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May 20, 2020

Docket Clerk
U.S. Department of Agriculture
Food Safety and Inspection Service
1400 Independence Avenue SW
Mailstop 3782
Room 6065
Washington, DC 20250-3700

Re: Docket Number FSIS-2020-0007 – Petition to Declare *Salmonella* in Meat and Poultry an Adulterant

Dear Madam or Sir:

We are writing to comment on the above-referenced petition to declare "outbreak" serotypes of *Salmonella enterica* to be adulterants under the meat and poultry inspection laws administered by FSIS. We believe this petition should serve as a springboard for overdue reform of the Hazard Analysis and Critical Control Points (HACCP) pathogen reduction regulatory framework that FSIS established in 1996.

Stop Foodborne Illness (STOP) is a non-profit organization that for over 25 years has worked with illness victims and their families to advocate for and support best practices and continuous improvement in food safety. STOP called for reforms in the FSIS inspection program following the Jack in the Box outbreak in 1992-93 and was part of the consumer-industry coalition that supported and gained enactment of the Food Safety Modernization Act ("FSMA") in 2011. In addition to constituent support and policy advocacy, STOP collaborates with food companies to bring personal experiences with serious illness into company training and food safety culture programs.

One of STOP's board members, Amanda Craten, is the mother of a son who at 18-months was seriously and permanently injured in an outbreak associated without *Salmonella* Heidelberg in chicken. Numerous STOP constituents have also suffered illnesses from *Salmonella* and *Campylobacter* in meat and poultry. These include Diana Goodpasture and Ruby Lee (a 10-month old infant) who were infected by multi-drug resistant *Salmonella* Heidelberg in ground turkey; Mary Graba, who was injured at age 16 by *Campylobacter* in chicken served in a restaurant; and Ken Koehler, who was made gravely ill and suffered permanent harm from *Salmonella* Typhimurium in ground beef.

The Center for Science in the Public Interest is America's food and health watchdog. Since 1971 CSPI has worked to improve the public's health through better nutrition and food safety. The organization's work is supported primarily by subscribers to its Nutrition Action Healthletter, the nation's largest-circulation health newsletter. CSPI is an independent organization that does not accept government grants or corporate funding.

Introduction

Salmonella causes more hospitalizations and deaths than any other foodborne pathogen monitored in CDC's FoodNet surveillance system,[1] with FSIS-regulated products, especially poultry, being major contributors to the persistence of *Salmonella* as a serious public health problem.[2]

The petition submitted by Marler Clark, LLP and others makes a compelling legal and factual case for declaring serotypes of *Salmonella* implicated in illness outbreaks to be "adulterants." By citing the personal stories of illness victims, the petition also underscores the dire human impact and long-term harm that can happen when people are sickened by *Salmonella*. For these reasons, we call on FSIS to take the Marler Clark petition seriously and act on it swiftly as a springboard for fundamental reform of its regulatory framework for pathogens in meat and poultry, beginning with poultry. Fundamental reform is needed because the HAACP/pathogen reduction regulatory framework, while innovative when adopted in 1996, is scientifically out of date and is simply not working to fulfill its prevention vision and protect public health.

This is not for lack of effort by FSIS and the industry to implement the framework. In the case of poultry, FSIS and many poultry companies have worked creatively and diligently to reduce the incidence of *Salmonella* contamination. FSIS and the industry have also stepped up their focus on *Campylobacter* in poultry. Based on data from CDC's latest FoodNet report[3] and presented in FoodNet FAST, however, the fact remains that these two pathogens together accounted in 2019 for over 72% of confirmed illnesses transmitted commonly by food and tracked by FoodNet, as well as 70% of resulting hospitalizations and 52% of deaths. Poultry remains a major source of these illnesses.[4] According to FoodNet data, the incidence of illnesses

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[1]CDC, *FoodNet FAST* (https://wwwn.cdc.gov/foodnetfast/) and CDC, FoodNet 2019 Preliminary Data (https://www.cdc.gov/foodnet/reports/prelim-data-intro-2019.html.

[2] Interagency Food Safety Analytics Collaboration. "Foodborne illness source attribution estimates for 2017 for Salmonella, Escherichia coli O157, Listeria monocytogenes, and Campylobacter using multi-year outbreak surveillance data, United States." GA and D.C.: U.S. Department of Health and Human Services, CDC, FDA, USDA-FSIS. 2019. *See also* John A. Painter, et al, "Attribution of Foodborne Illness, Hospitalizations, and Deaths to Food Commodities by Using Outbreak Data, United States, 1998-2008," *Emerging Infectious Diseases* (www.cdc.gov/eid), Vol 19, No. 3, March 2013.

[3] Danielle M Tack, et al, "Preliminary Incidence and Trends of Infections with Pathogens Transmitted Commonly Through Food — Foodborne Diseases Active Surveillance Network, 10 U.S. Sites, 2016–2019." *MMWR* Vol 69, No. 17, May 1, 2020.

[4] CDC, *FoodNet FAST* (https://wwwn.cdc.gov/foodnetfast/).

from *Salmonella* in 2019 was unchanged and the incidence from *Campylobacter* increased compared to the previous three-year period.[5]

In its recently issued 2019 FoodNet report, CDC notes that the persistently high incidence of reported illnesses caused by *Salmonella*, *Campylobacter* and other pathogens is likely due in part to improved detection of illnesses and outbreaks. CDC nevertheless concludes that: "FoodNet surveillance data indicate that progress in controlling major foodborne pathogens in the United States has stalled." CDC also concludes that:

> "To better protect the public and achieve forthcoming Healthy People 2030 foodborne disease reduction goals, more widespread implementation of known prevention measures and new strategies that target particular pathogens and serotypes are needed."[6]

We agree. We also believe that the persistence of poultry-related illnesses is due in part to the fact that the FSIS regulatory framework lags behind advances in science and technology and does not reflect modern understanding of preventive controls and best practices for food safety. This is the case in at least two critical ways that directly affect the safety of poultry: (1) the framework does not meaningfully address the high levels of contamination of live birds entering slaughter establishments, and (2) the current *Salmonella* and *Campylobacter* performance standards are not enforceable and do not target the serotypes of *Salmonella* that are most likely to make people sick.

We thus urge FSIS to initiate a rulemaking process that would:

1. **Address the need for pre-harvest controls** by making acceptance of live birds a critical control point (CCP) in slaughter plants and requiring HACCP plans to include critical limits for this CCP.

2. **Establish processor accountability for verifying grower controls** by requiring slaughter facilities to adopt and implement supplier verification programs.

3. **Modernize poultry safety standards** by (1) replacing the current FSIS *Salmonella* and *Campylobacter* performance standards with enforceable finished-product standards, and (2) targeting finished product standards for *Salmonella* on both *Salmonella spp.* and the *Salmonella* serotypes of greatest public health concern.

Stop Foodborne Illness and CSPI understand the complexity of devising and implementing these changes and thus urge FSIS to seek input from a wide range of consumer, industry, public health and academic experts. We welcome the opportunity to work with FSIS and other food safety stakeholders to accomplish what we consider much-needed public health reforms.

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[5] *See* fn. 3.
[6] *Ibid*. at 513.

Impetus and Scientific Basis for Reform

The impetus for STOP and CSPI to seek reform in the FSIS regulatory framework is the urgent need to reduce the burden of illness on individuals and families. We believe FSIS should use every tool at its disposal to do this, including modernization of its HACCP rules and pathogen reduction performance standards in keeping with today's science and continuing advances in best practices for food safety. We understand that leading poultry companies have already moved beyond what the regulatory framework legally requires, using microbial mapping, vaccines and other modern tools to control hazards in both their pre-harvest and processing programs. We applaud this. We also believe there should be a level playing field for industry and that today's best practices should become common practices. Modernization of the FSIS regulatory framework is key to doing that.

The impetus for reform also comes from FSIS's own recognition of the public health significance of *Salmonella* and *Campylobacter* in poultry and the need to take a modern, holistic, farm-to-table approach to minimizing risk to consumers. This is evidenced by the *DRAFT FSIS Compliance Guideline For Controlling Salmonella and Campylobacter in Raw Poultry* that FSIS issued in 2015, which includes extensive recommendations for both pre-harvest and processing interventions to reduce risk.[7]

The need and scientific basis for taking a modernized, public health approach to poultry safety is also documented in the 2019 report of the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) regarding *Salmonella* control strategies in poultry.[8] The NACMCF report specifically recommends as key opportunities to reduce *Salmonella* and prevent illness across the farm-to table spectrum: (1) serotype-specific pre-harvest controls, (2) strict process controls in slaughter establishments, and (3) identification and development of "approaches that exclude serotypes of greatest public health concern from raw poultry products."[9]

We agree with these NACMCF recommendations. The regulatory model that can be most effective in reducing illnesses associated with *Salmonella* and *Campylobacter* in poultry is one in which enforceable finished product standards that target actual public health risks are established and operate to drive adoption of needed preventive controls, all the way back to the farm, to meet the standards. The reforms we propose in the following section would accomplish that.

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[7] FSIS, *DRAFT FSIS Compliance Guideline For Controlling Salmonella and Campylobacter in Raw Poultry* (December 2015) (https://www.fsis.usda.gov/wps/wcm/connect/6732c082-af40-415e-9b57-90533ea4c252/Controlling-Salmonella-Campylobacter-Poultry-2015.pdf?MOD=AJPERES).

[8] NACMCF, "Response to Questions Posed by the Food Safety and Inspection Service Regarding Salmonella Control Strategies in Poultry," *Journal of Food Protection*, Vol. 82, No. 4, 2019, Pages 645–668.

[9] *Ibid.* at 661-663. See also, Gremillion, *Taking Salmonella Seriously – Policies to Protect Public Health Under Current Law* (Consumer Federation of America, November 2018).

Specific Reforms

As a general matter, HACCP remains a widely accepted and sound framework for designing and implementing effective preventive controls for food safety. This includes the flexibility for establishments to tailor controls to the particular hazards and conditions in their operations. In the case of poultry, however, the current framework utilizes obsolete *Salmonella* standards and fails to adequately incorporate the best current available pre-harvest controls. The following reforms are therefore needed to correct these gaps:

1. **Make acceptance of live birds a critical control point (CCP) in slaughter plants and require HACCP plans to include critical limits for this CCP.**

The HACCP regulations already require establishments to consider hazards that occur outside and before entry of livestock and birds into an establishment (9 CFR 417.2) and to establish critical control points with critical limits designed to ensure that food safety hazards reasonably likely to occur are "prevented, eliminated, or reduced to acceptable levels" (9 CFR 417.1 and 417.2(c)). The highly contaminated condition of many flocks of live birds entering slaughter establishments is clearly a "hazard reasonably likely to occur." Acceptance of those birds therefore should be considered a CCP and could be deemed a CCP without new rulemaking.

Likewise, current rules already require establishments to set critical limits for each CCP. We do not necessarily envision that critical limits will be identical for every establishment since they should be geared to the firm's overall control system for meeting the enforceable finished product standards proposed below. FSIS should, however, provide guidance and perhaps general criteria for establishing appropriate critical limits, which could be done through guidance or rulemaking. Such critical limits, likely in the form of microbial specifications, should be sufficiently rigorous and specific to incentivize pre-harvest measures that: (1) minimize contamination of live birds with *Salmonella spp.*, key *Salmonella* serotypes of public health concern, and *Campylobacter* and (2) enable the facility to meet the new finished product standards proposed below.

This approach is not novel. Not only did FSIS call on poultry processors to implement pre-harvest controls in its 2015 guidance and recommend a multi-hurdle approach,[10] the European Union has applied serotype-specific *Salmonella* targets to broiler flocks at the pre-harvest, live-bird level since 2003, with the current annual prevalence targets set at 1% of flocks for *Salmonella* Enteritidis and *Salmonella* Typhimurium.[11] These are two of the serotypes identified

[10] These include vaccines, better management of breeder flocks, hatcheries and grow-out houses; better managing feed, water and other vectors that aid the spread of infection; and knowing flock pathogen status prior to harvest. *See also* Pew Charitable Trusts, *Food Safety From Farm to Table Fork – Interventions on Farms and Feedlots Can Improve U.S. Meat and Poultry Safety* (July 2017) (https://www.pewtrusts.org/en/research-and-analysis/reports/2017/07/food-safety-from-farm-to-fork).

[11] COMMISSION REGULATION (EU) No 200/2012 of 8 March 2012 (concerning a Union target for the reduction of *Salmonella* Enteritidis and *Salmonella* Typhimurium in flocks of

by NACMCF as deserving of targeted pre-harvest controls.[12]

2. **Require slaughter facilities to adopt and implement supplier verification programs.**

Supplier verification is widely recognized within the food industry as a food safety best practice[13] and is now a regulatory requirement for food facilities regulated by FDA.[14] It recognizes that processors are responsible for how their raw materials affect the safety of finished products and that they have an essential role to play in assuring that their suppliers are implementing proper preventive controls.

FSIS should amend its HACCP regulation to require that poultry slaughter facilities and possibly other meat and poultry processing establishments have in place supplier verification programs tailored to the risks inherent in their operations and the manner in which those risks are controlled. In the case of poultry, the supplier verification program would complement the new CCP and associated critical limits proposed above. Presumably, some form of pathogen testing of incoming flocks would be conducted to ensure that the applicable critical limits are being met. However, a CCP alone likely would be insufficient to ensure the adequacy of preharvest interventions, given the volume, sampling and cost limitations inherent in such testing in the poultry production setting. A supplier verification program is therefore necessary to confirm that pre-harvest interventions designed to meet the critical limits are in place and being properly implemented.

3. **Replace the current FSIS *Salmonella* and *Campylobacter* performance standards with enforceable finished-product standards that target both *Salmonella spp.* and *Salmonella* serotypes of greatest public health concern, as well as *Campylobacter*.**

This is the most critical need in order to make the HACCP/pathogen reduction regulatory framework effective in reducing the burden of illness associated with pathogens in poultry.[15] The agency's current pathogen reduction performance standards are unenforceable, meaning that FSIS will continue to inspect and pass products from establishments that are failing the standards. The standards also fail to target the serotypes of greatest public health concern,

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broilers, as provided for in Regulation (EC) No 2160/2003 of the European Parliament and Council).

[12] *See* fn. 8 at 663.

[13] The Global Food Safety Initiative (GFSI) is a broad coalition of food manufacturers and retailers organized to strengthen and promote supply chain management best practices for food safety, including supplier verification in accordance with recognized standards and accredited audits (https://mygfsi.com/who-we-are/overview/).

[14] 21 CFR Part 117, Subpart G (Supply-Chain Program) and 21 CFR 1.500 *et seq.* (Foreign Supplier Verification Programs for Food Importers). While FDA's authority to require supplier verification comes from FSMA, FSIS would ground its authority in 21 U.S.C. § 456,463, 608, 621 and related provisions, as discussed below.

[15] The HACCP regulations recognize that, to be effective in ensuring food safety, a HACCP plan must be designed to achieve recognized outcome measures or standards for food safety (9 CFR 417.2(c)(3)).

applying instead to the prevalence of all *Salmonella spp.*, incentivizing an over-reliance on chemical sanitization and other post-harvest processing interventions, rather than pre-harvest measures designed to target and eliminate the serotypes of greatest public health concern. The right enforceable finished product standards will correct these problems, driving the adoption of necessary preventive controls through the entire production process, from farm to fork.

Enforceable finished product standards can also give consumers confidence that the product they receive has been produced and inspected by FSIS under a standard that is a measure of the safety of the product itself. The current *Salmonella* prevalence standards do not provide that assurance. Rather, they are process control performance standards that allow, for example, a broiler slaughter establishment to meet the standard even if up to 9.8% of broiler carcasses are contaminated with *Salmonella* and without an assessment of what the contaminating serotypes are or whether they are likely to cause illness.[16] Moreover, because the current performance standards are not enforceable, facilities can keep producing and FSIS can keep inspecting and passing broilers from plants that exceed the 9.8% contamination prevalence for *Salmonella.* Based on what the food safety community has learned since 1996 and the persistent burden of illness documented by CDC, these "standards" can no longer be considered to be based on the latest science or adequate to protect public health.

We thus urge FSIS to initiate the rulemaking process needed to replace the current set of poultry process control performance standards with enforceable product standards, as follows:

- Serotype-Specific *Salmonella* Finished Product Standards – These standards should eventually apply to all categories of poultry products, beginning with broiler carcasses, parts and ground product as priorities. They should establish public health-protective standards for the serotypes of greatest public health concern. These could be non-detect, quantitative or prevalence standards, or a combination of these, as determined through the rulemaking process based on epidemiological data and information on such factors as virulence and anti-microbial resistance. If there are substantial regional differences in occurrence of the serotypes of public health concern, this should be taken into account in setting and implementing the standards. FSIS should also monitor future changes in the pattern of illnesses and outbreaks associated with specific serotypes and make corresponding changes in the serotype-specific standards.

- Quantitative *Salmonella spp.* Finished Product Standards – At least initially, it is likely that serotype-specific standards will apply to a small subset of *Salmonella* serotypes that have significant potential to cause illness. It thus remains necessary to have a *Salmonella spp.* standard to ensure that other pathogenic serotypes are under reasonable control in keeping with the risks they pose to consumers. This could be done by replacing the

[16] Similarly, the performance standard for *Campylobacter* allows establishments to meet the standard if up to 15.7% of broiler carcasses are contaminated. *See* FSIS, "Pathogen Reduction – *Salmonella* and *Campylobacter*" (July 31, 2019) (https://www.fsis.usda.gov/wps/wcm/connect/b0790997-2e74-48bf-9799-85814bac9ceb/28_IM_PR_Sal_Campy.pdf?MOD=AJPERES).

current prevalence performance standards with quantitative product standards for *Salmonella spp.* that take account of what is known about dose-response as well as feasibility of control.

- *Campylobacter* Finished Product Standards – As with *Salmonella*, we urge FSIS to establish a finished product standard for *Campylobacter* that provides a meaningful incentive for processors to implement the holistic program of pre-harvest and processing controls needed to prevent illness. FSIS should consider whether the standard should apply to *Campylobacter spp. or Campylobacter jejuni,* the single serotype that is the predominant cause of foodborne illness,[17] and whether it should be a non-detect or quantitative standard.

We believe all these standards should operate as benchmarks for product release by the company and as the standards under which FSIS will deem product "inspected and passed" and grant the mark of inspection. Product not meeting the standards could be diverted to a cooking process.

We recognize the significance of these policy and regulatory changes in the context of the current FSIS regulatory program, but they are fully in line with widely accepted best practices throughout the food industry. Certainly, broad stakeholder engagement and the marshaling of the best available science and expertise will be needed to devise how the proposed standards and practices will be effective and workable in the case of poultry. We also recognize that, depending on the serotypes identified and costs involved, industry may require a substantial phase-in period before compliance with the new standards will be considered mandatory. Given what is at stake, however, in terms of the burden of illness and consumer confidence, we urge FSIS to begin the reform process now.

Legal Authority

FSIS has ample legal authority under the Poultry Products Inspection Act (PPIA) to conduct the rulemaking and set the standards we propose.

The PPIA charges FSIS with verifying through the continuous inspection of slaughter and processing establishments that products leaving those establishments are not adulterated.[18] The PPIA specifically empowers FSIS to promulgate such "rules and regulations as are necessary to carry out" this purpose,[19] which are codified in 9 CFR Part 381. FSIS has exercised this broad rulemaking authority to prescribe that inspection be "rendered pursuant to the regulations and under such conditions and in accordance with such methods as may be prescribed or approved by the Administrator" (9 CFR 381.4), and has made the grant of inspection contingent on the establishment having in place a validated HACCP plan (9 CFR 381.22(b)).

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[17] Melo, Robert T., et al., "Campylobacter jejuni strains isolated from chicken meat harbour several virulence factors and represent a potential risk to humans," *Food Control* Volume 33, Issue 1, September 2013, Pages 227-231.
[18] 21 USC §§ 451 & 452.
[19] 21 USC § 463(b).

In training materials for FSIS inspectors, the agency says:

> "The HACCP regulations require establishments to identify the hazards to health that may arise as a result of their operation and to address those that are reasonably likely to occur. If those hazards are not properly addressed and prevented, the result is adulterated product."[20]

In these ways, FSIS has rightfully claimed and exercised sweeping authority to set the conditions under which it will deem inspected products not to be adulterated. FSIS has also made clear that, in deciding whether to pass product, the burden of proof rests not on FSIS to prove adulteration but rather on inspected establishments to show that a product is NOT adulterated.[21] FSIS has properly exercised its authority in numerous ways to set the conditions under which it will find that burden has been met, including by successful implementation of HACCP. Based on today's science, the safety of poultry depends on having a HACCP framework that includes what we propose: (1) CCPs and critical limits for raw materials entering poultry slaughter facilities, (2) supplier control and verification programs, and (3) product standards for pathogens that are enforceable and public health oriented.

The Fifth Circuit Court of Appeals decision in *Supreme Beef v USDA*[22] does not preclude modernizing the HACCP/Pathogen Reduction framework to address food safety holistically and with product standards that protect consumers. The *Supreme Beef* case focused specifically on a beef grinding operation that had purchased ground beef "trimmings" that had high levels of contamination with *Salmonella*, resulting in a ground beef product with prevalence of positive *Salmonella* samples that exceeded the prevalence permitted in the FSIS *Salmonella* performance standard for ground beef. The court held that the ground beef performance standard could not be enforced by withdrawing inspection because USDA had not determined *Salmonella* to be an adulterant, and had not established that "a deleterious change in the product" had occurred while it is being "prepared, packed or held" in the beef grinding establishment.[23]

Our proposals for rulemaking present a completely different legal issue, namely whether through rulemaking FSIS can implement a HACCP framework that meets modern standards for preventing foodborne illness. Notably, our proposal envisions an enforceable product standard, under which *Salmonella* serotypes of greatest public health concern may be targeted as adulterants. In addition, the controls we propose are necessary to prevent "a deleterious change"

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[20] FSIS, *FSIS Statutes Mission and Authority* (2/21/2019) (https://www.fsis.usda.gov/wps/wcm/connect/c0c8145f-927f-4a36-8c3e-b815adb24811/2_IM_Statutes.pdf?MOD=AJPERES

[21] As stated in "FSIS Statutes and Your Role, Training for FSIS Public Health Veterinarians" (11/6/13) (https://www.fsis.usda.gov/wps/wcm/connect/b751f8c8-ed46-428b-8867-0e5f70c3e394/PHVt-Statutes_Role.pdf?MOD=AJPERES): "Remember that product cannot move out of the establishment into commerce until it has been inspected and marked as passed. This means that you must be able to find that product is NOT adulterated. The burden of proof is on the establishment."

[22] 275 F.3d 432 (5th Cir. 2001).

[23] *Ibid.* at 440.

in the product when dangerous pathogens are transferred from incoming live birds to the processing environment, other birds being processed and the previously sterile meat during slaughter, and will address both incoming pathogen contamination of live birds and outgoing contamination in the finished products.

In addition, in the rulemaking, FSIS could build a record and spell out why the acceptance and commingling of live birds in a poultry slaughter facility are a CCP under the HACCP framework and why acceptance into a slaughter establishment of birds highly contaminated with disease-causing *Salmonella a*nd *Campylobacter* constitutes an insanitary condition that may render the food injurious to health. The rulemaking would also establish the factual and legal basis for a supplier verification requirement. This would entitled the agency to deference under *Chevron* principles.[24]

With respect to the proposed product standards for *Salmonella* and *Campylobacter*, we would expect FSIS to base its determination on an appropriate scientific and legal rationale, utilizing its broad authority to set conditions for granting the mark of inspection and releasing product for consumption by the public. As scientifically supported and necessary to protect public health, this could include findings that some or all serotypes are adulterants.

Whether based on a finding of adulteration or not, we believe FSIS must stand firmly behind its authority to mandate modern preventive controls through the HACCP/pathogen reduction framework and set product standards that protect public health. If FSIS concludes it lacks authority to do this, it should say so and seek the authority it needs from Congress.

Conclusion

We appreciate the opportunity to provide these comments and look forward to working with FSIS in achieving the reforms proposed here. They are needed to protect public health and meet the reasonable expectations of America's consumers.

Mitzi Baum
CEO, Stop Foodborne Illness

Peter Lurie
President, Center for Science in the Public Interest

cc: Dr. Mindy Brashears, Under Secretary for Food Safety, USDA
Paul Kiecker, Administrator, FSIS/USDA

[24] Chevron U.S.A, Inc. V. Natural Resources Defense Council, 467 U.S. 837 (1984).