

SAFE FOOD COALITION

1620 I Street, NW, Suite 200, Washington, DC 20006 202-797-8551

April 19, 2013

Docket Clerk
U.S. Department of Agriculture
Food Safety and Inspection Service
Patriots Plaza 3
1400 Independence Ave SW
Mailstop 3782 Room 8-163A
Washington, DC 20250-3700

Re: Docket No. FSIS-2012-0007

To Whom It May Concern:

The undersigned members of the Safe Food Coalition appreciate the opportunity to comment on the notice from the Food Safety and Inspection Service (FSIS) on the HACCP Plan Reassessment for Not-Ready-to-Eat (NRTE) Comminuted Poultry Products and Related Agency Verification Procedures (Docket No. FSIS-2012-0007).

Salmonella in poultry products remains a serious public health concern

We share FSIS' concern with the recent *Salmonella* outbreaks linked to ground poultry products. The 2011 *Salmonella* Hadar outbreak linked to turkey burgers sickened 12 consumers in 10 states and resulted in a recall of 54,960 pounds of frozen, raw turkey burgers.¹ The 2011 multidrug resistant *Salmonella* Heidelberg outbreak linked to ground turkey infected 136 people in 24 states; one person died.² Thirty-six million pounds of ground turkey were recalled in August 2011, plus an additional 185,000 pounds a month later.

According to the Centers for Disease Control and Prevention (CDC), approximately 42,000 cases of salmonellosis are reported in the United States each year,³ although the CDC estimates that over 1 million cases of *Salmonella* occur each year.⁴ Raw or undercooked poultry is a frequent source of *Salmonella* illnesses. A report by the University of Florida's Emerging Pathogens

¹ Centers for Disease Control and Prevention, "Multistate Outbreak of *Salmonella* Hadar Infections Associated with Turkey Burgers." Accessed February 7, 2013 via <http://www.cdc.gov/salmonella/hadar0411/040411/index.html>

² Centers for Disease Control and Prevention, "Multistate Outbreak of Human *Salmonella* Heidelberg Infections Linked to Ground Turkey." Accessed February 7, 2013 via <http://www.cdc.gov/salmonella/heidelberg/111011/index.html>

³ Centers for Disease Control and Prevention website, "Salmonella." Accessed April 4, 2012, via <http://www.cdc.gov/salmonella/general/index.html>.

⁴ Scallan E, et. al., "Foodborne Illness Acquired in the United States – Major Pathogens." *Emerging Infectious Diseases*, 17(1): January 2011.

Institute ranked as fourth *Salmonella* in poultry in terms of causing the greatest disease burden to the public in both Quality Adjusted Life Years and cost of illness in dollars.⁵

Further, FSIS testing reveals that ground chicken and ground turkey products consistently have the highest *Salmonella* percent positive rates of all product classes.⁶

Unfortunately, the U.S. has made almost no progress in reducing illnesses from *Salmonella* in the past decade. The incidence of *Salmonella* infections has remained at essentially the same level since 2003 and in recent years has been increasing. In 2011, the incidence of salmonellosis was 16.47 cases per 100,000, well above the 2020 National Health Objective of 11.4 cases per 100,000.⁷

In light of these recent outbreaks and the importance of reducing illnesses from *Salmonella*, we agree that as a first step, plants producing NRTE comminuted poultry products should reassess their HACCP plans to determine whether they are adequately addressing and controlling microbial hazards such as *Salmonella*. NRTE comminuted poultry products include ground, mechanically separated, or hand- or mechanically-deboned poultry that is further chopped, flaked, minced or otherwise processed to reduce particle size but not battered or breaded. Given the process for creating NRTE comminuted poultry, along with the mixing of products from many birds into a single product, there are reasonable concerns about increased contamination levels in these products. As a result, we agree that plants should consider pre-harvest factors and interventions that may influence *Salmonella* contamination of these products. Based on the results of its inspection checklist survey of chicken and turkey slaughter and processing plants, FSIS should take appropriate regulatory action in plants for which the agency has concerns about the adequacy of the plant's food safety system.

Adulteration of product associated with outbreaks

We agree with FSIS' determination that when NRTE poultry or meat products are associated with an outbreak of foodborne illness and contain pathogens that are not officially considered adulterants, the agency should still consider the products linked to the outbreak as adulterated and should conduct appropriate regulatory action. Clearly, product that has made consumers sick is "unsound, unhealthful, unwholesome, or otherwise unfit for human food."⁸

We further agree that associated product should also be considered adulterated because it was likely "prepared, packed or held under insanitary conditions whereby it may have become contaminated with filth or whereby it may have been rendered injurious to health."⁹ If, in FSIS' traceback activities, it discovers additional product produced at another establishment that is linked to the adulterated product, FSIS should consider that product as adulterated, particularly if the product was produced under similar conditions. A plant should be required to satisfactorily

⁵ Batz M, Hoffman S, Morris G, "Ranking the Risks: The 10 Pathogen Food Combinations with the Greatest Burden on Public Health." Emerging Pathogens Institute, University of Florida, 2011.

⁶ Food Safety and Inspection Service, "Progress Report on *Salmonella* and *Campylobacter* Testing of Raw Meat and Poultry Products, 1998-2011." http://www.fsis.usda.gov/PDF/Progress_Report_Salmonella_Testing_1998-2011.pdf

⁷ Centers for Disease Control and Prevention, "Trends in Foodborne Illness in the United States, 1996-2011." Accessed February 7, 2011 via <http://www.cdc.gov/foodnet/data/trends/trends-2011.html>.

⁸ 21 U.S.C. 453(g)(3)

⁹ 21 U.S.C. 453(g)(4)

demonstrate that its food safety system is capable of producing unadulterated product before the plant is allowed to continue distribution of product into commerce.

FSIS' determination that products meeting the above conditions should be considered adulterated is an important clarification of agency policy. However, FSIS should expand its definition of adulteration to include specific strains of *Salmonella*, similar to the agency's determination that certain strains of pathogenic *E. coli* are adulterants. As a first step, the agency should grant a petition by the Center for Science in the Public Interest to declare certain antibiotic-resistant strains of *Salmonella* as adulterants.¹⁰

FSIS verification sampling and testing

We support FSIS' decision to expand its *Salmonella* verification sampling program to include NRTE comminuted poultry products. We tentatively support FSIS' decision to reduce the number of samples in a set from 53 to 26 samples only if FSIS uses the additional testing capacity to increase the number and frequency of the *Salmonella* sampling sets the agency performs. Increasing the number of sampling sets performed is important because the accompanying analysis of FSIS sampling data for raw and ground poultry from FY09-11 calculated that it would take nearly six years to sample all 140 eligible establishments only once.¹¹ Consequently, FSIS should consider adding an unscheduled, random sampling component to its sampling program in order to provide greater assurance that any plant could be selected for sampling.

We also strongly support FSIS' intention to develop new performance standards for NRTE comminuted poultry products for *Salmonella* and *Campylobacter*. According to the accompanying analysis of FY09-11 sampling data, the current performance standard (which was based on data from 1995) is much higher than the establishment percent positive rates during that time period. We maintain that those percent positive rates remain unacceptably high. Tightened performance standards in addition to the change described below could help further drive down percent positive rates.

FSIS' current approach permits plants that meet 50% or less of the performance standard to be classified as Category 1 plants. The *Salmonella* categories were developed in 2007 in order to incentivize plants to achieve a certain level of performance for Category 1 which was at or below half of the standard.¹² In light of the recent outbreaks and the consistently high *Salmonella* percent positive rates for ground poultry products, we believe that FSIS should apply a more stringent measure of 25 percent of the national prevalence for categorizing Category 1 plants. A more stringent measure is consistent with the concept of continuous improvement and would help drive improvement in reducing contamination in ground poultry plants that produce NRTE comminuted poultry products.

¹⁰ Center for Science in the Public Interest, "Citizen's Petition for an Interpretive Rule Declaring Specific Strains of Antibiotic-Resistant *Salmonella* in Ground Meat and Poultry to be Adulterants." May 25, 2011.

¹¹ Food Safety and Inspection Service, "Changing the Set Sizes in Raw Ground Poultry Sampling," August 2012, http://www.fsis.usda.gov/PDF/Set_Sizes_in_Ground_Poultry_Sampling.pdf

¹² Food Safety and Inspection Service, Federal Register Notice, Docket No. 04-026N, "*Salmonella* Verification Sample Result Reporting: Agency Policy and Use in Public Health Reporting." February 27, 2006. <http://www.fsis.usda.gov/Frame/FrameRedirect.asp?main=http://www.fsis.usda.gov/OPPDE/rdad/FRPubs/04-026N.htm>

FSIS states that the agency intends to use its verification testing program to determine the prevalence of *Salmonella* in NRTE comminuted poultry products. We question this approach. In the document “Use of FSIS Regulatory Verification Sampling to Generate Prevalence Estimates,”¹³ FSIS’s own analysis determined that calculating an accurate prevalence estimate using its *Salmonella* verification data was not possible. It is unclear how FSIS now believes it can use this same verification testing program to determine prevalence in NRTE comminuted poultry products. FSIS should provide further scientific justification on how it intends to use its verification testing program to establish prevalence of *Salmonella* in NRTE comminuted poultry products.

The undersigned groups appreciate the opportunity to submit these comments.

Sincerely,

Center for Foodborne Illness Research & Prevention

Center for Science in the Public Interest

Consumer Federation of America

Food & Water Watch

Government Accountability Project

National Consumers League

STOP Foodborne Illness

U.S. Public Interest Research Group

¹³ DCC Prevalence Estimate Workgroup, “Use of FSIS Regulatory Verification Sampling to Generate Prevalence Estimates,” April 2012.