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May 21, 2015

Docket Clerk
U.S. Department of Agriculture, Food Safety and Inspection Service
Patriots Plaza 3, 355 E Street S.W., Mailstop 3782, Room 8–163B
Washington, DC 20250–3700.

RE: Changes to the *Salmonella* and *Campylobacter* Verification Testing Program: Proposed Performance Standards for *Salmonella* and *Campylobacter* in Not-Ready-to-Eat Comminuted Chicken and Turkey Products and Raw Chicken Parts and Related Agency Verification Procedures and Other Changes to Agency Sampling [Docket No. FSIS–2014–0023]

The Pew Charitable Trusts (Pew) appreciates this opportunity to comment on the U.S. Department of Agriculture (USDA) Food Safety and Inspection Service's (FSIS's) proposed changes to the *Salmonella* and *Campylobacter* Verification Testing Program. Pew applies a rigorous, analytical approach to improve public policy, inform the public and stimulate civic life. Through our Safe Food Project, we seek to reduce health risks from foodborne pathogens by strengthening federal government authority and the enforcement of food safety laws.

Infections by *Salmonella* and *Campylobacter* have been estimated to cause approximately 1.9 million foodborne illnesses in the U.S. each year (Scallan *et al.* 2011). The resulting annual public health toll has been estimated at 28,000 hospitalizations and nearly 500 deaths (Scallan et al. 2011). Numerical estimates for the fraction of infections attributable to poultry vary across studies – for example, estimates based on (Batz *et al.* 2012, Interagency Food Safety Analytics Collaboration 2015) range from 17 to 35% for *Salmonella*, and from 10 to 72% for *Campylobacter*. However, it is clear that the consumption of contaminated poultry is an important contributor to these illnesses (Batz et al. 2012, Interagency Food Safety Analytics Collaboration 2015).

The potential public health impact of the proposed changes to the verification testing program is illustrated, for instance, by the fact that, according to FSIS (USDA-FSIS 2015a), the products newly regulated by the proposed performance standards account for 87 percent of illnesses attributable to chicken consumption (81 percent from chicken parts and 6 percent from comminuted chicken such as ground or minced chicken). Once finalized, the proposed performance standards as well as the other proposed changes to the verification testing program will go a long way towards reducing preventable illnesses from contaminated poultry. The performance standards will be instrumental in reaching the Healthy People 2020 goals of reducing all human illnesses from *Salmonella* and *Campylobacter* by 25 and 33 percent, respectively.

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As detailed in the relevant Federal Register notice, the proposed changes to the *Salmonella* and *Campylobacter* verification testing program include the establishment of new pathogen reduction performance standards for *Salmonella* and *Campylobacter* in poultry products that are commonly consumed and contaminated at considerable frequency, but that were not previously covered by FSIS performance standards. These include raw chicken parts, comminuted chicken, and comminuted turkey. Other proposed changes to the verification program concern the mechanism of sample collection and the initiation of exploratory baseline studies.

Pew commends the agency for undertaking such wide-ranging changes to the *Salmonella* and *Campylobacter* verification sampling program, and in particular strongly supports several key elements that will be protective of public health, including:

- The establishment of *Salmonella* and *Campylobacter* performance standards for chicken parts, comminuted chicken, and comminuted turkey that:
  - Cover products that pose a significant public health risk due to their frequency of contamination and consumption, but that were not previously covered;
  - Are based on public health risk assessments and directly linked to public health outcomes; and
  - Are proposed to be updated regularly to reflect changes in industry practices and data availability.

- The replacement of the current 'set-approach' to sample collection with 'routine' sampling throughout the year for all products included in the verification program, because it will:
  - Prevent bias caused by the conduct of announced pathogen testing that will be known to establishments ahead of time;
  - Allow the calculation of national prevalence rates, which in turn will enable the agency to track the impact of the new performance standards and other industry changes over time; and
  - Provide a more representative picture of industry by preventing disproportionate reliance on past performance during sampling allocation.

- The use of a moving window approach for assessing process control because it will allow:
  - The inclusion of eligible products from low-volume producers in the verification testing program; and
  - The monitoring of establishment performance in real time and the initiation of follow-up sampling and corrective actions as soon as the maximum number of positive samples has been exceeded.

- The web posting of process-control performance status for all eligible establishments because it will provide an incentive for establishments that are currently out of compliance to implement changes that will bring the establishments into compliance with the performance standard.

- The initiation of intensive follow-up sampling as soon as the maximum number of positive samples permissible under the performance standard has been exceeded, and the initiation of a for-cause food safety assessment (FSA) at the establishments.

- The concurrent use of a more sensitive enrichment method for a subset of samples tested for *Campylobacter*, and the potential revision of the *Campylobacter* performance standards based on the

new data, to account for the potential impact of insufficiently-sensitive testing methods in the establishment of *Campylobacter* performance standards.

- The initiation of testing of selected imported raw poultry products for *Salmonella* and *Campylobacter,* the enumeration and serotyping of individual isolates to identify trends and determine associations with human illnesses, and the public posting of testing results.

- The initiation of exploratory sampling of raw pork products.

At the same time, Pew makes the following recommendations for improving the proposal:

1. **Establish a formalized process for the periodic re-evaluation and potential updating of all performance standards to ascertain whether the standards continue to reflect current industry practices and the best available data, and are appropriate for reaching the agency's public health goals.**

As discussed in the supporting FSIS risk assessment (USDA-FSIS 2015b), the current performance standards were selected based on their expected public health impacts. These predicted public health impacts are based on risk assessments and statistical analyses, which require major assumptions that cannot currently be validated with the available data. While such assumptions are commonplace in the risk-assessment domain, they can have major implications for the model predictions and therefore need to be validated to the greatest extent possible (Dearfield *et al.* 2014). Major assumptions in the establishment of the proposed performance standards that are currently difficult or impossible to verify fall into three broad categories:

a. **Current industry performance with regard to the proposed performance standards**
As stated in the supporting FSIS risk assessment (USDA-FSIS 2015b), some proposed standards (e.g., standards for comminuted chicken and turkey) are currently based on performance data for a limited number of establishments, collected during a limited period of time (i.e., 8 months). Therefore, as stated in the FSIS risk assessment, the estimated number of establishments currently in compliance for these standards is uncertain, and because the public health impact of a performance standard is a function of the fraction of establishments currently in compliance, it is highly uncertain for some standards.

Similarly, as detailed in the Federal Register notice, low-quantity establishments are not currently sampled and products such as injected products marinated in a clear solution were not consistently sampled during the baseline study, leading to data gaps and resulting uncertainty. The implementation of the proposed performance standards will allow the agency to collect more and better data (e.g., for more establishments, and over a longer period of time) on current industry performance, and the performance standards should be re-evaluated once sufficient industry data have been collected (and periodically thereafter).

b. **The fraction of establishments that will come into compliance once the performance standards have been implemented.** As stated in the supporting FSIS risk assessment and the Federal Register notice, the fraction of establishments that will come into compliance in response to the new performance standards being issued cannot be known, but is a crucial component of the estimated public health impact of a proposed standard. While the current assumption of 50% compliance in two years may be a reasonable estimate because it is based on previous agency experience, it may be overly optimistic. In part, this fraction will depend on how many establishments are currently 'out of compliance,' what incentives these establishments have to improve their performance, and how easy it will be for establishments to implement changes that will allow them to become compliant.

   As analyzed in the supporting FSIS risk assessment, if the fraction of establishments that comes into compliance remains below 50 percent (i.e., 30 or 40 percent in the risk assessment scenarios), a considerably more stringent performance standard will be needed to achieve the agency's public health objective. The agency should carefully track what fraction of establishments indeed comes into compliance in response to the proposed performance standards, and periodically consider whether the performance standards need to be updated to account for the actual fraction in compliance and the agency's public health targets.

c. **Model assumptions.** The mathematical model used to predict the public health impact achieved by the performance standard is itself based on numerous key assumptions, such as proportionality between the change in the fraction of establishments meeting the performance standards and the change in attributable illnesses, or the proportionality of the risk of various products and their production volume shares. While these assumptions may be acceptable and appropriate in the absence of other data, their appropriateness should be reviewed periodically in light of the newly collected data, and performance standards should be updated as needed to reflect the most appropriate models and assumptions.

2. **Reconsider the analytical methods for *Campylobacter* testing. Routinely use the more sensitive enrichment-based method instead of the standard (non-enrichment) method for all *Campylobacter* testing. Evaluate whether *Campylobacter* performance standards need to be updated based on data collected using the more sensitive sampling method, and continue to evaluate the usefulness of new diagnostic methods, in particular those suitable for multiple *Campylobacter* species, as they are developed.**

As stated in the supporting FSIS risk assessment (USDA-FSIS 2015b), contrary to the situation for *Salmonella,* the majority of the industry currently produces poultry products in which *Campylobacter* is not present in quantities above the limit of detection of the routine analytical method (i.e., without enrichment). However, this does not necessarily mean that these products are free of *Campylobacter,* or that products from these facilities do not pose a risk to consumers. The standard analytical method for

Campylobacter is currently considerably less sensitive than for *Salmonella* (USDA-FSIS 2015a). It is possible that the true prevalence of *Campylobacter* is actually considerably higher than the apparent prevalence that can currently be determined based on the relatively insensitive analytical method.

As stated in the Federal Register notice, FSIS plans to evaluate the adequacy of the current standard method used for *Campylobacter* testing by analyzing a subset of samples using both the standard (non-enrichment) and the more sensitive enrichment-based *Campylobacter* detection method. Pew shares FSIS's concerns about the adequacy of the standard (non-enrichment) method. However, we believe that FSIS should immediately switch to the more sensitive enrichment-based methods for all *Campylobacter* testing instead of relying on the less-sensitive method for the foreseeable future. The central importance of test performance for establishing effective pathogen monitoring programs and performance standards for *Campylobacter*, and the public health importance of the pathogen warrants such an approach.

In particular, Pew suggests switching to the enrichment-based method immediately for the following reasons:

1. The enrichment-based method is more sensitive than the non-enrichment based method;
2. The enrichment-based method has already been validated, is included in the relevant FSIS testing method (MLG 41), and is immediately available to FSIS for routine use;
3. The benefit of the non-enrichment based method is the ability to quantify *Campylobacter* concentrations, which is no longer possible after enrichment; however, FSIS is not using the non-enrichment based method for *Campylobacter* quantification, and the proposed performance standard does not include any reference to *Campylobacter* quantities; therefore, the routine use of the non-enrichment based method would not provide any measurable benefits over the enrichment-based method.

Once sufficient data have been collected using the enrichment-based method, the agency should re-evaluate whether the performance standards for *Campylobacter* need to be updated. In addition, because *Campylobacter* testing poses several unique challenges, such as the susceptibility of the organism to oxygen, low temperatures, and other stress, and the selectivity of culture methods to certain *Campylobacter* species, diagnostic methods continue to be refined and new methods will likely be developed in the future (Gill 2014). The agency should keep monitoring the development of new diagnostic methods for *Campylobacter*, and incorporate advances in diagnostic testing when appropriate.

3. **Consider how to use the performance standards to maximize consumer protection and to incentivize the implementation of the new performance standards. Close facilities that do not meet the new performance standards until corrective actions have been implemented, and recall product produced in the absence of adequate process control.**

As already discussed, the rate with which 'non-compliant' establishments will come into compliance plays a major role in the public health impact achieved by the performance standard, and ultimately in

reaching the agency's overall health-protection goals. Pew commends the agency for planning to conduct follow-up testing and for-cause FSAs in non-compliant facilities, and to publish performance data on the internet. However, these actions alone may not be sufficient to incentivize facilities to implement costly or difficult changes, and may not satisfactorily protect public health. The latter may be particularly true if contaminated product, produced before corrective actions can be implemented, reaches the consumer.

Facilities that do not have adequate process control, as indicated by a failure to meet performance standards, pose a public health hazard. These facilities should be closed until they can demonstrate that adequate controls are in place, and product produced without adequate process control should be recalled. This would protect consumers, and also provide incentives to the facility to become and remain compliant. If the current laws and regulations do not provide sufficient authority to close plants under such circumstances, then the necessary changes to the underlying laws should be considered to allow FSIS to fulfill its mandate of keeping consumers safe. In addition, because incentives will be critical to motivate the adoption of processes that allow facilities to come into compliance, the agency should also consider what other incentives may be available to it, such as different inspection approaches or testing frequency based on plant performance, and implement them as appropriate.

4. ***Salmonella* contaminated raw chicken and turkey pose a risk to consumers. These products should not be allowed to enter the market. Imported raw poultry determined to be *Salmonella* contaminated should be denied entry.**

Pew commends the agency for beginning to sample imported raw chicken and turkey, for conducting additional evaluations of positive samples (e.g., serotyping), and for posting the data (in aggregated form) on the internet. However, the absence of a regulatory action to prevent contaminated imported raw product from entering the U.S. poses a risk to consumers. These products should not be allowed to enter the U.S. market, and neither should *Salmonella*-contaminated domestic raw products. The potential public health impact of *Salmonella*- contaminated raw chicken is illustrated, for instance, by the foodborne-illness outbreaks linked to Foster Farm chicken products (The Pew Charitable Trusts 2013). The agency should prevent *Salmonella*-contaminated foods from entering the market, regardless of whether these products are raw or ready-to-eat, imported or domestically produced. If the current laws and regulations do not provide sufficient authority to do so, the necessary changes to the underlying laws should be considered to allow FSIS to fulfill its mandate of keeping consumers safe.

5. **Develop a systematic approach to periodically measuring the impact of the performance standards on public health.**

As detailed above, the predicted public health impact of the proposed performance standards depends heavily on (currently limited) data and key assumptions. In addition, other factors may impact public health outcomes, such as unrelated rules or regulations (e.g., performance standards for whole

carcasses), unrelated changes in industry practices, and changing consumer preferences and behaviors. The agency, in collaboration with other agencies as appropriate, should systematically and periodically track the impact of the performance standards on the public health burden, for instance through source attribution, case-control studies, or surveys of pathogen prevalence and concentration at slaughter, processing and/or retail. Eventually, performance standards should be evaluated in light of their actually measured (instead of predicted) public health impact, and updated as needed to meet the agency's public health goals.

6. **Use the data collected through the proposed, as well as existing, performance standards to evaluate whether establishment performance on different products (e.g., whole carcasses and parts) is correlated.**

As discussed in the FSIS risk assessment (USDA-FSIS 2015b), a sizable number of establishments produce whole carcasses as well as parts. Both types of products will now be subject to performance standards. If data are collected and recorded adequately by the agency, it will be possible to determine whether an establishment's performance on different products is correlated. This information has important implications for the expected public health impact of the performance standards, as discussed in detail in the FSIS risk assessment. In addition, it is important information for policymakers, industry, and other stakeholders, and can be instrumental for targeting potential interventions.

7. **Re-evaluate whether additional pathogen reduction performance standards may be needed. Assess whether additional products should be covered by performance standards, and consider establishing performance standards that specify maximum permissible pathogen contamination levels at the time animals enter the slaughter facility.**

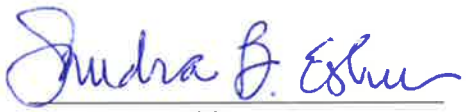
While the agency will cover the majority of poultry consumed in the U.S. once the proposed standards are finalized, several poultry products are not covered, including products that are contaminated at a considerably higher frequency than currently covered products, such as necks and giblets (USDA-FSIS 2015a). The agency should re-consider whether additional standards for more highly contaminated products are needed, especially if there is indeed a positive correlation between an establishment's performance on different products. In addition, the agency should consider establishing performance standards that cover maximum pathogen levels on animals as they enter the slaughter facility. This may reduce contamination on all products produced in the facility by limiting *Salmonella* quantities present in the facility. If the current laws and regulations do not provide sufficient authority to do so, the necessary changes to the underlying laws should be considered to allow FSIS to fulfill its mandate of keeping consumers safe.

8. **Use the data collected as part of the *Salmonella* and *Campylobacter* verification sampling program to more rapidly detect, investigate and control outbreaks linked to products incorporated in the verification sampling.**

Data on the types of pathogens that are present in different poultry products produced in different establishments can be instrumental for identifying and tracing foodborne-illness outbreaks. These data would help protect public health by removing contaminated product from the market more quickly, by being able to reach exposed consumers more effectively, and to prevent further illnesses. However, to do so, the pathogens have to be adequately described (e.g., serotyped and PFGE-typed), and the testing data have to be made available to public health officials in appropriate repositories such as PulseNet. FSIS should ensure that the data collected as part of the *Salmonella* and *Campylobacter* verification testing program are generated, recorded and used in ways that make the maximum public health use of the data.

In conclusion, Pew commends the agency for proposing the changes to the *Salmonella* and *Campylobacter* verification testing program outlined above. Adequate, public health based pathogen reduction performance standards, which are regularly updated to reflect current practices and public health objectives; which are based on appropriate sampling design and methodologies; and which can be followed up with agency actions that will prevent contaminated, potentially hazardous food from reaching the consumer, will be instrumental for improving food safety and reducing foodborne illness.

Sincerely,



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