Comments of Consumers Union on
United States Department of Agriculture (USDA) Food Safety Inspection Service (FSIS)
Final determination on Shiga Toxin-Producing *Escherichia coli* in Certain Raw Beef Products
Docket Number FSIS—2010—0023
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Consumers Union[1] (CU) welcomes the opportunity to comment on the US Department of Agriculture (USDA), Food Safety and Inspection Service's (FSIS) policy to start sampling and testing raw beef and beef components (e.g. trim,) for six serogroups of Shiga toxin producing *Escherichia coli* (STEC) (O26, O45, O103, O111, O121, and O145) in addition to *E. coli* O157:H7. We commend FSIS for this sampling and testing policy,and strongly agree with thetm that these six non-O157 STEC should be classified as adulterants when found in non-intact raw beef products and product components, for the reasons outlined below. We also urge FSIS to begin the sampling and testing in March 2012 as scheduled and not to delay implementation. Further, we urge FSIS not to switch to a less sensitive sampling method (collecting one 325-gm sample rather than collecting five 65-gm sub-samples) until they have released the Agency study that supported making the switch for comment by the public. In addition, we urge FSIS to go further and to declare these 6 non-O157 STECs adulterants when they appear on *any* beef ingredients, and not just when found on non-intact raw beef product and product components. Next, FSIS should expand the testing and sampling policy to include other non-O157 STECs as well.

FSIS regulatory sampling plan for the "Big 6" non-O157 STECs is appropriate

CU strongly supports FSIS's decision to declare six STECs (O26, O45, O103, O111, O121, and O145) in addition to *E. coli* O157:H7 as adulterants. According to USDA, there are 300-400 STEC serotypes, but only some of them have been associated with human illnesses.[2] In 2003, Dr,. Karmali, a scientist with Health Canada and colleagues proposed a classification system for the STEC strains and divided them into 5 seropathotypes, based on their reported frequencies in human illness, and their known associations with outbreaks and severe outcomes such as HUS (hemolytic uremic syndrome) and hemorrhagic colitis.[3] There are five seropathotype classifications, A through E, with seropathotype A being associated with highest incidence of human disease and associated with outbreaks and severe disease. The serotype A

[1] *Consumers Union is the public policy and advocacy division of Consumer Reports. Consumers Union works for telecommunications reform, health reform, food and product safety, financial reform, and other consumer issues. Consumer Reports is the world's largest independent product-testing organization. Using its more than 50 labs, auto test center, and survey research center, the nonprofit rates thousands of products and services annually. Founded in 1936, Consumer Reports has over 8 million subscribers to its magazine, website, and other publications* .

[2] Office of Public Health Science (FSIS/USDA). 2011. DRAFT Risk Profile for Pathogenic Non-O157 Shiga Toxin-Producing *Escherichia coli* (non-O157 STEC). At: http://www.fsis.usda.gov/PDF/Non_O157_STEC_Risk_Profile.pdf

[3] Karmali MA, Mascarenhas M, Shen S, Ziebell K, Johnson S, Reid-Smith R, Isaac-Renton J, Clark C, Rahn K and JB Kaper. 2003. Association of genomic O island 122 of *Escherichia coli* EDL 933 with verocytotoxinproducing *Escherichia coli* seropathotypes that are linked to epidemic and/or serious disease. *J Clin Microbiol*. 41(11):4930-40. At: http://jcm.asm.org/content/41/11/4930.full.pdf

includes the *E. coli* O157 strains that most commonly cause outbreaks. Seropathotype B has "moderate" incidence in human disease, but also involved in outbreaks and can result in severe disease symptoms. Serotypes in B include O26, O45, O103, O111, O121, and O145[4], i.e. the STECs that USDA is considering classifying as adulterants. According to data from Centers for Disease Control and Prevention (CDC) Bacterial Foodborne and Diarrheal Disease National Case Surveillance Annual reports from 2003-2006, these 6 STECs represented some 70%-83.5% of the serogroups of human non-O157 STECs infections/illnesses[5]. As USDA notes, all of the "Big 6" non-O157 STEC strains can cause hemorraghic colitis, and all but O45 have been shown to cause hemolytic uremic syndrome, thus indicating that they can cause severe disease. Seropathotype C, the atypical enterohemorhhagic *E. coli*, are less frequently involved in hemorrhagic diseases than B, but are still a frequent cause of diarrhea, and include O91, O113 and O104.

We also agree with USDA's reasoning that the "Big 6" non-O157 STECs should be considered adulterants because they fulfill the four conditions that were used to declare *E. coli* O157:H7 an adulterant: the pathogen is not killed by traditional and accepted cooking practices; only a small number of bacteria are needed to cause illness; the illness can cause severe, life-threatening damage to major organ systems, particularly in children and the elderly; and the pathogens can spread from person-to-person. USDA provided enough scientific detail in their Draft Risk Profile for Pathogenic Non-O157 Shiga Toxin-Producing *Escherichia coli* (non-O157 STEC) to support the conclusion that the non-O157 STECs do indeed meet these four conditions.

In addition, CDC notes that illnesses from non-O157 STECs are on the rise. Data from the CDC FoodNet, reproduced as Figure 1 in the Draft Risk Profile, clearly show that the relative rate of laboratory-confirmed infections with STEC O157 has remained relatively steady between 2001-2003 and 2009, while the relative rate for non-O157 STEC has increased more than four-fold[6]. Indeed, just last year, FSIS investigated an outbreak of *E. coli* O26 involving three people in Maine and New York that was traced to beef and which resulted in a Pennsylvania firm recalling approximately 8,500 pounds of ground beef that may have been contaminated with *E. coli* O26. This was the first recall of a non-O157 STEC contaminated beef in the US.

Finally, CDC estimates that for every case of non-O157 STEC illness diagnosed, there could be more than 106 illnesses not diagnosed[7]. In addition, the number of non-O157 STEC illnesses continues to increase. In 2010, for the first time, CDC FoodNet data showed that non-O157 STEC reported illnesses and incidence surpassed those of *E. coli* O157:H7, with the number of non-O157 STEC infections more than doubling from 2008 to 2010, going from 205 to 451 cases, respectively[8].

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[4] Bosilevac JM and M Koohmaraie. 2011. Prevalence and Characterization of Non-O157 Shiga Toxin Producing *Escherichia coli* Isolated from Commercial Ground Beef in the United States. *Appl Environ Microbiol*. At: http://aem.asm.org/content/early/2011/01/21/AEM.02833-10.full.pdf+html

[5] See Table 1 in FSIS/USDA. 2011. Op cit.

[6] Figure 1, pg. xx in FSIS/USDA. 2011. Op cit.

[7] Scallan E, Hoekstra RM, Angulo FJ, Tauxe RV, Widdowson M-A, Roy SL, Jones JL, and PM Griffin. 2011. Foodborne illness acquired in the United States – major pathogens. *Emerg Infect Dis*., 17(1): 7-15. At: http://wwwnc.cdc.gov/eid/article/17/1/pdfs/p1-1101.pdf

[8] See Table 5, pg. xiv in FSIS/USDA. 2011. Op cit.

Given the increasing incidences of the non-O157 STEC illnesses, and the potential serious health impacts that result from these infections, we strongly support FSIS/USDA's decision to declare the "Big 6" non-O157 STECs (e.g. O26, O345, O103, O111, and O145) as adulterants when found in non-intact raw beef products and product components and also urge USDA to begin their routine sampling program for these 6 non-O157 STECs in March 2012. We applaud FSIS for finally declaring the "Big 6" non-O157 STECs as adulterants, and are dismayed by the opposition from certain members of industry and other beef exporting countries. This proposed rule is a significant and necessary minimum step forward.

However, we urge USDA/FSIS to move even further on this policy. We think that FSIS should declare the "Big 6" non-O157 STECs be declared to be adulterants when found on any beef components, not just when found in non-intact raw beef products and product components. Since any one of the Big 6 non-O157 STECs can cause severe disease in humans, and so therefore can be considered as pathogens, the simple presence of that pathogen on meat product should render that product adulterated. Butchers, or even consumers, may grind meat themselves, leading to a situation where pathogens may not be killed by cooking. In addition, given that there is some evidence of thermostability for the non-O157 STECs, one cannot always assume that cooking will always destroy the non-O157 STEC.

Further, FSIS should consider expanding surveillance to other STECs and including them as adulterants when they appear in meat. We agree with the October 5, 2009, Marler Clark, LLP, PS, et al parties petition asking FSIS to issue an interpretive rule declaring all enterohemorrhagic STEC to be adulterants within the meaning of the Federal Meat Inspection Act (FMIA). At the very least, FSIS could start testing for the serotype in seropathotype C, e.g. O91, O113, O104, as they are a frequent cause of diarrhea. Indeed, O113 has been associated with an outbreak of three cases of HUS in Australia[9], while STEC O104 was associated with 852 hospitalizations and 32 deaths in Germany this past summer associated with sprouts.[10]

Suggestions for baseline survey of non-O157 STEC prevalence in certain raw beef products

We have one suggestion in terms of the implementation policy for the STEC routine sampling. FSIS states that they will now test up to two portions of product (up to 325 gm per portion) collected from each establishment for the six non-O157 STEC (e.g. O26, O345, O103, O111, and O145). Previously, FSIS had collected and tested five separate 65-gm subsamples at each establishment for *E. coli* O157:H7 testing. FSIS argues that testing a single 325-gm sample rather than testing five separate sub-samples will save money without causing a loss in testing sensitivity. FSIS notes that an "Agency study showed the new method to be not as sensitive as the old method in detecting the lowest levels (1–4 CFR/325g) of *E. coli* O157:H7 cells. However, the difference in sensitivity was not statistically significant."[11] FSIS then argues that since "the sensitivity of the new method is comparable, if not actually equal, to that of the

[9] Paton AW, Woodrow MC, Doyle RM, Lanser JA and JC Paton. 1999. Molecular characterization of a Shiga toxigenic *Esherchia coli* O113:H21 strain lacking *eae* responsible for a cluster of cases of hemolytic-uremic syndrome. *J. Clin. Microbiol.*, 37: 3357-3361.

[10] See CDC. http://www.cdc.gov/ecoli/2011/ecolio104/

[11] Pg. 58160 in 76 FR 182. September 20, 2011. At: http://69.175.53.6/register/2011/Sep/20/2011-24043.pdf

present method, FSIS expects the new approach to yield laboratory cost efficiencies with no significant statistical difference in the analytical results."[12]

We disagree with FSIS' reasoning. First, there is no reference nor link to the aforementioned Agency study, so it cannot be examined. Even though the study found no "statistically significant" differences in the sensitivity of the two methods, it would be important to know what the sample size of the study and also the "statistical power" of the study. If the sample size is fairly small, or the data are very variable, it is possible that there could be a 50% or greater decrease in the sensitivity of the new test compared to the old (e.g. use one 325-gm sample vs. five separate 65-gm sub-samples, respectively), without that difference being statistically significant. In other words, a given result could be practically significant, but not statistically significant. Thus, a 50% decline in detecting the lowest levels of *E. coli* O157:H7, which we know can still result in serious disease, could mean that such contaminated meat may escape detection and enter the food supply, only to cause illness.

Given the serious nature of the STECs, especially to young children and the elderly, we should not move toward the less sensitive method if it will result in more children or elderly being sickened. FSIS should release the full Agency study for comment, so that the public may evaluate exactly how much less sensitive the new method is compared to the old method (e.g. use one 325-gm sample vs. five separate 65-gm sub-samples, respectively). Without releasing the details of this Agency study, we cannot independently verify FSIS' argument that the switch to the less sensitive method would indeed "yield laboratory cost efficiencies with no significant difference in the analytical results." Indeed, FSIS should not make the decision to move toward a less sensitive sampling methodology without presenting stronger evidence to support their decision. Thus, FSIS should release for public comment, the Agency study which purports to show that taking one 325-gm sample, rather than five 65-gm sub-samples, does result in a "significantly" decreasing the sensitivity of the detection of low levels of STECs. In the meantime, we recommend that FSIS should use the present methodology (e.g. five 65-gm sub-samples) for sampling for both O157 and non-O157 STECs.

The arguments of exporting countries (Australia, New Zealand, Uruguay) are not valid

A coalition of trade groups from the US and the major beef exporters to US (Canada, New Zealand, Australia and Uruguay), sent a letter Agriculture Secretary Tom Vilsack in early December asking for a delay in implementing the FSIS new policy on non-O157 STECs. The letter argues that, "Given that STEC other than *E. coli* O157:H7 are not considered a major public health concern within countries such as Australia, New Zealand, among others and that the majority of non-*E. coli* O157 STEC are attributed to non-beef sources.. . legitimate WTO questions exist."[13]

We disagree for a number of reasons. First, the notion that non-O157 STECs are not a major public health concern is some of the countries is not true, and, even if true, is irrelevant. Thus, in Australia, a study found that serotype O111:NM was reported to be more common than

[12] IBID

[13] Bottemiller, H. 2011. Meat industry again asks for delay on non-O157 policy. *Food Safety News*, December 13, 2011. At: http://www.foodsafetynews.com/2011/12/meat-industry-again-asks-for-delay-on-non-o157-policy/

O157:H7 in causing hemolytic uremic syndrome.[14] So, if *E. coli* O157:H7 is considered a public health problem in Australia, as it should be, then *E. coli* O111:NM, should be considered a public health problem as well. An USDA study of imported and domestic boneless beef trim published in 2007 did find non-O157 STECs in product from US, Australia, New Zealand and Uruguay.and noted that the "Non-O157 STEC prevalence was 10% in NZL [New Zealand] samples and about 30% in all of the other samples."[15] Although, non-O157 STEC were less prevalent in NZL beef trim, compared to that produced in the US, one of the "Big 6" non-O157 STECs, O26, was found in two of the four NZL non-O157-positive samples, demonstrating the presence of this pathogen in New Zealand.[16]

Second, whether the "Big 6" non-O157 STEC are associated with disease in Australia and New Zealand is not really relevant. Since the "Big 6" have been shown to be associated with disease in the US, the FSIS policy is designed to protect US consumers, who are indeed exposed to the "Big 6" non-O157 STECs. The fact that some or all of the "Big 6" have not been found in Australia, New Zealand and Uruguay could simply be a reflection of the lack of surveillance for those pathogens. Since the "Big 6" non-O157 STECs are known human pathogens, we feel that their presence on any raw or ready-to-eat meat product, regardless of where it comes from, should render that product adulterated. This, in fact, provides the level playing field that the World Trade Organization demands

The fact that according to the CDC, a majority of the illnesses attributed to the "Big 6" non-O157 STECs are not linked to beef is also irrelevant in terms of human safety. In fact, over a third of the non-O157 STEC illnesses (36,700 of 113,000) are linked to beef. These illnesses can and should be prevented. In addition, ruminants, especially cattle, are the main reservoir for the non-O157 STECs and so are invariably the ultimate source of these pathogens, even if other food sources, such as raw milk or produce are the vectors that spread it. If the "Big 6" non-O157 STECs are declared adulterants, hopefully this will result in establishments determining ways to raise and slaughter beef that minimize the presence of these pathogens, leading to decreased incidence of such pathogens in beef, similar to the decline seen in O157 levels seen since it was declared an adulterant. This, in turn, should reduce the incidence of all "Big 6" non-O157 STEC illnesses, whatever the source. The fact is that the "Big 6" non-O157 STECs cause potentially severe illness in people and so the presence of such pathogens on any raw meat product should render it adulterated, within the meaning of the FMIA, as it could be injurious to human health.

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[14] Elliott EJ, Robins-Browne RM, O'Loughlin EV, Bennett-Wood V, Bourke J, Hennibng P, Hogg GG, Knight J, Powell H and D Redmond. 2001. Nationwide study of haemolytic uraemic syndrome: clinical, microbiolgocial, and epidemiological features. *Arch. Dis. Child.*, 85: 125-131.

[15] Pg. 440 in Bosilevac JM, Guerini,MN, Brichta-Harhay DM, Arthur TM and M Koohmaraie. 2007. Microbiological characterization of imported and domestic boneless beef trim used for ground beef. *J Food Protechion*, 70(2): n 440-449.

[16] IBID.