

November 8, 2017

**FSIS Response to the Food and Water Watch comment on the Information Collection renewal for the Salmonella Initiative Program (SIP).**

**Food and Water Watch:** “[T]he data collection that occurred under the existing information collection was fraudulent. The agency has admitted that the buffering solution it had been using prior to July 1, 2016 was masking the presence of Salmonella on poultry carcasses, therefore the agency was basing its rulemaking for the New Poultry Inspection System (NPIS) on flawed data.”

**FSIS:** FSIS strongly disagrees that the information collection for SIP was “fraudulent.” The Agency analyzed the Neutralizing Buffered Peptone Water (nBPW) and concluded that the previous BPW formula was not masking pathogens, but rather proved to have inadequate buffering capacity in particular scenarios in which significant carryover of chemical interventions occurred at the sampling point. The buffer formula was therefore improved in order to address the changes in predominant interventions used throughout the industry.

The SIP sampling data was not, as suggested, used to determine NPIS rulemaking, with a couple of exceptions; SIP waivers were used to update 9 CFR 381.1 for poultry ready-to-cook standards and 9 CFR 381.66 (b) for poultry chilling requirements, neither of which were dependent on microbiological data.

**Food and Water Watch:** “We also urge that the agency establish a policy that all regulatory waiver requests made by meat, poultry, egg processing, and siluriformes plants be subject to public notice and comment in the Federal Register.”

**FSIS:** FSIS regulations (specifically 9 CFR 303.1(h), 381.3(b), and 590.10)) authorize the Administrator to waive for limited periods any provisions of the regulations to permit experimentation so that new procedures, equipment, and processing techniques may be tested to facilitate definite improvements. As described in the July 13, 2011 Federal Register Notice entitled, [Salmonella Verification Sampling Program: Response to Comments on New Agency Policies and Clarification of Timeline for the Salmonella Initiative Program \(SIP\)](#), “[the] Salmonella Initiative Program (SIP) [is] for meat and poultry slaughter establishments that agree to share internal food safety data with FSIS in order to receive waivers of regulatory requirements. SIP benefits public health in that it encourages slaughter establishments to test for microbial pathogens and to respond to the ongoing results by taking steps when necessary to regain process control and thus to minimize the presence of pathogens of public health concern.”

Establishments that request waivers of any kind go through a rigorous process in which they provide the basis for the waiver request, the scientific support, and any sampling or data requirements to continuously support the efficacy of their process with a waiver in place. When effective new technologies result in rulemaking, the rule and its support are published in a Federal Register Notice, allowing for a public comment and an opportunity for FSIS to respond and revise as needed.

**Food and Water Watch:** “Since the Salmonella Initiative Program simply entails an agency waiver of undetermined regulatory requirements with the condition that establishments perform microbiological testing and share all sample results with FSIS, the agency has an independent duty to ensure that any regulatory requirements that are relaxed as part of the SIP program do not result in an inspection

program that conflicts with the Act, including the requirement that inspectors be able to critically appraise carcasses.”

**FSIS:** FSIS operates within the Act when granting waivers and continuing inspection under a waiver. The same sampling and verification tasks occur in SIP establishments as in non-SIP establishments. This includes, but is not limited to, ante-mortem and post-mortem carcass-by-carcass inspection, FSIS verification sampling for pathogens at the same frequency as comparable establishments without a waiver, and identical performance standards as the rest of industry. The modified approach was addressed in 284 F.3d 125, 350 U.S.App.D.C. 290 (AFL-CIO v. Sec. of USDA), when appraising the HIMP inspection approach. That decision asserted that “[b]ecause the modified program calls for federal inspectors in participating poultry plants to personally examine each poultry carcass leaving the slaughter line, the USDA is complying with the PPIA's requirement that “the carcass of each bird processed” be inspected for adulteration. 21 U.S.C. § 455.”

SIP establishments may only propose waivers that they can demonstrate a definite improvement upon the current process that the regulation covers. This includes scientific support and data collection submitted with the waiver application, as well as testing and data sharing while under the waiver that is above and beyond that required in the regulations. The burden of the waiver process is on the requesting establishment both in supporting that their proposal is addressing food safety, and in providing FSIS full access to inspect and verify the food safety system throughout their establishment.