

## **Mr. President, Can You Hear Us Now?**

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Food Safety News Op-Ed

June 06, 2011

Link: <http://www.foodsafetynews.com/2011/06/mr-president-can-you-hear-us-now>

Like the familiar cell phone coverage commercial on television, we are beginning to wonder if the President and his appointees at the U.S. Department of Agriculture (USDA) and the Office of Management and Budget (OMB) are getting any of the many messages being delivered daily about the danger of non-O157 Shiga toxin-producing E. coli (STECs) and the need to declare them adulterants in ground beef. You would think the enormous, tragic outbreaks of E. coli illnesses caused by serotype O would be hard to miss.

Perhaps messages are getting through to the folks at OMB, but the ones having an impact come from U.S. trading partners. Some of our partners haven't had a problem with E. coli O157:H7, but do have evidence of other Shiga toxin-producing E. coli in their food supply. They aren't eager to have their exports tested. Those folks clearly have the ear of the U.S. Trade Representative and he, in turn, makes their case to the President.

We know the American Meat Institute, which went to court in 1994 trying to prevent FSIS from treating E. coli O157:H7 as an adulterant, has been to OMB to argue its case against declaring additional strains of E. coli as adulterants. We don't know what possible arguments they could make for inaction given recent developments showing these pathogens are both virulent and common in U.S. meat.

We know, as well, whose advice the White House apparently does not take on food safety and the dangers of Shiga toxin-producing E. coli. The ones without influence would include the USDA's Under Secretary for Food Safety and the Food Safety and Inspection Service. They are the people responsible for the safety of the meat, poultry and egg products (maybe catfish someday) in the U.S. In January of this year, they asked OMB to approve expanding the per se adulteration designation to several non-O157 STECs.

The list of those not being clearly heard also includes consumer organizations, some of whom went to OMB in April urging them to approve the FSIS proposal. Instead of moving forward, the OMB extended the review period. According to the FSIS staff, the Agency asked OMB to extend the review. That's usually a sign they thought that was the only alternative to having the proposal rejected outright.

The bottom line is, however, that the USDA's food safety staff read the literature, examined the data and sought action to reduce the chance of more people getting sick from pathogenic E. coli serotypes in addition to O157:H7. They have been overruled by more powerful forces and Americans are subject to a greater risk than we should be.

Rulemaking takes at least two years, and usually more when the regulated industry is opposed to the action. If OMB reverses its current position and frees FSIS to move ahead, it will still be

months or years before meat coming into the U.S. from other countries will be tested to be sure it is free of the pathogen that recently has caused over 2,000 illnesses in Europe.

By comparison, it only took weeks to get Interim Rules into effect after the U.S. found its first cow that had "Mad Cow Disease," a necessary move so we could resume exporting beef to our trading partners. No one in the U.S. has ever become ill with variant CJD from eating meat from a U.S. cow.

It is possible that the FDA will, as part of its rulemaking under the new FDA Food Safety Modernization Act, name E. coli O104:H4 as an adulterant in fresh produce before USDA is freed to require companies to keep it out of our meat supply. As public policy, that's hard to support. The immediate vector in Europe may be produce but the original pathogenic E. coli was almost surely harbored in the intestine of an animal used for food, most likely a beef animal.

At the time we are writing this, news is coming that the culprit food may be sprouts. If so, they would have likely become contaminated by being exposed to water contaminated with animal waste. But regardless of the vector for this most recent disaster, the current issue on the table of OMB is what to do about these pathogens in our meat.

One month ago, May 2, 2011, to be exact, we joined forces to [write an OpEd](#) for **Food Safety News** trying to bring readers up to date on new developments regarding non-O157 STECs, and debunking some of the most commonly stated reasons for not declaring them adulterants in ground beef.

In the 30-plus days since we penned that opinion piece, we have seen two international outbreaks of epic proportions.

Japan has nearly 100 ill from the non-O154 STEC known as O111. There are 23 victims with hemolytic uremic syndrome and 4 dead. All from eating beef. And it was steak, not ground beef.

Germany has been the country of origin for over 2,153 illnesses from a non-O157 STEC known as O104:H4, with over 625 cases of HUS and 22 deaths. It is the third largest E. coli outbreak in history, and probably the deadliest.

In our May 2 piece we noted that HUS cases in illnesses from the only banned E. coli, known as O157:H7, are usually in the 8 percent range of all victims. In these two international outbreaks, the HUS rate is near (Japan) or well over (Germany) 25 percent of all victims. For those who have long contended these pathogens are not as virulent as O157:H7 and can therefore be ignored, we say, as we did on May 2, tell that to the families of the deceased or those who will have life-long health issues from their kidney damage.

In these 30 short days, some more information regarding the frequency of non-O157 STECs in (or on) the beef we eat has come to light, helping to squelch another argument against taking any action at this time.

A graduate student at Texas Tech University, Jessie Vipham, working with world famous E. coli expert Dr. Guy Loneran and others, bought beef and sampled whole muscle cuts and ground beef for E. coli and other pathogens. Her findings showed that 5.9 percent of all beef was contaminated with non-O157 STECs. She found the pathogens in 7 percent of ground beef, and 4.1 percent in whole muscle cuts.

She was looking for what is known as the Big Six, the six most prevalent non-O157s thought to cause human illnesses in the U.S. She found O26, O145, O103 and the afore-mentioned O111 that caused Japan's outbreak. She did not find O121 or O45, the other two listed in the Big Six, and she did not test for O104:H4.

The Big Six is important because these are the six pathogens we think FSIS will try to declare as adulterants. That will not help us with any new pathogens that mutate and become killers, like the O104:H4 bug found in so many victims in Germany and from recent travelers to Germany in 11 other countries. The Big Six would be a Big Start, but maybe we need to rethink this in light of the last 30 days of new information and just say any Shiga toxin-producing E. coli should be banned?

The Food and Drug Administration noted last Friday that "the FDA considers any disease causing strain of E. coli in food to be illegal."

President Obama named Mike Taylor the food safety guru at the FDA. This is the same Mike Taylor who, as Acting Under Secretary for Food Safety, changed the landscape of meat and poultry safety by declaring E. coli O157:H7 to be an adulterant in ground beef in 1994. He did not go through the rule-making process to get there but based his decision on the language of existing law. You need a sense of urgency to create change and Taylor had the Jack in the Box disaster. We now have Germany dwarfing the Jack in the Box for numbers.

It appears the FDA and Taylor are now ready to treat E. coli serotypes, in addition to O157:H7, as adulterants in FDA-regulated products. Does the Obama Administration apply different scientific standards to the FDA than it does to the FSIS?

Secretary Vilsack, on the other hand, has publicly dismissed the urgency of expanding protection against other disease-causing E. coli strains. At a press conference last week he said nothing in his prepared statement about the European E. coli outbreak and made no appeal to USDA to act on the rest of the more common and virulent species of E. coli in the U.S. Responding to a question, he allowed as how he has "no reason to believe what is specifically occurring in Europe is going to happen over here, because of what happened in Europe."

Perhaps he should have consulted his scientists in FSIS and ARS. They could have told him about Salmonella enteritidis, the serotype that began in European chickens and eggs, then skipped across the Atlantic and spread across the U.S. to become the most common form of Salmonella food poisoning. Our food system is global. Bugs mutate and travel. We have reason to believe this form of E. coli can, and probably will, happen here.

Robert Tauxe M.D., a foodborne illness expert with the Centers for Disease Control, perhaps put it better when he was quoted as saying: "It's a wake-up call, around the world." We hope the President has heard this "call" and the others mentioned above.

The President, his OMB officials, the Secretary of Agriculture and the House Ag Appropriations Committee need to wake up, recognize the danger, and heed the cries of pain emanating from Europe. The infectious disease experts at the CDC are obviously concerned and see the need for action.

We, two former public officials sworn to protect the public against illnesses caused by contaminated meat and poultry, add our appeal to those of the CDC infectious disease experts and the USDA's current food safety leaders. Please, Mr. President, direct the USDA to declare that any meat product that shows evidence of any disease-causing E. coli organism is adulterated. Require FSIS to sample and test for the presence of these dangerous strains of E. coli.

Can't we learn from Japan and Germany and act before more illnesses start to turn up in the U.S.? Politics and trade must take a back seat to preventing serious illnesses and deaths. Go find any infected meat that is out there and get it off the market now. Make sure the "USDA inspected and approved" stamp applied to products that meet FSIS's standards continues to mean someone cares and is acting to protect the public's health.

Mr. President, can you hear us now?

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