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

**Re: 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)**

The Center for Science in the Public Interest (CSPI) appreciates the opportunity to comment on the draft risk assessment for *Escherichia coli* (*E. coli*) O157:H7 in ground beef prepared for the Food Safety and Inspection Service (FSIS). CSPI is a non-profit consumer advocacy and education organization that focuses primarily on food safety and nutrition issues and is supported principally by 800,000 subscribers to its *Nutrition Action Healthletter*.

### **Summary**

We support the farm-to-table risk assessment approach adopted in the draft document and agree that it represents the best way to address problems with *E. coli* O157:H7 during production. However, at several points the draft risk assessment either underestimates the risk of *E. coli* O157:H7 associated with the consumption of ground beef or fails to consider the risk entirely. We therefore urge the risk assessment committee to re-examine assumptions and conclusions as outlined below:

- The risk assessment should use assumptions that are more protective of public health.
- The risk assessment should account for contamination as a result of conditions during transport of the cattle to slaughter.
- The exposure assessment should account for the impact of individual plant characteristics and practices in estimating the likely number of *E. coli* O157:H7 organisms reaching the combo bin for grinding.
- The hazard characterization should be revised to account for all reported outbreaks of *E. coli* O157:H7 illnesses linked to ground beef.
- FSIS should not delay risk management decisionmaking for completion of the risk assessment.

## **1. The Risk Assessment Should Use Assumptions That Are More Protective of Public Health**

The *E. coli* O157:H7 draft risk assessment does not adequately characterize all the risks associated with consumption of *E. coli* O157:H7-contaminated ground beef and uses assumptions that are not sufficiently protective of public health. Although less common than other foodborne bacteria, *E. coli* O157:H7 has a low infectious dose, is especially virulent, and can cause devastating illness and death, especially in young, elderly and immuno-compromised consumers. The low infectious dose coupled with the severity of the disease caused by *E. coli* O157:H7 means that, if anything, FSIS should err on the side of caution when making assumptions about this pathogen. In particular, we recommend the following revisions to the draft risk assessment:

### **a. The Draft Risk Assessment Does Not Adequately Account For Risks to Children.**

Children are at an increased risk of *E. coli* O157:H7 illness, according to surveillance data and peer-reviewed studies cited in the draft risk assessment.<sup>1</sup> For example, a survey of FoodNet sites in

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<sup>1</sup> *Escherichia coli* O157:H7 Risk Assessment Team, *Draft Risk Assessment of the Public Health Impact of Escherichia coli* O157:H7 in Ground Beef (Sept. 7, 2001) [hereinafter *Draft Risk Assessment*].

1999 found that 35.3% of reported *E. coli* O157:H7 cases occurred in children between one- and ten-years old, and 17.6% of cases occurred in ten- to 20-year olds.<sup>2</sup> Other surveillance data showed that children aged 14 and under had a higher incidence of *E. coli* O157:H7-related illness than the rest of the population.<sup>3</sup> Despite this clear evidence of the risk of *E. coli* O157:H7 illness to children, the assessors failed to perform a separate dose-response analysis for children.<sup>4</sup>

Moreover, the draft risk assessment only documented the increased risk of illness to children aged five or less.<sup>5</sup> A child aged six or above was considered as invulnerable (or vulnerable) to *E. coli* O157:H7 illness as an adult.<sup>6</sup> As a result, the draft risk assessment is not sufficiently protective of children. We urge the risk assessors to revise their analysis to address the increased risks to children from consumption of *E. coli* O157:H7-tainted ground beef.

**b. The Draft Risk Assessment Fails to Address the Increased Risk of Illness Among the Elderly.**

The elderly, too, are more susceptible to severe *E. coli* O157:H7 illnesses than the general population.<sup>7</sup> For example, 1999 FoodNet data showed that 14.1% of *E. coli* O157:H7 cases occurred in individuals over age 60.<sup>8</sup> Seniors are particularly vulnerable to thrombotic thrombocytopenic purpura

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<sup>2</sup> *Draft Risk Assessment* at 20.

<sup>3</sup> *Draft Risk Assessment* at 20.

<sup>4</sup> *Draft Risk Assessment* at 123.

<sup>5</sup> *Draft Risk Assessment* at 152; FSIS, Interpretive Summary, *Draft Risk Assessment of the Public Health Impact of Escherichia coli O157:H7 in Ground Beef*, at p. 17 [hereinafter FSIS, *Interpretive Summary*].

<sup>6</sup> FSIS, *Interpretive Summary*, at 15. “The risk of illness from *E. coli* O157:H7 in ground beef was about 2.5 times higher for children aged 0 to 5 than for the rest of the population.” FSIS, *Interpretive Summary*, at 15.

<sup>7</sup> FSIS, *Interpretive Summary*, at 4.

<sup>8</sup> *Draft Risk Assessment* at 20.

(TTP), which can have a mortality rate as high as 50% in the elderly.<sup>9</sup> A recent study on an *E. coli* O157:H7 outbreak in Scotland concluded that victims over age 65 were at a significantly higher risk of developing hemolytic uremic syndrome (HUS),<sup>10</sup> a complication related to TTP.<sup>11</sup> However, the draft risk assessment did not treat the elderly as a sensitive subpopulation.<sup>12</sup> This oversight is especially critical given the aging of the U.S. population. Public health protection demands that the assessors estimate the risk of illness to the elderly from the consumption of *E. coli* O157:H7-contaminated beef.

**c. The Draft Risk Assessment Does Not Adequately Account For the Risks Posed By Other Beef Products.**

We recognize that the draft risk assessment is limited in scope and evaluates only *E. coli* O157:H7 exposure and the risk associated with consumption of ground beef. However, FSIS itself has recognized that the public health risk presented by raw beef products contaminated with *E. coli* O157:H7 is not limited to just raw ground beef products.<sup>13</sup> FSIS cannot adequately assess the risk associated with *E. coli* O157:H7 until it fully considers the additional risks posed by all raw beef, including blade-tenderized, non-intact cuts of beef, as well as the cross-contamination of infected beef with ready-to-eat foods that require no additional cooking. Thus, FSIS should expand its risk assessment and regulatory strategies to address all beef products that harbor this deadly pathogen.

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<sup>9</sup> FDA, *Bad Bug Book*, *E. coli O157:H7* [hereinafter *Bad Bug Book*]. In a 1986 outbreak in Washington, for example, three seniors developed TTP, two of which later died. In all, 37 people were sickened in this outbreak. *Bad Bug Book*.

<sup>10</sup> Stephanie Dundas *et al.*, *The Central Scotland Escherichia coli O157:H7 Outbreak: Risk Factors for Hemolytic Uremic Syndrome and Death among Hospitalized Patients*, 33 *Clinical Infectious Diseases* 923-31(2001).

<sup>11</sup> *Bad Bug Book*.

<sup>12</sup> FSIS, *Interpretive Summary*, at 15.

<sup>13</sup> FSIS, Background, *FSIS Policy on Non-intact Raw Beef Products Contaminated with E. coli O157:H7* (Jan. 1999) <<http://www.fsis.usda.gov/oa/background/O157policy.htm>>. See also 64 Fed. Reg. 2803 (Jan. 19, 1999).

## **2. The Draft Risk Assessment Does Not Adequately Account For Potential Cross-Contamination of Cattle During Transport.**

The draft risk assessment only estimates *E. coli* O157:H7 exposures generated from **infected** cattle (culled breeding and feedlot) entering U.S. slaughter plants, without considering cross-contamination during transit.<sup>14</sup> *E. coli* O157:H7 is shed in the feces of colonized cattle, not only infecting other animals but contaminating their hides as well. While recognizing that transit between the farm and slaughter plant “may be important in causing changes in hide prevalence,” the exposure assessment does not model transportation effects on hide contamination because there are no data on *E. coli* O157:H7 hide-contaminated cattle at the farm and only limited data on hide prevalence at the slaughter plant.<sup>15</sup>

The lack of data does not provide a basis for ignoring the potential for hide contamination during transport and its role in subsequent carcass contamination. The American Academy of Microbiology has recognized the importance of cross-contamination during transit:

[A]nimals are often transported to the slaughterhouse under conditions that not only increase the likelihood of pathogen transmission but also make the animals more susceptible to stress-induced reactions such as increased fecal shedding of organisms. Additionally, the impact of the fasting of animals on their microbiota before and during transport to the processing plant is not well understood. Because of the difficulty in decontaminating crates and trucks used to ship animals, pathogens from one shipment of animals may contaminate succeeding shipments.<sup>16</sup>

The assessors’ failure to address the role of cross-contamination in transit likely results in an underestimation of the number of *E. coli* O157:H7-contaminated carcasses ultimately reaching the trim

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<sup>14</sup> *Draft Risk Assessment* at 31.

<sup>15</sup> *Draft Risk Assessment* at 54.

<sup>16</sup> Stephanie Doores, American Academy of Microbiology, *Food Safety: Current Status and Future Needs* 12 (1999).

box or combo bin destined for grinding, a point that the draft risk assessment recognizes as one of the factors that “most influence[s]” the occurrence and extent of *E. coli* O157:H7 contamination in ground beef, as well as the subsequent risk of illness.<sup>17</sup>

Moreover, hide contamination prevalence may be higher among breeding cattle than feedlot cattle since they pass through livestock markets and are in transit longer. This assumes importance since greater proportions of deboned breeding cattle carcasses contribute to ground beef than feedlot cattle.<sup>18</sup> As a result, the assumption that “incorporating the effect of hide contamination may be inconsequential” does not appear to be justified.<sup>19</sup>

The risk assessors should develop a transportation module using data on surrogate pathogens, much as the assessors used surrogates in developing the dose-response function.<sup>20</sup> Both government and university researchers have found correlations between *Salmonella* contamination and conditions of transit.<sup>21</sup> Unless the risk assessors address the potential effects of hide contamination and cross-contamination during transportation, the risk assessment likely will underestimate the prevalence of *E. coli* O157:H7 in ground beef.

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<sup>17</sup> *Draft Risk Assessment* at 4.

<sup>18</sup> *Draft Risk Assessment* at 61, 70 (noting that for cow/bull carcasses, “approximately 90% of the surface area goes into trim”).

<sup>19</sup> *Draft Risk Assessment* at 55.

<sup>20</sup> In developing the dose-response function, the risk assessors used *Shigella dysenteriae* and EPEC as surrogates for *E. coli* O157:H7. *Draft Risk Assessment* at 117.

<sup>21</sup> See, e.g., Grandin, Temple, *Cutting off contamination at the front door*, *Meat&Poultry*, 71 (July 2001).

### **3. The Exposure Assessment Does Not Adequately Account For The Impact Of Individual Slaughter Plant Characteristics And Practices On Process Controls In Estimating The Likely Number Of *E. coli* O157:H7 Organisms Reaching The Combo Bin Or Trim Box.**

The slaughter module recognizes that slaughterhouse operating procedures can either facilitate or mitigate the probability of *E. coli* O157:H7 contamination on beef carcasses or trim.<sup>22</sup> However, in modeling the slaughter process, the exposure analysis does not adequately consider individual plant characteristics and manufacturing practices, such as production line layouts and line speeds, the effects that poor sanitation and hygiene during slaughter and processing can have on contamination of the meat, or that individual plants may apply decontamination treatments in different combinations. A study by the USDA's Economic Research Service noted that "differences in plant size, plant procedures, general sanitation practices, worker training, auditing and management competency may account for the wide range of observed contamination of beef carcasses among plants."<sup>23</sup> Yet the draft risk assessment appears to assume uniformity among slaughterhouse operations and practices. Accordingly, these differences and uncertainties should be addressed in the exposure assessment.

In addition, although the exposure analysis models variability among large plants using steam pasteurization as a second decontamination step, it merely assumes that all large plants use a steam pasteurization process with four steps.<sup>24</sup> While steam pasteurization has been described as providing beef processors with "the most effective bacterial reduction technology available,"<sup>25</sup> the draft

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<sup>22</sup> *Draft Risk Assessment* at 59.

<sup>23</sup> Tanya Roberts, Scott A. Malcolm, & Clare A. Narrad, *Probabilistic Risk Assessment and Slaughterhouse Practices: Modelling Contamination Process Control in Beef Destined for Hamburger*, published in *PROBABILISTIC SAFETY ASSESSMENT PSA '99: RISK-INFORMED PERFORMANCE-BASED REGULATION IN THE NEW MILLENNIUM*, Mohammad Modarres, ed., American Nuclear Society: LaGrange Park, Illinois (1999).

<sup>24</sup> *Draft Risk Assessment* at 66.

<sup>25</sup> Kansas State University Research and Extension, Program Updates and Highlights (Jan. 1998). There is no evidence in the draft risk assessment concerning how many slaughterhouses actually employ this technology.

assessment does not analyze how many large plants actually employ this intervention strategy as a second decontamination step. Indeed, at a December 2001 National Academy of Sciences meeting on the draft risk assessment, Dr. Randall Huffman, vice president of scientific affairs at the American Meat Institute, stated that steam pasteurization is not used by every large plant, as the assessors assumed.

The exposure analysis also fails to consider the potential for re-contamination after steam pasteurization as the carcass completes the fabrication process. As one study has found, “[w]ithout the foundation of good plant design, proper sanitation, hygiene and good manufacturing practices, even the best decontamination technologies will fail.”<sup>26</sup>

With respect to small plants, the exposure analysis indicates that they typically use a hot water rinse, sometimes supplemented with organic acids, as a second decontamination step.<sup>27</sup> Yet, the exposure analysis does not model for any variability in the use of hot water rinses either with or without supplemental organic acids. One report has noted that investigators have observed differences in the effectiveness of acid treatments between lean and fat tissue and among different portions of the carcasses.<sup>28</sup> Moreover, the application of spraying or rinsing treatments to carcasses may cause penetration of bacteria into the meat or spreading and redistribution on the carcass, depending on the spraying pressure.<sup>29</sup>

Even where an intervention strategy is used, it may not uniformly achieve the desired

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<sup>26</sup> John F. Sofos, et al., *Processes to Reduce Contamination with Pathogenic Microorganisms in Meat*, Department of Animal Sciences, Center for Red Meat Safety, Colorado State University (1999), at p. 10 [hereinafter *Sofos*].

<sup>27</sup> *Draft Risk Assessment* at 66.

<sup>28</sup> *Foodborne Disease Significance of E. coli O157:H7* at 73.

<sup>29</sup> *Sofos* at 5.



effectiveness. Indeed, the fact that a little over one third of all *E. coli* O157:H7 positives in ground beef since 1994 (59 out of 171) were found in 2001 alone demonstrates that intervention strategies are not working to reduce contamination, cross-contamination, or re-contamination during processing.<sup>30</sup> Moreover, because trimmings from many sources are combined at off-site grinding operations, even untainted product may become contaminated at the grinder.<sup>31</sup>

As a result of these uncertainties, the number of individual carcasses having some *E. coli* O157:H7 contamination at the end of the slaughter module is likely higher than predicted by the models. Thus, the probability of consumer exposure (and the risk of illness) is likely higher than the assessors predicted.

#### **4. The Hazard Characterization Understates the Number of Illnesses Due To Consumption Of *E. coli* O157:H7-Contaminated Ground Beef.**

The draft-risk assessment likely underestimates the risk of *E. coli* O157:H7-related illness from consumption of ground beef because of the nature of the outbreak data the assessors used. Relying, in part, on *E. coli* O157:H7 outbreak data from the Centers for Disease Control and Prevention (CDC), the risk assessors found that between 1994<sup>32</sup> and 1999 ground beef was the most likely vehicle in 44 (30.1%) of 146 reported outbreaks of *E. coli* O157:H7 with an identified vehicle and 11.1% of cases

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<sup>30</sup> FSIS, Electronic Reading Room: *Microbiological Testing Program, Microbiological Results of Raw Ground Beef Products Analyzed for Escherichia coli O157:H7*, Calendar Year 2001 (Updated Dec. 28, 2001), <<http://www.fsis.usda.gov/OPHS/ecoltest/ecpositives.htm>>.

<sup>31</sup> FSIS, Technical Information, *Color of Cooked Ground Beef as It Relates to Doneness* (Aug. 1998, revised May 2000) [hereinafter *FSIS Technical Information*].

<sup>32</sup> Although the draft risk assessment states that data from 1996-1999 were used, this is apparently a typographical error. According to Kathleen Orloski, FSIS, Office of Public Health and Science, Risk Assessment Division, the risk assessment team actually used data from 1994-1999. *Telephone conversations by Kristina Barlow with Kathleen Orloski* (Dec. 11 & 14, 2001).

(418/3,773).<sup>33</sup> These data were then used in a Monte Carlo simulation, which estimated a median of 19,000 symptomatic cases of *E. coli* O157:H7 infection per year from consumption of ground beef.<sup>34</sup> However, the outbreak information used by the risk assessment team may not accurately reflect the true number of outbreaks linked to *E. coli* O157:H7-contaminated ground beef for two reasons: (1) the inclusion of non-food-related outbreaks confounds the risk analysis, and (2) the CDC data used are not the most complete data set available on foodborne-illness outbreaks.

The CDC data used by the risk assessors include outbreaks with non-food sources of transmission, even though the risk assessment is narrowly focused on determining the risk of foodborne infection from the consumption of ground beef. Using outbreaks with non-foodborne modes of transmission in the Monte Carlo simulation confounds the analysis by broadening the scope to include the entire universe of *E. coli* O157:H7 infections and ultimately may underestimate the risk of illness from ground beef.

Of the 146 outbreaks resulting in 3,773 illnesses with identifiable vehicles listed by the CDC, only 88 outbreaks and 1,957 illnesses are directly associated with a food source.<sup>35</sup> The remaining 58 outbreaks and 1,816 illnesses were linked to other vehicles such as person-to-person contact, or transmission of the organism by swimming water. However, a distinction between ground-beef related and non-ground-beef related outbreaks is too simplistic and ignores the fact that *E. coli* O157:H7 outbreaks attributed to swimming pools and other non-food vehicles may have been secondary cases

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<sup>33</sup> *Draft Risk Assessment* at 113.

<sup>34</sup> *Draft Risk Assessment* at 113.

<sup>35</sup> CSPI obtained the 1994-1996 CDC outbreak data through a Freedom of Information Act (FOIA) request fulfilled in September 1997 and the 1997 data through a FOIA request we received in May 1998. The 1998 and 1999 outbreak data were published on CDC's website at [http://www.cdc.gov/ncidod/dbmd/outbreak/ecoli\\_sum.htm](http://www.cdc.gov/ncidod/dbmd/outbreak/ecoli_sum.htm).

associated with primary illnesses from consumption of tainted ground beef.<sup>36</sup>

These secondary transmission cases should not be used where the risk analysis is narrowly focused on examining infection from a foodborne mode of transmission. If the assessors considered only the 88 outbreaks and 1,957 illnesses related to foodborne *E. coli* O157:H7 that were identified by the CDC, 50% of the outbreaks (44/88) and approximately 21% (418/1,957) of illnesses can be attributed to ground beef. Thus, using only foodborne-illness outbreak data in the Monte Carlo simulation would likely increase the median number of symptomatic *E. coli* O157:H7 illnesses.

Another flaw in the analysis results from the CDC data set that the assessors used. The CDC *E. coli* O157:H7-outbreak data are not the most complete set of foodborne-illness outbreak data available. Since 1999, CSPI has maintained its own database of foodborne-illness outbreaks, which contains confirmed outbreaks reported by state-health departments and scientific and medical journals, in addition to outbreaks identified by CDC.<sup>37</sup>

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.<sup>38</sup> Using these outbreak numbers to

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<sup>36</sup> Consumption of contaminated ground beef has been the suspected cause in a number of waterborne outbreaks. For example, a June 1998 *E. coli* O157:H7 outbreak at an Atlanta water park was investigated for association with tainted ground beef recalled in May 1998. Paul Blake *et al.*, *Memorandum on Outbreak of Escherichia coli O157:H7 infections caused by exposures at a water park*, (July 21, 1999) <<http://www.ph.dhr.state.ga.us/epi/manuals/pdf/waterparks.pdf>> (ultimately the ground beef isolate was ruled out). Person-to-person transmission often occurs following an initial outbreak caused by food. Ten percent (48/501) of the victims of the 1993 Jack in the Box outbreak were secondary cases. Two of the secondary case patients died. Beth Bell *et al.*, *A Multistate Outbreak of Escherichia coli O157:H7-Associated Bloody Diarrhea and Hemolytic Uremic Syndrome From Hamburgers: The Washington Experience*, 272 *J. Am. Med. Ass'n.* 1349-53.

<sup>37</sup> These data have been published in CSPI's *Outbreak Alert!*, updated October 2001, a copy of which is attached. CSPI's database includes foodborne-illness outbreaks occurring between 1990 and 2001 with a confirmed etiology and food vehicle. Our full database documents 124 *E. coli* O157:H7 outbreaks, which sickened a 3,397 people, from 1990 to date. Forty-seven percent (58/124) of these outbreaks and 41% of the illnesses (1,388/3,397) were linked to *E. coli* O157:H7-tainted ground beef.

<sup>38</sup> The sources for these data are listed in "*E. coli* O157:H7 Outbreaks 1994-1999," a copy of which is attached.

calculate the percentages of outbreaks and illnesses from ground beef results in higher percentages (47% and 22%, respectively) than those obtained by the risk assessment team (30% and 11%, respectively). Using CSPI's data set in the Monte Carlo simulation would likely result in an increase in the relative proportion of *E. coli* O157:H7 outbreaks associated with ground beef.

#### **5. FSIS Should Not Delay Taking Risk Management Actions Pending Completion Of This Risk Assessment.**

CSPI strongly urges FSIS not to suspend risk management decisionmaking with respect to *E. coli* O157:H7 in ground and other cuts of beef while the final risk assessment document is being prepared. Protection of public health demands that efforts to refine the risk assessment should not delay management of the risk posed by this pathogen.

Since 1994, when FSIS began its microbiological testing program, 171 ground beef samples have tested positive for *E. coli* O157:H7. Of these, over one-third (59) tested positive in calendar year 2001 alone, resulting in 25 recalls.<sup>39</sup> This demonstrates that despite implementation of the Pathogen Reduction/Hazard Analysis and Critical Control Point (HACCP) system, slaughterhouse practices and processes continue to allow this dangerous pathogen to contaminate beef carcasses.

Rather than assessing measures by the slaughterhouses and producers to reduce and eliminate *E. coli* O157:H7 in ground beef, the draft risk assessment concludes that “[r]educing the number of *E. coli* O157:H7-contaminated ground beef servings may reduce risk of illness more than reducing the amount of *E. coli* O157:H7 in contaminated servings.”<sup>40</sup> This conclusion places the burden on the

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<sup>39</sup> FSIS, Electronic Reading Room: Microbiological Testing Program, *Microbiological Results of Raw Ground Beef Products Analyzed for Escherichia coli O157:H7, Calendar Year 2001* (Updated Dec. 21, 2001), available at <<http://www.fsis.usda.gov/OPHS/ecolitest/ecpositives.htm>>.

<sup>40</sup> *Draft Risk Assessment* at 151.

consumer to avoid consumption of ground beef and suggests that moderating consumer behavior with respect to handling and cooking ground beef is more important than requiring slaughter plants to operate cleaner facilities and use the most up-to-date intervention strategies.<sup>41</sup>

We strongly urge FSIS to move forward with its risk management strategies, focusing on the slaughterhouses and processors that are producing beef contaminated with this deadly pathogen. FSIS should use the information currently available to design and implement new programs to address the risk of *E. coli* O157:H7 in ground and other cuts of beef.

FSIS also must step up enforcement of the existing zero tolerance standard, particularly since the draft risk assessment demonstrates that the frequency of servings still contaminated *after cooking* is between 1 in 15,000 and 1 in 3,300 in the high prevalence season and between 1 in 36,000 and 1 in 7,600 in low prevalence season.<sup>42</sup> Based on these estimates, **approximately two million servings of contaminated, cooked ground beef are eaten each year in the U.S., and nearly 100,000 of those contaminated servings contain 11 or more *E. coli* O157:H7 organisms.**<sup>43</sup> This risk is unacceptably high for consumers.

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<sup>41</sup> Nearly 30% of consumers participating in a Kansas State University focus group study preferred their hamburgers medium-rare. Christiane Schroeter *et al.*, *Consumer Perceptions of Three Food Safety Interventions Related to Meat Processing*, 21 Dairy, Food and Environmental Sanitation 570-81 (2001). Although researchers have shown that color and texture are not reliable indicators of doneness, *FSIS Technical Information*, a 1998 FDA consumer survey showed that many consumers still practice risky behaviors such as eating cooked meat without using a thermometer to check for the proper internal temperature. FDA, *Keeping Food Safety Surveys Honest: Video Checks Up on Consumer Meal Preps* (Sept.-Oct. 1999).


<sup>42</sup> FSIS, *Interpretive Summary*, at 12.

<sup>43</sup> These estimates were calculated using the predicted number of ground beef servings consumed each year and the mean results of simulations showing the percentage of cooked ground beef servings that are predicted to have one or more surviving *E. coli* O157:H7 for the low and high prevalence seasons (0.007% and 0.018%, respectively). FSIS, *Interpretive Summary*, at 12 (Table 3), 14.

**Conclusion**

We commend FSIS and the risk assessment team for their efforts in preparing the *E. coli* O157:H7 draft risk assessment for ground beef. However, FSIS has long been aware of the danger posed by consumption of *E. coli* O157:H7-contaminated ground beef. Consumers should not have to wait to see progress in controlling this severe public-health threat.

Sincerely,

  
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Karen L. Egbert, Senior Food Safety Attorney

  
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Charlotte Christin, Senior Food Safety Attorney

Caroline Smith DeWaal, Food Safety Director