



Centers for Disease Control and Prevention



National Center for Emerging and Zoonotic Infectious Diseases
1600 Clifton Rd., MS E-93
Atlanta GA 30329

April 15, 2016, 2016

Mr. Bryant “Corky” Messner, Esq.
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Dear Mr. Messner,

This is in response to your letter, dated December 21, 2015 from Messner Reeves, LLP. In your letter you express concern that certain web updates related to multistate outbreaks of Shiga toxin-producing *Escherichia coli* O26 (STEC O26) infections linked to Chipotle Mexican Grill restaurants (<http://www.cdc.gov/ecoli/2015/o26-11-15/index.html>) do not include “the most accurate information available” and that they “actually misinform the public.” You also raise concerns that these web updates “...do not conform with CDC guidelines, and Office of Management and Budget (“OMB”) and Department of Health and Human Services (“HHS”) regulations concerning dissemination of information to the public.”

Background

The Centers for Disease Control and Prevention (CDC) is the lead federal agency for protecting the health and safety of people at home and abroad, providing credible information to enhance health decisions and promoting health through strong partnerships. CDC follows guidance as specified in OMB Guidelines for Ensuring and Maximizing the Quality, Objectivity, and Integrity of Information Disseminated by Federal Agencies (see <http://www.whitehouse.gov/sites/default/files/omb/fedreg/reproducible2.pdf> and <http://aspe.hhs.gov/infoquality/Guidelines/cdcinfo2.shtml>). CDC also follows the Transparency and Open Government Memorandum for Heads of Executive Departments and Agencies, which requires us to take appropriate action, consistent with law and policy, to disclose information rapidly in forms that the public can readily find and use (https://www.whitehouse.gov/the_press_office/TransparencyandOpenGovernment). This guidance was issued to ensure the public trust and establish a system of transparency, public participation, and collaboration.

CDC, the U.S. Food and Drug Administration, the U.S. Department of Agriculture Food Safety and Inspection Service, and public health and regulatory officials in several states investigated two outbreaks of STEC O26 infections. Fifty-five people were infected with the outbreak strain of STEC O26 from eleven states in the initial outbreak. The DNA fingerprint of this STEC O26 was extremely rare, providing strong laboratory evidence that the illnesses were all linked to a common contaminated food item. Twenty-one ill people were hospitalized. There were no

reports of hemolytic uremic syndrome and no deaths. The majority of illnesses were reported from Washington and Oregon during October 2015. The epidemiologic evidence available at that time suggests that a common meal item or ingredient served at Chipotle Mexican Grill restaurants in several states was a likely source of this outbreak. The investigation did not identify what specific food was linked to illness. Forty-seven (87%) of 54 ill people interviewed reported eating at a Chipotle Mexican Grill restaurant in the week before their illness started. CDC also investigated a second, more recent outbreak of another rare DNA fingerprint of Shiga toxin-producing *E. coli* O26 (STEC O26) linked to Chipotle Mexican Grill. Because it was not known whether these infections were related to the initial outbreak of STEC O26 infections, these illnesses were not included in the case count for that outbreak. All five (100%) people infected in the second outbreak reported eating at a Chipotle Mexican Grill in the week before illness started. Three ill people ate at a single Chipotle location in Oklahoma and two ill people ate at a single Chipotle location in Kansas. This investigation also did not identify what specific food was linked to the illnesses. On February 1, 2016, CDC posted a final web update declaring that the two outbreaks appeared to be over.

Responses to concerns raised in your letter:

Regarding your statement on page 1, “*Despite no ongoing threat, with four weeks passing between the last exposure date and the most recent web update, the web updates did not serve to protect the public and, in fact, led to inaccurate conclusions,*” CDC has the following response:

An infected person is included in the case-count of an outbreak if he/she meets a specific case-definition. The development of case definitions for an outbreak investigation is a cornerstone of public health epidemiology practice, the principles of which are amply described in standard reference textbooks (e.g., Gregg MD. *Field Epidemiology*, Second Edition. New York: Oxford University Press, 2002). The case definitions for these two investigations define cases as those that appear on reports of ill people to the PulseNet system (<http://www.cdc.gov/pulsenet>) infected with the molecularly-defined outbreak strain of the pathogen; they are not based on whether a person consumed food at Chipotle Mexican Grill before becoming ill. All multistate foodborne outbreak caused by *Escherichia coli*, *Salmonella enterica*, and *Listeria monocytogenes* use this type of “molecular” case definition. It is a basic tenant of the science of epidemiology that using an exposure as a part of a case definition biases epidemiologic assessment of the outbreak source. In other words, requiring exposure to Chipotle restaurants in order to meet the case definition would preclude the ability to assess other exposures as potential causes of the outbreak.

PulseNet, a program coordinated by CDC, is the national subtyping network of public health and food regulatory agency laboratories that work together to detect and investigate foodborne and other outbreaks. DNA “fingerprinting” is performed on *E. coli* and other bacteria isolated from ill people by using a technique called pulsed-field gel electrophoresis (<http://www.cdc.gov/pulsenet/pathogens/pfge.html>) or PFGE. PulseNet manages a national database of these DNA fingerprints to identify possible outbreaks. It takes an average of 2 to 3 weeks between the time a person becomes ill and when the illness is reported to PulseNet (<http://www.cdc.gov/ecoli/reporting-timeline.html>). For non-O157 STEC infections like STEC O26, published estimates suggest that there are over 100 illnesses that remain undiagnosed for each one that is reported to PulseNet (http://wwwnc.cdc.gov/eid/article/17/1/P1-1101_article), meaning that the official case counts typically substantially underestimate the impact of outbreaks.

In the initial outbreak of 55 cases linked to Chipotle Mexican Grill Restaurants, the case definition is an *E. coli* O26 infection with isolate matching PFGE pattern EVCX01.1180 reported to PulseNet with an isolation date on or after October 20, 2015. In the second outbreak linked to Chipotle Mexican Grill Restaurants, the case definition is an *E. coli* O26 infection with isolate matching PFGE pattern EVCX01.0670 with an isolation date on or after November 24, 2015. Reported illness onset dates in these two outbreaks range from October 19, 2015 to December 1, 2015. Given that two to three weeks typically pass between when a person becomes ill to when the illness is reported to PulseNet and the most recent illness onset date of December 1, 2015, we disagree that there was “no ongoing threat” at the time of the web postings, particularly since the investigation of these two outbreaks linked to Chipotle Mexican Grill Restaurants has not identified a specific cause. A public health professional would not conclude that transmission had ceased until at least several weeks after the last reported case.

CDC believes that the web postings served to protect and inform the public as well as inform public health and regulatory partners at the federal, state, and local level about this ongoing outbreak investigation in three ways. First, information provided in these web posting provided people who may have become ill after eating at Chipotle Mexican Grill locations with information they might need to seek diagnosis and treatment for a potentially serious illness (*E. coli* O26 infection); medical attention would also entail provision of information on measures to prevent secondary transmission of STEC infection to other close contacts such as family members. Second, this information also could assist in identifying additional ill people who might provide critical information essential to determine the specific cause of the outbreak. Third, the web postings provided information the public might use to protect themselves by choosing to avoid certain food exposures associated with the outbreak.

Regarding your statement on page 3, “*Chipotle has concerns that various web updates do not meet the standards promulgated by the CDC. Each web update must stand on its own and independently comply with the CDC guidelines, and it appears that many of the web updates do not.*” CDC has the following response:

Each web posting by CDC followed and complied with all applicable agency guidelines and policy. This included a formal review and clearance process before release as specified in “Guidelines for Ensuring the Quality of Information Disseminated to the Public” (<http://aspe.hhs.gov/infoquality/Guidelines/cdcinfo2.shtml>)

Regarding your statements on page 3, “*The CDC’s December 4, 2015 web update misinformed the public as the current status of the outbreak*” and “*... in the web update CDC made no effort to advise the public that these ill individuals had no known connection with Chipotle,*” CDC has the following response:

The December 4, 2015 web posting provided the public as well as public health and regulatory partners in federal, state, and local agencies with updated information regarding an ongoing investigation. This included information on the seven ill people which had been newly identified since the preceding web posting on November 20, 2015. CDC reported in this posting that several of these individuals did not recall eating at Chipotle Mexican Grill in the week before their illness began. Specifically, the December 4, 2015 web posting includes the following statement in the “What’s New “ and “Investigation Update” sections: “Of the three most recent illnesses reported in November, only one ill person, whose illness started on November 10,

reported eating at Chipotle Mexican Grill in the week before their illness began.” The December 4, 2015 web posting also included the information that seven additional ill people had been reported from California (1), Illinois (1), Maryland (1), Ohio (2), Pennsylvania (1), and Washington (1) since the preceding update. Two of these people became ill in October and five became ill in November 2015. The update also stated that Illinois, Maryland, and Pennsylvania had been added to the list of states reporting illnesses, bringing the total to nine states. In all multistate foodborne outbreak investigations coordinated by CDC, including these, ill people are included on the basis of the “DNA fingerprint” of the bacterium causing illness. In this investigation, the fingerprint of both STEC O26 strains are extremely rare, indicating that ill people are highly likely to be related to a common contaminated food source. Several reasons could explain why ill people included in such investigations may not report consuming the food item causing the outbreak. First, these people may not remember eating at Chipotle Mexican Grill before they got sick, but actually did. It can be several weeks from the time a person gets sick until they are confirmed to be part of an outbreak and interviewed by the health department. Second, they may have gotten sick by “secondary transmission,” that is, through close contact with someone else who got sick after eating at a Chipotle Mexican Grill. There is evidence of secondary transmission as the mode of infection for at least two people in this investigation who did not report eating at Chipotle before becoming sick. Third, it could be due to a contaminated ingredient served at Chipotle restaurants having been sent to a limited number of other places, where the person ate the contaminated and then became ill.

Regarding your statement on page 4, “... *Chipotle does not believe the web updates between November 4, 2015, and November 6, 2015 provided the public with information that was clear and useful, as mandated by CDC regulations,*” CDC has the following response:

The web postings on November 4, 2015, November 5, 2015, and November 6, 2015 provided information regarding the ongoing outbreak investigation linked to Chipotle Mexican Grill that, at the time, was limited to illnesses in Washington and Oregon. At that point in the investigation, the content of the web updates summarized information that had already been released publicly by health officials in Washington and Oregon. As stated previously, each of these web postings followed and complied with all applicable agency guidelines and policy which included a formal review and clearance process prior to release as specified in “Guidelines for Ensuring the Quality of Information Disseminated to the Public” (<http://aspe.hhs.gov/infoquality/Guidelines/cdcinfo2.shtml>). The web postings served to protect and inform the public as well as inform public health and regulatory partners at federal, state, and local agencies about this ongoing outbreak investigation in three ways. First, information provided in these web posting provided people who may have become ill after eating at Chipotle Mexican Grill locations with information they might need to seek diagnosis and treatment for a potentially serious illness (*E. coli* O26 infection); medical attention would also entail provision of information on measures to prevent secondary transmission of STEC infection to other close contacts such as family members. Second, this information also could assist in identifying additional ill people who might provide critical information essential to determine the specific cause of the outbreak. Third, the web postings provided information the public might use to protect themselves by choosing to avoid certain food exposures associated with the outbreak.

Regarding your statement on page 5, “*Similarly, on November 20, 2015, the CDC reported six cases of E. coli O26 throughout four additional States. It does not appear that the information provided in this update was useful to the public.*” CDC has the following response:

The November 20, 2015 CDC web posting provided the public as well as public health and regulatory partners in federal, state, and local agencies information regarding the ongoing investigation. This included information on the eight ill people which had been newly identified since the previous posting on November 17, 2015. CDC believes that the web postings served to protect and inform the public as well as inform public health and regulatory partners at federal, state, and local agencies about this ongoing outbreak investigation in three ways. First, information provided in these web posting provided people who may have become ill after eating at Chipotle Mexican Grill locations with information they might need to seek diagnosis and treatment for a potentially serious illness (*E. coli* O26 infection); medical attention would also entail provision of information on measures to prevent secondary transmission of STEC infection to other close contacts such as family members. Second, this information also could assist in identifying additional ill people who might provide critical information essential to determine the specific cause of the outbreak. Third, the web postings provided information the public might use to protect themselves by choosing to avoid certain food exposures associated with the outbreak.

Regarding your statement on page 6, *“The HHS has adopted various guidelines for the dissemination of adverse information through the media. See 45 C.F.R. 17.1 et seq. It is the CDC’s position that these regulations not apply to CDC.”* CDC has the following response:

CDC adheres to applicable sections 45 C.F.R. 17.1 et seq. However, 45 C.F.R. 17.4 applies only to regulatory investigations and trial-type proceedings. CDC is not a regulatory agency with respect to food and the food supply. As such, this section does not apply to CDC.

Regarding your statement on page 7, *“...CDC officials have made misleading statements and unnecessary comments to the media about matters which relate to an ongoing agency investigation. On November 20, 2015, a CDC representative was quoted by a national new outlet as follows: The cause of the outbreak hasn’t been determined, but it ‘probably wasn’t meat,’ Matt Wise, a CDC epidemiologist who is leading the investigation, said in an interview. He noted that a ‘couple of vegetarians’ are among those sickened. ‘The fact that these outbreaks don’t seem to be confined to a geographical region is harmful to the brand’, he said Chipotle’s brand-perception problem has just gone coast to coast.”* CDC has the following response:

The first two statements attributed to Dr. Wise are correctly attributed to Dr. Wise and constitute an accurate characterization of the investigation findings to date (“The cause of the outbreak hasn’t been determined, but it ‘probably wasn’t meat,’ Matt Wise, a CDC epidemiologist who is leading the investigation, said in an interview. He noted that a ‘couple of vegetarians’ are among those sickened.”). As shown on page 1 of Exhibit B in the Information Quality Challenge submitted by Messner Reeves, LLC, the third statement (“The fact that these outbreaks don’t seem to be confined to a geographical region is harmful to the brand”, he said, “Chipotle’s brand-perception problem has just gone coast to coast”) is clearly attributed to Asit Sharma, “an Analyst at the Motley Fool” who is not an employee of CDC or any Department of Health and Human Services agency.

Regarding your statement on page 7, *“It is our understanding that the CDC is relying upon the holding of Dimare Fresh Inc. v U.S. in its justification of the web updates.”* CDC has the following response:

CDC is not relying upon the holding of *Dimare Fresh Inc. v U.S.* with regards to web updates for the multistate outbreaks of Shiga toxin-producing *Escherichia coli* O26 infections linked to

Chipotle Mexican Grill Restaurants (<http://www.cdc.gov/ecoli/2015/O26-11-15/index.html>). While *Dimare* may support CDC's actions in this investigation, the agency's actions are governed by its statutory authority as a federal public health agency.

We hope these explanations answer your concerns. If you wish to appeal this response to your request for a correction, you may send a written hard copy or electronic request for reconsideration within 30 days of receipt of the agency's decision. The appeal must state the reasons why the agency response is insufficient or inadequate. You must attach a copy of their original request and the agency's response to it. Clearly mark the appeal with the words, "Information Quality Appeal," and send the appeal by mail to CDC/ATSDR, Attn: Mailstop D-72 (attn.: Office of Science Quality); 1600 Clifton Road, N.E., Atlanta, GA 30333 or by e-mail to InfoQuality@cdc.gov.

Sincerely,

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CDC
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