

MEMORANDUM

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Re: **FSIS Performance Standards for Chicken Parts and Comminuted Poultry**

The U.S. Department of Agriculture's (USDA's) Food Safety and Inspection Service (FSIS) released its final pathogen reduction performance standards for *Salmonella* and *Campylobacter* in raw chicken parts and not-ready-to-eat (NRTE) comminuted chicken and turkey products, entitled *New Performance Standards for Salmonella and Campylobacter in Not-Ready-to-Eat Comminuted Chicken and Turkey Products and Raw Chicken Parts and Changes to Related Agency Verification Procedures: Response to Comments and Announcement of Implementation Schedule* (the Notice). The new standards set a high bar for *Salmonella* and *Campylobacter* reduction, and FSIS speculates that a significant percentage of the poultry industry initially will not meet the standards.

FSIS maintains that the new performance standards are necessary because, according to FSIS, poultry represents the largest fraction of *Salmonella* and *Campylobacter* illnesses attributed to FSIS regulated products. As support, FSIS referenced evidence of an alleged connection between Salmonellosis and contaminated NRTE comminuted poultry products in recent outbreaks. USDA Secretary Vilsack said that the new standards, "in combination with greater transparency about poultry companies' food safety performance and better testing procedures, will help prevent tens of thousands of foodborne illnesses every year...."

The final performance standards and implementation procedures are very similar to the standards FSIS proposed in January 2015, with some key differences described in further detail below. Although the performance standards technically are not binding requirements, the Agency historically has applied other regulatory pressures to enforce them as if they are binding, and the Agency indicates it will continue to do so for the new standards.

A copy of the advance draft of this *Federal Register* Notice is attached. 1/

1/ This memorandum is based on an advance draft of the performance standards Notice released by FSIS before publication in the *Federal Register*. The advance draft is subject to editing before it is officially published. Substantive changes are not expected, but we will update this memorandum if any occur.

The New Performance Standards

FSIS will apply the following performance standards, which are the same standards FSIS originally proposed in January 2015. FSIS said it based these standards on a variety of sources, including sampling data, Centers for Disease Control and Prevention (CDC) foodborne illness outbreak data, and the most recent available research, such as the Healthy People 2020 goals.

Product	Max. Acceptable Percent Positive		Performance Standard	
	<i>Salmonella</i>	<i>Campylobacter</i>	<i>Salmonella</i>	<i>Campylobacter</i>
Comminuted Chicken (325g sample)	25.0%	1.9%	13 of 52	1 of 52
Comminuted Turkey (325g sample)	13.5%	1.9%	7 of 52	1 of 52
Chicken Parts (4 lb sample)	15.4%	7.7%	8 of 52	4 of 52

FSIS speculates that 63 percent of raw chicken parts producing establishments and 62 percent of NRTE comminuted chicken producing establishments will fail to meet the new *Salmonella* standards and that 46 percent of raw chicken parts producing establishments and 24 percent of raw chicken parts producing establishments will fail to meet the *Campylobacter* standards.

Effective Date for New Performance Standards

FSIS will begin assessing compliance with chicken parts and comminuted poultry performance standards 90 days from the date the Notice is officially published in the *Federal Register*. FSIS will evaluate compliance beginning with samples collected 90 days from the date of publication. As a result, establishments have roughly 90 days to prepare to meet the performance standards. Further, as outlined further below, the Agency will begin posting information publicly about establishment categories and aggregate information on a tiered schedule.

Sample Collection

FSIS will base the number of samples it collects on the establishment's production volume and history of sampling results. The Agency generally will collect 4 or 5 samples per month (one a week) from the largest volume establishments and will decrease incrementally its samples from establishments with less production volume. It may collect up to 6 samples per month from the highest-volume establishments, especially those that produce high volumes of several products. FSIS established the following minimum number of annual samples for each product category:

Product	Minimum number of samples to assess process control in a moving window	
	<i>Salmonella</i>	<i>Campylobacter</i>
Broiler Carcass	11	10
Turkey Carcass	14	19
Comminuted Chicken	10	52
Comminuted Turkey	10	52
Chicken Parts	10	13

In addition to establishing sample collection parameters for comminuted poultry and chicken parts, FSIS has increased the minimum *Salmonella* samples for broiler carcasses from 10 to 11 samples per year. FSIS made this change because it realized that its existing minimum annual *Salmonella* samples for broiler carcasses, combined with the performance standard of 9.8 percent, would have created a zero-tolerance standard.

FSIS said it will sample product at both the primary and secondary producing establishments. However, FSIS has issued instructions to its inspection program personnel that make clear that product that is only repackaged and not subject to further processing is not subject to sampling. FSIS declined to provide any additional explanation regarding the method or location of its samples, explaining that it has already issued the necessary notices and directives related to these issues. ^{2/}

Covered Products

FSIS will sample legs (comprised of the drumstick and thigh portions either separately or combined), wings, and breasts for compliance with the chicken parts performance standard. After concluding that the sample results for injected or marinated products do not differ significantly from intact parts, FSIS said it will sample and apply the performance standard to these products. FSIS will not apply the performance standards at this time to necks, giblets, half carcasses and quarter carcasses. FSIS has indicated, however, that it will begin an exploratory sampling program of these products in fiscal year 2016 to understand their prevalence rates better.

The Agency will sample finished NRTE ground chicken and turkey and other types of NRTE comminuted chicken and turkey products to assess compliance with the comminuted performance chicken or turkey standards. FSIS also will sample raw sausage in casing. FSIS will not sample dumplings, wontons, egg rolls, or other comminuted or turkey products wrapped in dough or similar casings.

Although FSIS will continue to sample mechanically separated chicken and turkey that is not intended to be processed in an RTE product, it will not subject these products to the performance standards for comminuted poultry. The Agency indicated that it may, however, implement a performance standard for mechanically separated poultry in the future. In the meantime, FSIS recommends that industry begin implementing quality control procedures for ensuring that extraneous materials such as intestinal tract and other internal organ fragments do not contaminate the source carcass frames, regardless of whether or not the product is destined for RTE processing.

Moving Window Approach

FSIS will evaluate establishments using a 52-week moving window approach. The number of samples FSIS collects during the 52-week period will vary depending on the volume of product the establishment produces. FSIS will assess compliance based on any 52-week period that ended over the last three months, instead of over the last six months as FSIS originally proposed. ^{3/} If an establishment has exceeded the *Salmonella* or *Campylobacter* performance standard during any completed 52-week moving window over the last three months, it will be placed in Category 3, at least until FSIS re-categorizes establishments a month later (and possibly longer, depending on

^{2/} FSIS referenced Directive 10,250.1 and FSIS Notices 16-15, 22-15, 23-15, 31-15, and 31-15.

^{3/} For example, if FSIS were assessing compliance with the performance standards on May 1, 2018, the Agency would look at each 52-week moving window that ended on a day within the past three months—*i.e.*, three months' of moving windows. For example, the moving window that ended on April 15, 2018, would be included in that review and would encompass the 52-week period from April 16, 2017, through April 15, 2018.

where in the series of moving windows the positive results occurred).

FSIS declined to adopt requests to include in the 52-week evaluation supplemental test samples that establishments provide to the Agency. However, the Agency is considering initiating a pilot project using volunteer establishments to evaluate the feasibility of including establishment data in the 52-week window. One of FSIS's stated reasons for choosing not to include establishment data was the variation in industry sampling and testing methodologies. To address this challenge, FSIS intends to issue a compliance guideline for standardizing data collection and reporting.

As explained further below, FSIS plans to conduct follow-up sampling if an establishment fails a performance standard. FSIS plans to include this follow-up sampling in the moving window calculation when assessing compliance with the performance standards. FSIS had originally proposed to exclude these samples, but decided that including the samples will allow the Agency to assess more quickly whether establishments have regained process control.

Establishment Categories

FSIS generally will carry forward its current process for identifying compliance categories, with an exception for *Campylobacter* in comminuted chicken and turkey:

Category 1: Establishments that have achieved 50 percent or less of the performance standard during all completed 52-week moving windows over the last three months.

Category 2: Establishments that meet the standard for all completed 52-week moving windows but have results greater than 50 percent of the standard during any completed 52-week moving window over the last three months.

Category 3: Establishments that have exceeded the performance standard during any completed 52-week moving window over the last three months.

Because the comminuted chicken and turkey performance standards allow only one positive for *Campylobacter*, FSIS views the Category 1/2/3 distinction as not meaningful. FSIS therefore will categorize establishments producing these products as either "passing" or "failing."

FSIS will reevaluate establishments' compliance categories and update its web-postings monthly. The monthly updates will be based on FSIS's evaluation of the 52-week moving windows that ended during the previous three months. Therefore, although web postings will be updated monthly, it may take longer for an establishment actually to drop into a lower category, depending on where in the moving windows the positive samples occurred.

Internet Posting of Category Information

FSIS plans to post a list of establishments that fall under each of the three categories, rather than only the establishments that fall under Category 3 as the Agency had been doing recently for the whole-bird performance standard. FSIS will update establishment categories monthly.

Whole Bird Performance Categories: Beginning 90 days after FSIS publishes its Notice in the *Federal Register*, the Agency will begin posting on its website the category status of all establishments subject to the existing poultry carcass performance standards, based on the sample results FSIS has collected from May 2015 onward. This will include establishments in all categories. May 2015 is the date FSIS stopped its set-based, consecutive day testing and began routine sampling throughout the year, meaning the Agency will have about 52 weeks of data.

Comminuted Poultry and Chicken Parts: As noted, FSIS will begin assessing establishment

compliance beginning 90 days after publication of the Notice. Sample results affecting whether establishments meet the new standards will begin with the first sample collected as part of the moving window on or after 90 days from the publication date. Once FSIS samples the first 52-week moving window of sampling, it will begin posting establishment categories. FSIS advised that it may begin posting category information sooner if establishments' overall performance does not improve or appears to be worsening before the completion of the first moving window.

Aggregate Information: FSIS will begin to post quarterly aggregate information covering all establishments subject to sampling under the new performance standards. These postings will not identify specific establishments by name. FSIS's Notice, which is still in prepublication form, contains conflicting dates for when these postings will begin, either 90 or 180 days after publication.

Prevalence Estimates: FSIS will post calendar-year prevalence estimates for *Salmonella* and *Campylobacter* in its annual report.

Regulatory Consequences of Failing the Performance Standards

Although the performance standards technically are not binding on industry, FSIS's Notice indicates that failure to meet them will result in significant increased Agency oversight. According to FSIS,

Product produced by an establishment that does not meet the standard is not necessarily adulterated. However, failing to meet the standard provides evidence that the production process is not well controlled, and FSIS will take steps to ensure that the establishment improves its production process to reduce variability and to gain more consistent process control.... [P]ersistent failure to meet the pathogen reduction performance standards can be used as a rationale to progressively encourage the establishment to implement more effective food safety controls or to discontinue production of product.

FSIS plans to schedule a Public Health Risk Evaluation (PHRE) and possibly a Food Safety Assessment (FSA) based on Agency sample results for:

- establishments that do not meet the performance standards;
- establishments that have produced products with repetitive *Salmonella* or *Campylobacter* serotypes of public health concern or repetitive antibiotic resistant *Salmonella*; and
- establishments with *Salmonella* or *Campylobacter* with pulsed-field gel electrophoresis (PFGE) (or whole-genome sequencing, as it becomes available) patterns matching those found in recent outbreaks or epidemiologically linked to illnesses.

FSIS will collect 16 or 8 follow-up samples, depending on establishment size, on a daily or per-shift basis as soon as possible after the establishment fails to meet the performance standards. These additional samples will count toward the samples included in the 52-week moving window.

For 90 days after an establishment fails to meet the standards, FSIS will monitor CDC's PulseNet for any food isolates that match those FSIS obtained in its samples. As whole genome sequencing becomes available, the Agency also will search for official sequencing database matches between FSIS-regulated NRTE product and human illnesses. FSIS also plans to alert its public health partners so they can be on the lookout for an emerging outbreak. In addition, FSIS said it may collect the failing establishment's consignee list so it can focus its attention on the area in which the product was distributed.

As part of the PHRE, FSIS will assess the establishment's Hazard Analysis and Critical Control Points (HACCP) plan and Sanitation Standard Operating Procedures (SSOPs), with a focus on

corrective actions, and develop a plan to determine whether a failing establishment has implemented corrective actions. FSIS also will scrutinize corrective actions if product is linked to an outbreak, even if the establishment satisfies the performance standards. If after 90 days the establishment has not regained process control and the establishment has not taken corrective actions, FSIS will take enforcement action (e.g., issue a Notice of Intended Enforcement Action (NOIE) or suspend inspection). FSIS will not issue an NOIE or suspend inspection based solely on the fact that an establishment did not meet a performance standard.

The Notice states that, generally, if an establishment produces product associated with an outbreak or has failed to meet the performance standards and has not addressed those hazards in its HACCP plan, the establishment would need to reassess its HACCP plan for that product. According to FSIS, the establishment would have to address the pathogen in its HACCP plan, rather than through a prerequisite program.

For those establishments that fail to meet the standards, FSIS anticipates that they will need to make changes to their production processes to lower the prevalence of the pathogens in their products. FSIS provides several examples of potential changes, many drawn from procedures the Agency suggested in its draft *Compliance Guideline for Controlling Salmonella and Campylobacter in Raw Poultry*, ^{4/} such as vaccination programs, supplier contract guarantees of pathogen-free flocks, and applying antimicrobial agents to parts and source materials for comminuted poultry product.

Based on the initial PHRE, FSIS will determine whether to schedule an FSA, using the decision making process outlined in FSIS Directive 5100.4. FSIS states that it typically will not schedule an FSA based solely on an establishment moving from Category 1 to Category 2.

Additional Policy Decisions

The Notice also announced several related policy decisions:

- Enrichment Method: FSIS will continue assessing establishment performance for *Campylobacter* reduction based on direct plating of a 1 mL portion size, but it also will continue to perform the 1 mL direct plating method alongside the 30 mL enrichment-based method and analyze the data generated from both analytical approaches.
- Sharing of Rinsate: FSIS does not intend to share rinsate with establishments. FSIS stated it “is satisfied with the competency of its laboratory personnel and the procedures they implement, which are able to reliably detect pathogens.” The Agency encourages establishments to conduct their own sampling rather than relying on FSIS sampling results.
- International Trade: Responding to industry concerns related to the implications of the performance standards on international trade, of significance, FSIS reiterated that “*Salmonella* is not an adulterant in NRTE poultry products” and said a positive test result for *Salmonella* in imported NRTE poultry product would not result in regulatory control actions at a port-of-entry.

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The new performance standards reflect a significant expansion of the use of verification sampling that promises to have a substantial impact on industry. FSIS plans to use an establishment’s failure to satisfy the standards as justification for increased regulatory oversight. Poultry processors should review their operations carefully in light of the final standards.

Please do not hesitate to contact us if we can provide additional information.

^{4/} FSIS, *Draft FSIS Compliance Guideline for Controlling Salmonella and Campylobacter in Raw Poultry* (Dec. 2015).