Comments of Consumers Union on
United States Department of Agriculture (USDA) Food Safety Inspection Service (FSIS)
HACCP Plan Reassessment for Not-Ready-To-Eat Comminuted Poultry Products and
Related Agency Verification Procedures
Docket No. FSIS-2012-0007
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Consumers Union[1] (CU) welcomes the opportunity to comment on the United States Department of Agriculture (USDA) Food Safety Inspection Service's (FSIS') decision to require that establishments producing not-ready-to-eat (NRTE) comminuted poultry products reassess their Hazard Analysis and Critical Control Points (HACCP) plans for such products to take account of recent *Salmonella* outbreaks associated with consumption of comminuted NTRE turkey products and for the Agency to develop performance standards for *Salmonella* and, perhaps *Campylobacter*, for the NRTE comminuted poultry products.

Reasons for Concern

We share FSIS' concern about *Salmonella* in poultry products. In 2011 there were two outbreaks involving ground/comminuted turkey product. The 2011 multiple-drug-resistant *Salmonella* Hadar outbreak associated with turkey burgers that sickened 12 people in 10 states and lead to a recall of 54,960 pounds of turkey burger.[2] The 2011 multiple-drug-resistant *Salmonella* Heidelberg outbreak associated with ground turkey product sickened 136 people in 24 states and lead to 1 death; more than 36 million pounds of ground turkey were ultimately recalled.[3] A 2011 report by the University of Florida's Emerging Pathogens Institute on pathogen food combinations with the greatest impact on public health ranked *Salmonella* in poultry as fourth in terms of contaminated foods causing the greatest decline in Quality Adjusted Life Years, and third in terms of hospitalizations and death.[4] Overall, the report found that contaminated poultry ranked as the number 1 food category with the greatest public health impact. In addition, according to Centers for Disease Control and Prevention (CDC) estimates, based on

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[1] *Consumers Union, publisher of Consumer Reports, is an expert, independent nonprofit organization whose mission is to work for a fair, just, and safe marketplace for all consumers and to empower consumers to protect themselves. To achieve this mission, we test, inform, and protect. To maintain our independence and impartiality, Consumers Union accepts no outside advertising, no free test samples, and has no agenda other than the interests of consumers. Consumers Union supports itself through the sale of our information products and services, individual contributions, and a few noncommercial grants. Over 8 million people subscribe to Consumer Report or Consumer Reports online.*

[2] Centers for Disease Control and Prevention (CDC). 2011a. Investigation Announcement: Multistate Outbreak of *Salmonella* Hadar Infections Associated with Turkey Burgers. At: http://www.cdc.gov/salmonella/hadar0411/040411/index.html

[3] CDC. 2011b. Investigation Update: Multistate Outbreak of Human *Salmonella* Heidelberg Infections Linked to Ground Turkey. At: http://www.cdc.gov/salmonella/heidelberg/111011/index.html

[4] Batz MB, Hoffman S, and JG Morris. 2011. *Ranking the Risks: The 10 Pathogen Food Combinations with the Greatest Burden on Public Health*. At: http://www.epi.ufl.edu/sites/www.epi.ufl.edu/files/RankingTheRisksREPORT.pdf

FoodNet Surveillance data, *Salmonella* is one of the few foodborne pathogens that have not declined in the past fifteen years. In 2012, the incidence of salmonellosis was 16.42 cases per 100,000, well above the 2020 National Health Objective of 11.4 cases per 100,000.[5] Further, data from the National Antimicrobial Resistance Monitoring System (NARMS) show that *Salmonella* levels in poultry products are five to ten times higher than levels see in ground beef or pork chops.[6] Clearly, FSIS needs to take action on *Salmonella* in poultry products.

Summary of comments

We commend FSIS for having establishments producing NRTE comminuted poultry products update their HACCP plans. We support expanding *Salmonella* testing beyond ground poultry product to include all comminuted NTRE poultry product. We also commend FSIS for deciding to survey establishments to see whether establishments have updated their HACCP plans. We further feel that FSIS should take action against any establishment where the Agency has concerns about their food safety system.

We agree that FSIS should develop new performance standards for *Salmonella* and *Campylobacter* in ground/comminuted poultry products. Based on the most recent survey of NARMS data,[7] FSIS should set a performance standard that is no greater than 12.3 percent for ground/comminuted turkey products. We further believe that FSIS must sample from all establishments producing ground/comminuted NRTE poultry products, and not just establishments in category 3 (e.g. those that have failed the present performance standard), when gathering data to develop the new performance standard for *Salmonella* and *Campylobacter* in ground/comminuted poultry products.

FSIS should declare any *Salmonella* strain/serotype with the same PFGE pattern as the *Salmonella* strain/serotype involved in an illness outbreak an adulterant, regardless of where it was produced. FSIS should also decide that any *Salmonella* serotype that appears on CDC's top 20 list of *Salmonella* serotypes of human health concern, and that is also antibiotic resistant will be considered an adulterant.

Finally, FSIS should urge establishments producing ground/comminuted NRTE poultry products to monitor for serotypes of *Salmonella* as part of their HACCP plan. We agree. Plants should concentrate on the CDC top 20 *Salmonella* serotypes of human health concern. In addition, plants should also measuring antibiotic resistance on the *Salmonella* they sample given that antibiotic resistant *Salmonella*, particularly multi-drug resistant Salmonella can result in infections that are harder to treat, thus causing potentially more severe illnesses than non-resistant strains of *Salmonella*.

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[5] Table 1 in CDC. Incidence and Trends of Infection with Pathogens Transmitted Commonly Through Food — Foodborne Diseases Active Surveillance Network, 10 U.S. Sites, 1996–2012. *MMWR*, 62(15): 283-287. At: http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6215a2.htm?s_cid=mm6215a2_e

[6] Table 6 in NARMS. 2013. *Retail Meat Report 2011*. At: http://www.fda.gov/downloads/AnimalVeterinary/SafetyHealth/AntimicrobialResistance/NationalAntimicrobialResistanceMonitoringSystem/UCM334834.pdf

[7] IBID

FSIS should change the definition of Category 1 to 25 percent of the current performance standard. However, FSIS should not cease testing of Categories 1 and 2.

More detailed comments are below.

HACCP reassessment in response to outbreaks

FSIS investigation of two recent *Salmonella* outbreaks involving comminuted NTRE turkey products has lead them to require establishments producing ground and comminuted NRTE poultry products to reassess their HACCP plans in terms of controlling microbial hazards, especially *Salmonella*. As FSIS has noted, the ground and comminuted poultry products tend to have higher levels of microbial contamination than non-ground product. The FSIS investigations associated with the two 2001 *Salmonella* outbreaks in turkey products showed that sanitation procedures are particularly important, so FSIS suggests that a plant's Sanitation Standard Operating Procedure (SOP) or HACCP plan be reassessed to ensure that all slaughter and further processing equipment, employee hands, tools, and clothing, and food contact substances are clean enough to minimize cross contamination both within and between lots of products. In addition, slaughter and dressing procedures should be designed to prevent contamination. We support these suggested changes.

We also support the range of other suggested changes to the HACCP plans, such as having establishments producing NRTE comminuted poultry products validate any cooking instructions to ensure that they are accurate, to consider changes in lotting practices (e.g. distinguishing one portion of production from another such that they are microbiologically independent), to both ensure that these lots can be prevented from contaminating each other, to be able to trace back product to the originating slaughter establishment (if applicable), and to evaluate the adequacy of any *Salmonella* interventions applied to product source materials or to product during or after grinding or blending. These changes in lotting practices make good sense and would serve to reduce the impact of potential future product recalls. By making lots microbiologically independent, recalls could be restricted just to those contaminated lots, not to all the production that happened in a given plant over a given period of time.

We further agree that evaluation of the adequacy of any *Salmonella* interventions should involve testing for *Salmonella* to quantify the extent of the *Salmonella* reduction. Without such quantification it would be virtually impossible to determine the adequacy of the *Salmonella* interventions that establishments make as part of their required reassessment of HACCP plans.

We also strongly agree that pre-harvest factors and interventions that may influence *Salmonella* contamination of comminuted poultry products (including breeder flock *Salmonella* status, hatchery management, biosecurity and pest control, feed manufacturing and feed withdrawal practices, and sanitation of pre-harvest environments including transport crates) should be considered as part of an establishment's reassessed HACCP plans.

We strongly support FSIS' suggestion that establishments producing comminuted poultry should consider taking serotype information on the *Salmonella* that they samples as part of its HACCP plan. We agree. Plants should concentrate on the CDC top 20 *Salmonella* serotypes of human health concern (at: http://www.cdc.gov/ncezid/dfwed/PDFs/SalmonellaAnnualSummaryTables2009.pdf). **However, Consumers Union urges plants to measure antibiotic resistance on the *Salmonella* they sample given that antibiotic resistant *Salmonella,* particularly multi-drug resistant Salmonella can result in infections that are harder to treat, thus causing potentially more severe illnesses than non-resistant strains of *Salmonella*.**

Finally, we agree that FSIS should conduct an inspection checklist survey of chicken and turkey slaughter and further processing establishments producing comminuted NRTE poultry products in order to document whether establishments have changed their HACCP plans in response to the required reassessment and to publish guidance for industry on best practices to reduce *Salmonella* in comminuted poultry. In addition, FSIS should take appropriate regulatory action in establishments for which FSIS has concerns about the adequacy of the establishment's food safety system. Establishments for which FSIS has concerns about the adequacy of their food safety system should have to convincingly demonstrate that their food safety system can produce unadulterated product before such establishments are allowed to continue distribution of the product.

Adulteration of product associated with outbreaks

We strongly agree with FSIS' determination that when NRTE poultry or meat products are associated with an illness outbreak and contain pathogens that are not considered adulterants, FSIS will consider the product linked to the illness outbreak to be adulterated and to request that the establishment recall the product. Clearly, a product that makes people sick is "unsound, unhealthful, unwholesome, or otherwise unfit for human food."[8]

We further agree with FSIS' determination that the associated product produced at the same establishment as the product associated with the illness outbreak would be considered adulterated because it was "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] We also commend FSIS' decision to evaluate whether the type of product produced at other establishments, when demonstrably linked to product associated with the outbreak, is adulterated because it was produced under substantially similar processes and insanitary conditions. The example that FSIS uses—associated product at another establishment produced from birds that came from the same grow-out house as the birds that were the source of the illness outbreak, and that were subject to substantially similar processing conditions—is an excellent example of a good preventative action that could prevent further human illnesses. Thus, we believe FSIS

[8] 21 U.S.C. 453(g)(3)
[9] 21 U.S.C. 453(g)(4)

should consider such associated product produced at other establishments to be adulterated when subject to substantially similar processing conditions.

Consumers Union strongly disagrees with FSIS' decision that "FSIS would not be likely, however, to consider product of the same type adulterated though it is found to have the pathogen associated with the illness outbreak, provided it was produced in other establishments that have no relationship to product involved in the illness outbreak." From a public health perspective, the presence of a pathogen associated with an outbreak should be sufficient for FSIS to take action (e.g. request a voluntary recall of the product), not whether the particular pathogen can be linked to the same establishment as the outbreak strain. The problem here may relate to what FSIS means by "pathogen associated with the illness outbreak," and we urge FSIS to clarify this. Does FSIS mean that if a *Salmonella* Hadar strain caused an illness outbreak, then any *Salmonella* Hadar strain would be considered would be considered as "associated with the illness outbreak," or do they mean *Salmonella* Hadar with the same Pulsed-Field Gel Electrophoresis (PFGE) pattern? We would define "pathogen associated with the illness outbreak" to be a pathogen with the same Pulsed-Field Gel Electrophoresis (PFGE) pattern. **We believe that any *Salmonella* strain/serotype with the same PFGE pattern as the *Salmonella* strain/serotype involved in an illness outbreak will likely pose a similar public health risk and therefore should be declared an adulterant, regardless of where it was produced.**

In addition, we believe that just as FSIS determined that certain serogroups of *E. coli* (e.g. O157:H7, O26, O45, O103, O111, O121, and O145) are adulterants,[10] certain serotypes of *Salmonella* should be considered adulterants. As an initial step toward this goal, **we believe that FSIS should decide that any *Salmonella* serotype that appears on CDC's top 20 list of *Salmonella* serotypes of human health concern,[11] and that is also antibiotic resistant should be considered an adulterant.** The serogroups of *Salmonella* on CDC's top 20 list are the ones causing the most human illness.

The definition of adulterant appears in the relevant Federal Meat Inspection Act (FMIA) and Poultry Products Inspection Act (PPIA) definitions, §§601(m)(1) and 453(g)(1). Both definitions require that to be an adulterant, the substance must either be added or, if natural, render the resulting food product ordinarily injurious to health. The presence of antibiotic resistance in *Salmonella*, especially resistance to multiple antibiotics, is partially due to human intervention, e.g. the widespread use of antibiotics for non-therapeutic purposes (e.g. growth promotion, disease prevention and prophylaxis) in agriculture. This would make the antibiotic resistant (ABR) *Salmonella* strains/serotypes an added substance and, thus, an adulterant. ABR strains/serotypes of *Salmonella* are harder to treat, thus causing potentially more severe illnesses than non-resistant strains of *Salmonella*; in other words, rendering the resulting food product to be ordinarily injurious to health, thereby justifying stricter treatment. While FSIS doesn't

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[10] FSIS. 2011. 9 CFR Parts 416, 417, and 430 [Docket No. FSIS–2010–0023] Shiga Toxin-Producing Escherichia coli in Certain Raw Beef Products. 76 *Federal Register*, No. 182, Tuesday, September 20, 2011. At: http://www.fsis.usda.gov/OPPDE/rdad/FRPubs/2010-0023.pdf

[11] At: http://www.cdc.gov/ncezid/dfwed/PDFs/SalmonellaAnnualSummaryTables2009.pdf

classify *Salmonella* as an adulterant, we believe serotypes of *Salmonella* on CDC's top 20 list that are also antibiotic resistant can meet either of the criteria to be defined as adulterants. At the very least, FSIS should grant the petition by the Center for Science in the Public Interest to declare four strains of *Salmonella* that are antibiotic resistant as adulterants.[12]

Agency verification sampling and testing

We strongly commend FSIS for expanding its *Salmonella* Verification Sampling Program beyond NRTE ground chicken and turkey to include all non-breaded, non-battered "NTRE comminuted" chicken or turkey products. FSIS defines "NRTE comminuted poultry" products as including "any non-breaded, non-battered raw or otherwise NRTE product that has been ground, mechanically separated, or hand- or mechanically-deboned and further chopped, flaked, minced, or otherwise processed to reduce particle size." As FSIS notes mechanically-separated or mechanically-deboned products were not typically used in poultry products in the past, but they increasingly are found in products, especially those for export. FSIS notes that one of the recent *Salmonella* outbreaks in turkey involved mechanically-separated and mechanically-deboned product. It is thus crucial that such products be included in the *Salmonella* Verification and Sampling Program. We also support FSIS' decision to include in its sampling non-breaded, non-battered NTRE comminuted poultry product after other ingredients such as spices have been added because the Agency expects establishments to control pathogens in final product regardless of the source of the pathogen, e.g. whether it came from the poultry or the added ingredient(s) such as spices..

We also can tentatively support FSIS' decision to reduce the number of samples in a set from 53 to 26, provided that FSIS uses the additional testing capacity to increase the number of sets that can be done in a given period of time. This increased set sampling is necessary as FSIS' analysis of their data on sampling ground poultry from FY09-11 found that it would take nearly six years to sample all 140 eligible establishments once.[13] Given this lengthy time period before all establishments could be sampled, we urge FSIS to add a random sampling component to the sampling program to provide more assurance that any establishment could be selected for sampling.

We strongly support FSIS' decision to develop new performance standards for NRTE comminuted poultry products for *Salmonella* and *Campylobacter*, since the current *Salmonella* performance standards were based on baseline surveys conducted more than 15 years ago, when establishments had much higher percent positive rates for *Salmonella* incidence compared to today. However, we believe that the present percent positive rates for *Salmonella* incidence are still too high and need to be reduced.

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[12] Center for Science in the Public Interest. 2011. 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. At: http://cspinet.org/new/pdf/cspi_petition_to_usda_on_abr_salmonella.pdf

[13] FSIS. 2012. Changing the Set Sizes in Raw Ground Poultry Sampling. August, 2012. At: www.fsis.usda.gov/PDF/Set_Sizes_in_Ground_Poultry_Sampling.pdf

Tightened performance standards and other changes could help further drive down percent positive rates.

At present, the *Salmonella* performance standard is 44.6 percent for ground chicken and 49.9 percent for ground turkey. In 2007, FSIS established three performance categories for establishments. Category 1 was set at an upper limit of no more than half the performance standard. Category 2 was set at more than half but not exceeding the standard, while Category 3 was for establishments exceeding the performance standard. FSIS also decided to publish the names of establishments in Categories 2 and 3 for any product class that did not have 90 percent of its establishments in Category 1. Thus, having a Category 1 status means that those establishments would not be listed by published, an incentive for the establishment to try to attain Category 1 status.

Given the recent *Salmonella* outbreaks in turkey products, the continued relatively high prevalence of *Salmonella* in comminuted chicken and turkey products, and the fact that the original *Salmonella* performance standard was based on a survey taken more than 15 years ago, we believe that a more stringent measure should be used to define Category 1 establishments. We agree with FSIS that it should apply the more stringent measure of 25 percent of the national prevalence for defining Category 1 status for comminuted NRTE poultry products. As FSIS notes, "a reduction of Category 1 to 25 percent of the performance standard would be consistent with the goals of the Healthy People 202 initiative." Given the current standard of 44.6 percent for ground chicken and 49.9 percent for ground turkey, the new Category 1 standards would be 11.1 and 12.5 percent, respectively.

However, we disagree with FSIS decision to discontinue sampling sets for ground poultry products from establishments in categories 1 and 2 and to only sample from category 3 establishments. **We believe that FSIS should sample from all establishments, not just category 3 establishments.** Many of the establishments presently in category 1 may not meet the new standard. In addition, all the establishments presently in category 2 would likely not meet the new standard. There are also no guarantees that Category 1 and 2 establishments will maintain good performance. While it makes sense to concentrate on the worst establishments, e.g. those in category 3, it makes no sense to ignore category 1 and 2 establishments completely.

Finally, FSIS states that it plans to use the *Salmonella* Verification Sampling Program "to allow for a more accurate measurement of the incidence of *Salmonella*" in comminuted poultry products, and then use these incidence data to develop performance standards. We have two concerns with this. First, it is unclear specifically which data will be used to develop the performance standard. Our reading of this documents suggests that FSIS is implying that the new performance standard will be based on the sampling from category 3 establishments: "FSIS intends to conduct a risk assessment based on at least three months of these new sampling and testing results and issue a new performance standard for these products for *Salmonella* and likely *Campylobacter* as well. With publication of this notice, FSIS will discontinue sampling sets for ground poultry product, except for establishments in category 3. … For these establishments, FSIS will

continue to schedule sets for ground chicken or turkey and would also sample other comminuted chicken or turkey products."[14] Does FSIS intend to use these data to determine national prevalence? If FSIS only uses data from the new sampling of category 3 establishments to determine *Salmonella* incidence, it will get a large overestimate of that incidence since category 3 establishments are those that failed the original performance standard of 44.2 percent and 49.9 percent for ground chicken and ground turkey, respectively. This would result in a performance standard that would be inappropriately lenient for *Salmonella*. Elsewhere, FSIS says that "The Agency will collect comminuted NRTE samples in establishments with an average daily production of greater than 1,000 pounds over the past month, but this may change as the program progresses." This comment suggests the Agency will sample from *all* establishments producing more than a given amount of NRTE comminuted and ground poultry product. So, will FSIS determine the new performance standards based on sampling from *all* establishments above a given size, or only from category 3 establishments? **To get an accurate estimate of the national prevalence of *Salmonella* to use in developing a performance standard, FSIS must sample from all establishments producing NRTE comminuted and ground poultry product.**

Second, FSIS has a problem since their own analysis, found in "Use of FSIS Regulatory Verification Sampling to Generate Prevalence Estimates," concluded, "Due to a variety of methodological and sampling related issues, FSIS does not believe it is possible to utilize existing pathogen verification testing projects to estimate prevalence for … Salmonella in all raw products, or Lm and/or Salmonella in RTE and post-lethality exposed products."[15] The conclusion of this paper seems to be at odds with FSIS' assertion that the verification sampling program can accurately determine prevalence of *Salmonella* in comminuted poultry products. FSIS should provide further scientific justification as to how it can accurately determine prevalence of *Salmonella* in comminuted poultry products using its *Salmonella* Verification Sampling Program.

FSIS should explicitly clarify how it intends to establish the new performance standards for *Salmonella* sets. Will they use data from all establishments or just those in category 3? For the performance standard to have any credibility, it must include samples for *all* establishments.

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[14] Pp. 72690-72691 in 77 *Federal Register* No. 235, December 6, 2012

[15] Pg. 4 in DCC Prevalence Estimate Workgroup. 2012. Use of FSIS Regulatory Verification Sampling to Generate Prevalence Estimates. April 2012. At: http://www.fsis.usda.gov/PDF/Prevalence_Estimates_Report.pdf