U.S. Poultry & Egg Association

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September 12, 2011

U.S. Department of Agriculture (USDA)
Food Safety and Inspection Service (FSIS)
Room 2-2127, George Washington Carver Center
5601 Sunnyside Avenue, Mailstop 5474
Beltsville, MD 20705-5474

Re: USDA, FSIS Docket No. FSIS–2008–0008

Dear Sir or Madam:

The U.S. Poultry & Egg Association (USPOULTRY) shares with our members and the regulatory food safety authorities a commitment to the common goal of producing a safe, wholesome and abundant food supply. We also believe in continually striving to improve the safety of the products in this food supply through the reasoned development, and fair implementation, of innovations and initiatives that are rooted in sound science. Consequently, we are opposed to the way in which the Food Safety and Inspection Service (FSIS) is attempting to implement the proposed new food safety regulatory policies in the above referenced Federal Register (FR) Notice. Consequently, on behalf of USPOULTRY, and the member companies we represent, we respectfully submit the following comments in response to USDA, FSIS Docket No. FSIS–2008–0008:

The FSIS is using previously granted HACCP-Based Inspection Models Project (HIMP) and On-Line Reprocessing (OLR) waivers to force establishments into participating in the "voluntary" *Salmonella* Initiative Program (SIP).

The FSIS labeled the SIP a "voluntary" program in both the January 28, 2008 FR Notice (i.e. Docket No. FSIS–2006–0034), and the July 13, 2011 FR Notice (i.e. Docket No. FSIS–2008–0008), and in neither case was that completely accurate. A major mandate of the SIP requires establishments currently operating with HIMP and OLR waivers to "participate in SIP or else drop their waivers and return to conventional inspection." Many of the processing plants who will be affected by this requirement have been operating under such waivers for upwards of a decade (or more), and have developed their entire operational capabilities around the continued use of them. Some establishments (and possibly the companies who own them) do not have the capacity to make the profound changes that would be required by the forfeiture of such waivers, and those that do so will suffer a competitive disadvantage when compared with the rest of the poultry industry.

Establishments operating under HIMP and OLR waivers that pre-date the SIP should not be forced to decide between volunteering to participate in said program or forgoing such waivers. The authority of the Agency to grant waivers of poultry regulatory requirements, contained in 9 CFR 381.3(b), allows the Administrator to waive provisions of the regulations to permit "experimentation so that new procedures, equipment, and processing may be tested to facilitate definite improvements." HIMP and OLR technologies that pre-date the SIP are not new, nor are the food safety improvements they have made in poultry processing in doubt. And, the FSIS has, since the inception of both, acknowledged as much through their words and deeds. There is, therefore, no need to require establishments operating under these old, proven, waivers to join the SIP which the Agency created (in part) to incentivize greater industry control of *Salmonella* by granting new, unproven, waivers to establishments.

The FSIS developed the HIMP and OLR, accepted the implementation of HIMP programs and/or use of a variety of OLR application systems and associated antimicrobial agents in, and granted reprocessing and inspection related waivers to, poultry processing establishments, so long as all was done in accordance with distinct, specifically defined, parameters. In so doing, the Agency effectively entered into a contractual agreement with each and every processing establishment that was granted a HIMP and/or OLR waiver. As was previously stated above, over many years these plants have come to rely on the promise of the continued use of these waivers so long as they continued to comply with their original agreements. Now, however, the FSIS is attempting to unilaterally alter such contracts, demanding the affected establishments accept the additional requirements of the SIP or face the nullification of their waivers if they refuse. This unfair practice, if implemented, may leave establishments and/or companies to wonder if the Agency may be trusted to not do likewise in the future with respect to other commitments they have made.

The above stated concerns support the need, and our request, for the FSIS, prior to implementation of the SIP, to revoke the mandate included in FR Notice FSIS–2008–0008 that requires establishments currently operating under HIMP and OLR waivers to "participate in SIP or else drop their waivers and return to conventional inspection." The Agency should make the SIP a truly voluntary program, by affording those establishments who see value in enrolling in it the opportunity to do so, and allowing the rest who do not to avoid participation without suffering any negative consequence(s).

The FSIS has proposed that the SIP will benefit public health without providing any scientific data and/or decision making documents adequate to support their assertions.

The Agency has stated that the SIP will benefit public health because "it encourages establishments to test for microbial pathogens," and "take steps to regain process control… if the establishment's results show it is not meeting the Agency's current performance standards." When the original SIP FR Notice, Docket No. FSIS–2006–0034, was written, the poultry industries were in a different place with respect to *Salmonella* testing and control than they are in now. It is no longer realistic to suggest that establishments require motivation to test for microbial pathogens and take steps to regain process control if their results show improvement is needed. Establishments are, and have been for some time, voluntarily conducting such testing and associated activities to ensure their compliance with the performance standards when the Agency performs verification sampling.

By requiring establishments enrolled in the SIP to comply with the current *Salmonella* standard for turkeys or for young chickens, the FSIS has inextricably linked this program to the new *Salmonella* and *Campylobacter* performance standards, and the problems associated with them, detailed in Docket No. FSIS–2010–0029, published on March 21, 2011. In said FR Notice, in response to previous public comments claiming they were violating the Administrative Procedure Act (APA) by effectively promulgating regulations without following required notice-and-comment policies, the Agency asserted that "the policies and performance standards…do not impose requirements on establishments." The SIP FR Notice, published less than four months later, states that an establishment participating in the SIP is "required to take samples for microbial analysis on each line every day and during each shift." It further stipulates that, in the event it fails to meet the current *Salmonella* standard with its own testing, an establishment must increase testing, investigate whether the waiver conditions in their process are "affecting its public health protection performance…and document its findings and the corrective and preventive actions taken to return to the current *Salmonella* standard of process control." It is difficult to understand how the FSIS did not know when it published the new performance standards that it would soon be requiring both testing and compliance with said standards in the new SIP FR Notice.

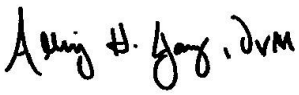
As in the recent FR Notice detailing the new *Salmonella* and *Campylobacter* performance standards, the Agency makes vague and unsubstantiated claims about the benefits to public health that are expected to result from aspects of the SIP that require establishments to test for microbial pathogens, a reported "key feature of effective process control," and submit their testing data to "inform Agency policy on pathogens." Over the past several years, the FSIS has clearly stated that failure to comply with performance standards does not have any direct enforcement consequences, but rather serves as an indicator of process control. The Agency has, however, never fully explained, and supported, exactly what they believe such failures indicate about process control, and (equally important) the proven impact on public health resulting from these failures. It is important, therefore, to know, before moving forward with their full implementation via the

SIP, what the FSIS believes the true value of their performance standards is, as well as how they correlate to public health goals/objectives, and if they have any data to support such beliefs. Only then can one have any hope of accurately assessing whether or not such policies may actually help decrease the occurrence of foodborne illnesses.

The above stated concerns support the need, and our request, for the FSIS, prior to the implementation of the SIP, to provide substantive responses to questions concerning Agency assertions of enhanced public health protection that will purportedly result from industry compliance with the new *Salmonella* and *Campylobacter* performance standards. In lieu of that, the Agency should remove from the SIP FR Notice all language related to increases in public health protection, as well as both new performance standards, until such time as these policies may be appropriately modified using sound science.

USPOULTRY looks forward to receiving a response to the above stated comments, questions and requests. Please do not hesitate to contact me if the Agency has any questions, or requires additional information, with respect to anything contained within this document. USPOULTRY stands ready to work with the FSIS to improve the SIP and new *Salmonella* and *Campylobacter* performance standards, and looks forward to the opportunity to do so.

Sincerely,



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