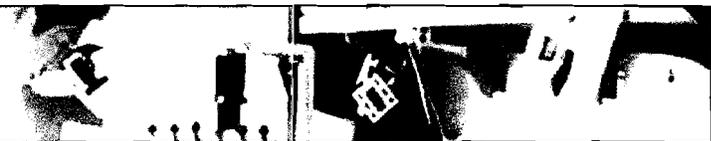
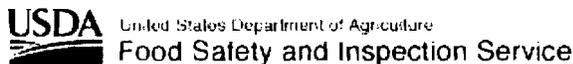
Outbreaks of non-O157 Shiga toxin-producing *E. coli* (STEC) infections, United States, through 2008, continued (preliminary data compiled by CDC, subject to change)

Year	Month	State	<i>E. coli</i> serogroup	Other pathogens	Setting	Vehicle (confirmed or suspected)	Associated with ill food worker(s) ^a	Total ill ^b	Reported hospitalization ^c	HUS Reported
2007	Apr	North Dakota	O111		Elementary school	Person-to-person	No	6	1	No
2007	Jul	North Dakota	O111		Private home (wedding reception)	Ground beef	No	23	0	No
2007	Jul	Colorado	O121, O26, and O84		Correctional facility	Pasteurized American cheese, margarine	Yes	135	10	No
2007	Oct	New Hampshire	O45		Fair (petting zoo)	Animal contact	No	5	0	No
2008	Aug	Oklahoma	O111		Restaurant	Unknown	Yes	344	71	Yes
2008	Sept	Minnesota	O111		Daycare	Person-to-person	No	3	0	No

^aIncludes confirmed and possible association with ill food worker(s)

^bIncludes confirmed and suspected cases

^cInformation about hospitalization may not have been obtained for all persons



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News Releases

Pennsylvania Firm Recalls Ground Beef Products Due to Possible E. coli O26 Contamination

Recall Release
FSIS-RC-050-2010

**CLASS I RECALL
HEALTH RISK: HIGH**

En Español PDF

Congressional and Public Affairs
(202) 720-9113
Atiya Khan

WASHINGTON, August 28, 2010 - Cargill Meat Solutions Corp., a Wyalusing, Pa. establishment, is recalling approximately 8,500 pounds of ground beef products that may be contaminated with *E. coli* O26, the U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS) announced today.

- The product subject to recall includes: [View Label]
- 42-pound cases of "GROUND BEEF FINE 90/10," containing three (3) - approximately 14 pound chubs each. These products have a "use/freeze by" date of "07/01/10," and an identifying product code of "W69032."

The products subject to recall bears the establishment number "EST. 9400" inside the USDA mark of inspection. These products were produced on June 11, 2010, and were shipped to distribution centers in Connecticut and Maryland for further distribution. It is important to note that the above listed products were repackaged into consumer-size packages and sold under different retail brand names. When available, the retail distribution list(s) will be posted on FSIS' website at www.fsis.usda.gov/FSIS_Recalls/Open_Federal_Cases/index.asp.

FSIS and the establishment are concerned that consumers may also freeze the product before use and that some product may still be in consumers' freezers. FSIS strongly encourages consumers to check their freezers and immediately discard any product subject

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PREPARING GROUND BEEF FOR SAFE CONSUMPTION

USDA Meat and Poultry Hotline
1-888-MPHOTLINE or visit www.fsis.usda.gov

Wash hands with warm, soapy water for at least 20 seconds before and after handling raw meat and poultry. Wash cutting boards, dishes and utensils with hot, soapy water. Immediately clean spills.

Keep raw meat, fish and poultry away from other food that will not be cooked. Use separate cutting boards for raw meat, poultry and egg products and cooked foods.

Consumers should only eat ground beef or ground beef patties that have been cooked to a safe internal temperature of 160° F.



September is National Food Safety Education Month @

EXHIBIT 2

to this recall.

FSIS became aware of the problem on August 5, 2010 when the agency was notified by the Maine Department of Agriculture, Food and Rural Resources of an *E. coli* O26 cluster of illnesses. In conjunction with the Maine Department of Health and Human Services, Maine Department of Agriculture, Food and Rural Resources, the New York State Department of Health, and New York State Department of Agriculture & Markets, two (2) case-patients have been identified in Maine, as well as one (1) case-patient in New York with a rare, indistinguishable PFGE pattern as determined by PFGE subtyping in PulseNet. PulseNet is a national network of public health and food regulatory agency laboratories coordinated by the Centers for Disease Control and Prevention (CDC). Illness onset dates range from June 24, 2010, through July 16, 2010.

Color is NOT a reliable indicator that ground beef or ground beef patties have been cooked to a temperature high enough to kill harmful bacteria such as *E. coli* O157:H7.

The only way to be sure ground beef is cooked to a high enough temperature to kill harmful bacteria is to use a thermometer to measure the internal temperature.

Refrigerate raw meat and poultry within two hours after purchase or one hour if temperatures exceed 90° F. Refrigerate cooked meat and poultry within two hours after cooking.

FSIS determined that there is an association between the ground beef products subject to recall and the cluster of illnesses in the states of Maine and New York. FSIS regulations and statute allow the agency to take action on a product under its jurisdiction in cases where the product is convincingly associated to illness by evidence collected through an epidemiological, traceback investigation, and/or laboratory analysis. FSIS is continuing to work with affected state public health partners and the company on the investigation.

E. coli O26 is a bacterium that can cause bloody diarrhea, dehydration, and in the most severe cases, kidney failure. The very young, seniors and persons with weak immune systems are the most susceptible to foodborne illness. Individuals concerned about an illness should contact a health care provider.

FSIS routinely conducts recall effectiveness checks to verify recalling firms notify their customers (including restaurant's) of the recall and that steps are taken to make certain that the product is no longer available to consumers.

FSIS advises all consumers to safely prepare their raw meat products, including fresh and frozen, and only consume ground beef that has been cooked to a temperature of 160° F. The only way to confirm that ground beef is cooked to a temperature high enough to kill harmful bacteria is to use a food thermometer that measures internal temperature.

Consumers with questions regarding the recall should contact the company's Consumer Line at (877) 788-4953. Media with questions regarding the recall should contact the company's Director of Communications, Mike Martin at (316) 291-2126.

Consumers with food safety questions can "Ask Karen," the FSIS virtual representative available 24 hours a day at AskKaren.gov. The toll-free USDA Meat and Poultry Hotline 1-888-MPHotline (1-888-674-6854) is available in English and Spanish and can be reached from 10 a.m. to 4 p.m. (Eastern Time) Monday through Friday. Recorded food safety messages are available 24 hours a day.

#

Retail Distribution List (PDF Only)



Food Safety Questions? Ask Karen!
 FSIS' automated response system can provide food safety information 24/7

Follow FSIS on Twitter at
twitter.com/usdafoodsafety

www.fsis.usda.gov

Last Modified: August 28, 2010

Product Label



USDA Recall Classifications	
Class I	This is a health hazard situation where there is a reasonable probability that the use of the product will cause serious, adverse health consequences or death.
Class II	This is a health hazard situation where there is a remote probability of adverse health consequences from the use of the product.
Class III	This is a situation where the use of the product will not cause adverse health consequences.

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