

RECEIVED
FEBRUARY 1 2002
5

January 31, 2002

FSIS Docket Room
Room 102 Cotton Annex
300 12th Street, S.W.
Washington, D.C. 20250-3700

Re: Addendum to CSPI Comment on Draft Risk Assessment for *Escherichia coli* O157:H7 in Ground Beef, Docket No. 00-023N, 66 Fed. Reg. 55,912 (Nov. 5, 2001)

Dear Docket Room:

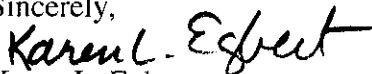
On January 4, 2002, the Center for Science in the Public Interest (CSPI) filed a comment on the Draft Risk Assessment for *Escherichia coli* O157:H7 in Ground Beef. In that comment, CSPI pointed out that the risk assessors had used *E. coli* O157:H7 outbreak data from the Centers for Disease Control and Prevention that does not represent the most complete set of foodborne-illness outbreak data available. We also indicated that CSPI's data show that between 1994 and 1999, 47% of outbreaks (45/96) and 22% of cases (470/2,105) from *E. coli* O157:H7 were linked to ground beef, and that these percentages are significantly higher than those obtained by the risk assessment team.

On page 11 of our comment, at footnote 38, we stated that the sources for CSPI's data were listed in an attached document, entitled "*E. coli* O157:H7 Outbreaks, 1994-1999." We did not, however, include that document with our comment. Enclosed please find the original and one copy of that document and another document, entitled, "Center of Science in the Public Interest's Outbreak-Tracking Methodology," which describes CSPI's outbreak-selection criteria and limitations of the database. Both of these documents should be included as addenda to our previously filed comment.

At the request of Dr. Michael Doyle, we also have recently submitted these documents, as well as the portion of our comment on the draft risk assessment relating to the estimated number of illnesses due to consumption of *E. coli* O157:H7-contaminated ground beef to the Committee on the Review of the Draft USDA *E. coli* O157:H7 Farm-to-Table Process Risk Assessment of the National Academies Institute of Medicine.

If you have any questions, please call me at (202) 332-9110, Extension 339.

Sincerely,


Karen L. Egbert
Senior Food Safety Attorney

Enclosures

cc: Dr. Allan Hogue, Branch Chief, USDA

**Center for Science in the Public Interest's Table:
E. coli O157:H7 Outbreaks 1994-1999***

#	Date	Vehicle	Etiology	Cases	States	Ref.
1994						
1	Jan-94	Ground beef	<i>Escherichia coli</i> O157:H7	21	2:OR, WA	2
2	Jan-94	Ground beef	<i>Escherichia coli</i> O157:H7	30	2:WA, OR	1, 3
3	Feb-94	Ground beef	<i>Escherichia coli</i> O157:H7	8	1:MN	1, 2
4	Apr-94	Ground beef	<i>Escherichia coli</i> O157:H7	24	1:NE	2
5	May-94	Ground beef	<i>Escherichia coli</i> O157:H7	33	1:ND	2
6	May-94	Ground beef	<i>Escherichia coli</i> O157:H7	9	1:CA	1, 2
7	Jun-94	Ground beef	<i>Escherichia coli</i> O157:H7	19	1:NY	2
8	Jun-94	Ground beef	<i>Escherichia coli</i> O157:H7	2	1:CT	2
9	Jun-94	Ground beef	<i>Escherichia coli</i> O157:H7	4	1:PA	2
10	Jul-94	Ground beef	<i>Escherichia coli</i> O157:H7	20	1:VA	2, 3
11	Jun-94	Hamburgers	<i>Escherichia coli</i> O157:H7	26	1:NJ	1,3
12	Jun-94	Hamburgers	<i>Escherichia coli</i> O157:H7	16	1:NY	1,3
13	Nov-94	Ground beef	<i>Escherichia coli</i> O157:H7	2	1:WA	1, 3, 5
14	Jul-94	Noodles with shrimp	<i>Escherichia coli</i> O157:H7	3	1:WA	5
15	Sep-94	Steak	<i>Escherichia coli</i> O157:H7	2	1:WA	1, 3, 5
16	Sep-94	Coleslaw; chicken soup	<i>Escherichia coli</i> O157:H7	11	1:MN	1
17	Sep-94	Potato salad	<i>Escherichia coli</i> O157:H7	37	1:NY	1
18	Sep-94	Salad bar	<i>Escherichia coli</i> O157:H7	26	1:TX	1

19	Nov-94	Dry cured salami	<i>Escherichia coli</i> O157:H7	15	1:WA	2, 5
20	Nov-94	Dry-cured salami	<i>Escherichia coli</i> O157:H7	23	2:CA,WA	1,3
21	Nov-94	Steak fingers	<i>Escherichia coli</i> O157:H7	20	1:NM	1
1995						
1	May-95	Ground beef	<i>Escherichia coli</i> O157:H7	2	1:MN	2
2	May-95	Ground beef	<i>Escherichia coli</i> O157:H7	4	1:MN	2
3	Jun-95	Ground beef	<i>Escherichia coli</i> O157:H7	3	1:SD	2
4	Jun-95	Ground beef	<i>Escherichia coli</i> O157:H7	8	2:GA, TN	2
5	Jun-95	Hamburger	<i>Escherichia coli</i> O157:H7	10	2: GA, TN	1,3
6	Jul-95	Ground beef	<i>Escherichia coli</i> O157:H7	12	1:NY	1, 2, 3
7	Jul-95	Ground beef	<i>Escherichia coli</i> O157:H7	21	1:CO	1, 2
8	Jul-95	Ground beef	<i>Escherichia coli</i> O157:H7	8	1:MA	2
9	Jul-95	Ground beef	<i>Escherichia coli</i> O157:H7	11	1:MA	1,3
10	Aug-95	Ground beef	<i>Escherichia coli</i> O157:H7	3	1:WA	5
11	Sep-95	Ground beef	<i>Escherichia coli</i> O157:H7	2	1:WA	2
12	Oct-95	Ground beef	<i>Escherichia coli</i> O157:H7	2	1:NY	1, 2, 3
13	Nov-95	Ground beef	<i>Escherichia coli</i> O157:H7	5	1:MN	2
14	Apr-95	Fish	<i>Escherichia coli</i> O157:H7	3	1:WA	5
15	Jul-95	Beef; veal	<i>Escherichia coli</i> O157:H7	12	1:NY	1
16	Jul-95	Lettuce (leafy green, red, romaine)	<i>Escherichia coli</i> O157:H7	74	1:MT	1, 2, 3
17	Aug-95	Roast beef	<i>Escherichia coli</i> O157:H7	31	1:MN	2
18	Aug-95	Roast beef	<i>Escherichia coli</i> O157:H7	11	1:MN	1,3

19	Sep-95	Caesar salad	<i>Escherichia coli</i> O157:H7	20	1:ID	1
20	Sep-95	Lettuce (iceberg)	<i>Escherichia coli</i> O157:H7	30	1:ME	1,3
21	Sep-95	Lettuce (romaine)	<i>Escherichia coli</i> O157:H7	20	1:ID	7
22	Oct-95	Beef; veal	<i>Escherichia coli</i> O157:H7	2	1:NY	1,3
23	Oct-95	Lettuce	<i>Escherichia coli</i> O157:H7	11	1:OH	1
24	Oct-95	Punch	<i>Escherichia coli</i> O157:H7	21	1:KS	1
25	Nov-95	Venison jerky	<i>Escherichia coli</i> O157:H7	11	1:OR	1, 2
1996						
1	Mar-96	Ground beef	<i>Escherichia coli</i> O157:H7	3	1:TX	6
2	Apr-96	Ground beef	<i>Escherichia coli</i> O157:H7	3	1:TX	1, 2
3	Apr-96	Hamburgers (suspected)	<i>Escherichia coli</i> O157:H7	2	1:IL	1
4	Jul-96	Ground beef	<i>Escherichia coli</i> O157:H7	2	1:NV	2
5	Aug-96	Ground beef	<i>Escherichia coli</i> O157:H7	9	1:PA	2
6	Sep-96	Ground beef	<i>Escherichia coli</i> O157:H7	7	1:OR	2
7	May-96	Lettuce (mesclun; red leaf)	<i>Escherichia coli</i> O157:H7	61	3:CT, IL, NY	1
8	Jun-96	Mesclun lettuce (suspected)	<i>Escherichia coli</i> O157:H7	7	1:NY	1
9	Jun-96	Pasta salad; cucumber; Italian dressing (suspected)	<i>Escherichia coli</i> O157:H7	60	1:NY	1
10	Oct-96	Apple cider	<i>Escherichia coli</i> O157:H7	12	1:CT	1,3
11	Oct-96	Apple cider	<i>Escherichia coli</i> O157:H7	6	1:WA	1, 2
12	Oct-96	Apple juice	<i>Escherichia coli</i> O157:H7	70	3:WA, CA, CO/1:BC	1, 3, 7
13	Nov-96	Venison	<i>Escherichia coli</i> O157:H7	2	1:IL	2

14	Dec-96	Venison	<i>Escherichia coli</i> O157:H7	4	1:OR	2
1997						
1	May-97	Ground beef	<i>Escherichia coli</i> O157:H7	5	1:FL	2
2	Jun-97	Ground beef	<i>Escherichia coli</i> O157:H7	15	2:CO, KY	2
3	Jun-97	Ground beef	<i>Escherichia coli</i> O157:H7	15	1:CO	1
4	May-97	Ice cream bars	<i>Escherichia coli</i> O157:H7	3	1:IL	1, 2
5	May-97	Melon/lemon bars	<i>Escherichia coli</i> O157:H7	9	1:OR	1, 2
6	Jun-97	Alfalfa sprouts	<i>Escherichia coli</i> O157:H7	108	2:VA, MI	1, 2
7	Oct-97	Unpasteurized apple cider	<i>Escherichia coli</i> O157:H7	6	1:IN	1
1998						
1	May-98	Ground beef	<i>Escherichia coli</i> O157:H7	2	1:WA	2
2	May-98	Ground beef	<i>Escherichia coli</i> O157:H7	22	4	2
3	Jun-98	Ground beef	<i>Escherichia coli</i> O157:H7	2	1:NY	2
4	Jun-98	Ground beef	<i>Escherichia coli</i> O157:H7	6	2:VA, NY	2
5	Jul-98	Ground beef (USDA); potatoes (FDA)	<i>Escherichia coli</i> O157:H7	10	1:UT	2
6	Sep-98	Ground beef	<i>Escherichia coli</i> O157:H7	8	1:WA	5
7	May-98	Cole slaw (cabbage)	<i>Escherichia coli</i> O157:H7	33	1:IN	2, 3
8	Jun-98	Cheese curds	<i>Escherichia coli</i> O157:H7	63	1:WI	2
9	Jun-98	Fruit salad	<i>Escherichia coli</i> O157:H7	40	1:WI	3
10	Jul-98	Cole slaw	<i>Escherichia coli</i> O157:H7	142	1:NC	2
11	Aug-98	Macaroni salad	<i>Escherichia coli</i> O157:H7	11	1:NY	2
12	Sep-98	Cake	<i>Escherichia coli</i> O157:H7	20	1:CA	2

13	Sep-98	Lasagna	<i>Escherichia coli</i> O157:H7	4	1:WA	5
14	Oct-98	Taco meat	<i>Escherichia coli</i> O157:H7	11	1:WA	5
1999						
1	Feb-99	Ground beef	<i>Escherichia coli</i> O157:H7	9	4:ME, MA, NH, MN	2
2	Apr-99	Ground beef	<i>Escherichia coli</i> O157:H7	24	6:CT, MA, NH, NY, RI, VA	2
3	Jun-99	Ground beef	<i>Escherichia coli</i> O157:H7	16	6:CT, MA, NY, RI, SD, VT	2
4	Jun-99	Hamburger	<i>Escherichia coli</i> O157:H7	5	1:WA	5
5	1999	Apple juice	<i>Escherichia coli</i> O157:H7	9	1:OK	4
6	Feb-99	Lettuce (iceberg)	<i>Escherichia coli</i> O157:H7	72	1:NE	2
7	Jun-99	Cole slaw	<i>Escherichia coli</i> O157:H7	16	1:OH	2
8	Jul-99	Cabbage	<i>Escherichia coli</i> O157:H7	11	1:OH	7
9	Sep-99	Romaine lettuce	<i>Escherichia coli</i> O157:H7	6	1:WA	5
10	Sep-99	Steer	<i>Escherichia coli</i> O157:H7	323	1:IL	2
11	Oct-99	Lettuce	<i>Escherichia coli</i> O157:H7	47	2:OH, IN	7
12	Oct-99	Romaine lettuce	<i>Escherichia coli</i> O157:H7	44	2:OR, PA	2
13	Oct-99	Unpasteurized apple cider	<i>Escherichia coli</i> O157:H7	17	1:OK	2
14	Nov-99	Beef tacos	<i>Escherichia coli</i> O157:H7	14	3:NV, AZ, CA	7
15	Nov-99	Hard shell tacos	<i>Escherichia coli</i> O157:H7	21	8:CA, AZ, IN, MA, MN, ND, NV, SD	2

Outbreaks	96
------------------	-----------

Cases	2,105
--------------	--------------

References

(Listed in order of importance)

1. Centers for Disease Control and Prevention, U.S. Foodborne Disease Outbreaks, 1990-1997 updated September, 2001. <http://www.cdc.gov/ncidod/dbmd/outbreak/us_outb.htm>
2. Centers for Disease Control and Prevention, *E. coli* O157 Outbreak Summaries, years 1994-1997 obtained by FOIA, years 1998-1999 obtained online at <http://www.cdc.gov/ncidod/dbmd/outbreak/ecoli_sum.htm>
3. Centers for Disease Control and Prevention, U.S. Foodborne Disease Outbreaks, 1990-1998 Obtained by FOIA from the CDC.
4. 66 Fed. Reg. 6181(Jan. 19, 2001)
5. Washington State Health Department, Confirmed Outbreaks of Foodborne Disease, Washington State, 1990-1999. Obtained by calling the Washington State Health Department.
6. State-health department news release or publication.
7. Newspaper or internet report verified by call to public-health official.

Number of outbreaks from the CDC's *E. coli* O157 Summaries: 54

Number of outbreaks from other sources (including other CDC lists): 42

*Prepared in response to a request made December 17th, 2001 by the National Academy of Sciences at a meeting of the Committee on the Review of the Draft USDA *E. coli* O157:H7 Farm-to-Table Process Risk Assessment. Source: CSPI's *Outbreak Alert!* (October 2001 edition).

Center for Science in the Public Interest's Outbreak-Tracking Methodology

Foodborne illness is estimated to cause 76 million illnesses and 5,000 deaths per year, yet outbreak investigation and reporting are woefully inadequate in the United States.¹ In 1997, the Center for Science in the Public Interest (CSPI) began to compile its database of foodborne-illness outbreaks when efforts to obtain a comprehensive list from the Centers for Disease Control and Prevention (CDC) failed. CSPI's *Outbreak Alert!* database details outbreaks that occurred in the U.S. and its territories between 1990-2001.² Incidents of foodborne illness were only included in CSPI's database if they met the definition of an outbreak,³ had an identified etiology and food vehicle, and were reported by a reliable source.⁴ CSPI's database was compiled from confirmed outbreaks with known causes and food sources listed on CDC's "U.S. Foodborne Illness Outbreaks, 1990-1997," CDC's "*E. coli* O157 Summaries," government publications, and scientific journal articles. Additional outbreaks were discovered in health-department postings and in newspaper and internet reports. Reports from these sources were verified by calls to public-health officials.

Once an outbreak report was found to meet CSPI's criteria, it was further evaluated to determine if it was already listed in the database or represented a new outbreak. If the new report simply updated information already in CSPI's database, the database was changed to reflect the

¹ See CSPI's *Outbreak Alert!* (October 2001 edition).

² Some illnesses from Canada and other countries were included if the outbreak also occurred in the U.S.

³ A foodborne disease outbreak is defined as an incident in which two or more people experienced a similar illness after ingestion of a common food, except in the case of botulism, where one illness is considered an outbreak.

⁴ The CDC's U.S. Foodborne Illness Outbreaks, 1990-1997 contained over 3,000 outbreaks with unknown etiology or vehicles that were not included in CSPI's database.

most recent or reliable information. A report was added as a new outbreak, however, if it had a reliable source and could not, *with certainty*, be identified with an outbreak already included in the database. Despite careful screening, a small number of listings may represent duplicate entries.

Other limitations of CSPI's database stem from inadequacies of foodborne-illness investigation and reporting in the U.S. The most critical limitation of the database is that foodborne illnesses are vastly under-reported, so information about outbreaks may never make its way into public record and is not included in CSPI's database.⁵ To increase outbreak reporting, CSPI has educated consumers about foodborne illness and has called for CDC to use computer-based systems to streamline outbreak reporting. In the years since these recommendations were made, the CDC has told CSPI that foodborne-illness reporting by the states has significantly increased. In fact, the CDC's most recent update of their general foodborne-illness database contained over 500 outbreaks that were not reported on their previous list.

Despite the recent improvements in numbers of outbreaks reported, reporting by the states is still not uniform because some states publish reports of food-poisoning outbreaks on a regular basis, while others do not release this information due to privacy concerns. CSPI has called for regular reporting by the states and has employed an active rather than a passive system of outbreak monitoring for its database.⁶ By actively monitoring non-CDC sources, CSPI has been able to increase the size of its database by approximately 10 percent.

⁵ In order for an outbreak to be reported: people who become ill must seek medical treatment; doctors must order diagnostic tests or sampling; tests must be able to detect low numbers of organisms; and diagnosed illnesses must be reported to public-health agencies.

⁶ The CDC passively monitors most outbreaks, i.e., they only list outbreaks in their database that the states report to them, while CSPI calls the states to ask them about outbreaks.

Third, outbreak information is often not released until months, or even years, after the outbreak is investigated. To address this limitation, CSPI monitors news releases, scientific journals, and state-health departments for the newest outbreak information. This has allowed CSPI to publish a database with outbreaks as recent as 2001, while the newest outbreaks on CDC's most comparable database (U.S. Foodborne Illness Outbreaks, 1990-1997) date from 1997.

Even with these limitations, CSPI's database can still be considered the most comprehensive and up-to-date database of its kind. This is due to CSPI's efforts to actively monitor outbreak reports and to use the most current information available. CSPI has also been working to increase public knowledge about foodborne illness and to encourage the CDC to make improvements in outbreak investigation and reporting. As these improvements are made in the reporting of outbreaks, this database can continue to provide an increasingly accurate picture of the scope of foodborne illness in the United States.

The *E. coli* O157:H7 Table

The attached table, "*E. coli* O157:H7 Outbreaks, 1994-1999," includes 96 outbreaks and 2,105 illnesses summarized from CSPI's *Outbreak Alert!* database. The source of each outbreak is indicated by a number in the reference column and is listed at the end of the document, in order of importance. CSPI's table only includes the confirmed outbreaks from the CDC's lists.⁷ Using CSPI's strict outbreak criteria (see above), only 54 out of the 88 outbreaks of foodborne *E.*

⁷ Also not included are outbreaks with numbers that have been updated by a more recent source or did not identify a specific food as the vehicle.

coli O157:H7 listed in the CDC Summaries could be included in CSPI's table.⁸ Forty-two other outbreaks were identified from other sources, including CDC's larger line listing, 1990-1997. Even taking into account differences in outbreak criteria, more foodborne outbreaks (96 vs. 88) are listed on CSPI's table than in the CDC's *E. coli* O157 Summaries used by the risk assessors. Thus, if the risk assessors used CSPI's more complete data in the analysis, the likely result would be a more accurate estimation of illness from *E. coli* O157:H7-contaminated ground beef.

⁸ The other 42 outbreaks did not meet CSPI's criteria. For example, some outbreaks used by the risk assessors had foodborne modes of transmission, but a specific-food vehicle was not identified. CSPI did not include these outbreaks because it could not be determined, with certainty, whether or not ground beef was involved.