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September 12, 2011

Docket Clerk
U.S. Department of Agriculture, FSIS
Room 2-2127
George Washington Carver Center
5601 Sunnyside Avenue, Mailstop 5474
Beltsville, MD 20705-5474

Re: Docket No. FSIS-2008-0008; Salmonella Verification Sampling Program; Response to Comments on New Agency Policies and Clarification of Timeline for Salmonella Initiative Program (SIP)

Dear Sir or Madam:

The National Chicken Council (NCC) appreciates the opportunity to comment on the "Salmonella Verification Sampling Program; Response to Comments on New Agency Policies and Clarification of Timeline for Salmonella Initiative Program (SIP)" published in the *Federal Register* by the U.S. Department of Agriculture (USDA) Food Safety and Inspection Service (FSIS). NCC represents vertically integrated companies that produce and process more than 95 percent of the chicken marketed in the United States. NCC's members would be directly affected by SIP as announced in the Notice.

NCC and our members are strongly committed to ensuring the safety of the products we produce. Indeed, through voluntary initiatives and in cooperation with FSIS, the chicken industry has successfully enhanced food safety. The industry continues to work with the Agency in developing, testing, and implementing evolving technologies designed to make our products as safe as possible.

Putting aside questions about the merits of SIP, NCC objects to the process by which FSIS is expanding the program. Rather than engaging in notice and comment rulemaking, the Agency continues to announce new and broad reaching policies informally. This is the same procedural approach the Agency followed in revising the *Salmonella* standards and creating *Campylobacter* standards. 1/ By requiring establishments to participate in SIP to maintain their operating waivers, FSIS is in effect making participation mandatory and imposing on establishments specific action levels for non-adulterant pathogens. As we explain in more detail below,

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1/ SIP is intertwined with the Agency's new *Salmonella* and *Campylobacter* performance standards addressed most recently in this Notice and in a Notice published at 76 Fed. Reg. 15282 on March 21, 2011. Although we focus our comments primarily on SIP, we have the same procedural concerns with the way the Agency has promulgated the *Salmonella* and *Campylobacter* performance standards.

imposing these standards on the industry in this manner violates the Administrative Procedure Act (APA).

The chicken industry recognizes the importance of preventing foodborne illness and ensuring a safe food supply. The industry has made great strides in recent years in reducing the number of broiler carcasses testing positive for *Salmonella*, achieving a two-fold reduction in the prevalence of *Salmonella* on chicken carcasses on a national basis since the industry's voluntary adoption of the NCC *Salmonella* Reduction Program in 2004. Even though the industry continues to reduce the prevalence of *Salmonella* on raw products and will strive for the lowest levels achievable, serious question remains as to the scientific basis of SIP and the standards on which it is based. Human illness rates are influenced by multiple factors and available data do not support FSIS's premise that a reduction in pathogen presence on poultry will result in a corresponding reduction in cases of human illness.

This comment explains the legal shortcomings of setting what in effect are enforcement levels for *Salmonella* and *Campylobacter* without engaging in the notice and comment rulemaking process. NCC is greatly concerned with the recent trend replacing reasoned, collaborative notice and comment rulemaking with mere *Federal Register* notices. The *Salmonella* and *Campylobacter* performance standards on which SIP are based, and SIP itself, are not the product of notice and comment rulemaking. Not only does this process result in legally infirm rules—creating an uncertain regulatory environment—but it also results in a less scientifically robust approach to food safety. As we explain below, the notice and comment rulemaking process is the proper vehicle for developing standards and programs such as these.

I. The Administrative Procedure Act Requires Notice and Comment Rulemaking for Substantive Rules such as SIP

We view as inappropriate the Agency's publication of a mere "Notice" in the *Federal Register* setting forth the new SIP mandates because this approach fails to afford the protections or meaningful and legitimate consideration required for the Agency to promulgate rules. Although some types of Agency action are expressly exempt from notice and comment rulemaking, this is not one of them.

The *Salmonella* and *Campylobacter* standards announced by FSIS clearly constitute a "rule" under the APA, which defines that term as "the whole or a part of an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy." 2/ The APA draws a distinction between legislative rules, which require notice and comment rulemaking for promulgation, and interpretive rules, which do not. 3/ "Legislative rules 'grant rights, impose obligations, or produce other significant effects on private interests,' while interpretive rules do not 'foreclose alternative courses of action or conclusively affect rights of private parties.'" 4/ FSIS's performance standards—and now SIP—do much more than

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2/ 5 U.S.C. § 551(4).

3/ *See* 5 U.S.C. § 553(b).

4/ *State of Ohio Dept. of Human Services v. U.S. Dep't of Health and Human Services*, 862 F.2d 1228, 1233 (6th Cir. 1988) (quoting *Batterton v. Marshall*, 648 F.2d 694, 701-02 (D.C. Cir. 1980)).

"only 'remind' affected parties of existing duties." 5/ Rather, the standards are legislative because they are "binding" on private parties 6/ and "create new law, rights, or duties." 7/

First, courts have held that, where there are clear and adverse consequences for failing to comply with a regulation, it constitutes a legislative rule and must be promulgated through notice and comment rulemaking. 8/ The SIP standards are effectively binding and mandatory for poultry establishments operating under waivers. Despite labeling the program "voluntary," FSIS states that "[e]stablishments currently operating under regulatory waivers will have to participate in SIP or drop their waivers." 9/ Establishments with waivers invest significant capital in their plants based on those waivers, an investment that is rendered worthless if the waiver is revoked. Moreover, waivers affect aspects such as line speed and processing capacity, so revoking a waiver can significantly change an establishment's incoming and outgoing volume. Thus, an establishment operating under a waiver effectively has no choice but to participate in SIP; the cost of losing a waiver is too high. Notwithstanding the procedural concerns regarding SIP, we do recognize that voluntary SIP can be advantageous to those poultry establishments that are able to increase their line speeds and otherwise experiment with new technologies. We encourage the Agency to allow more companies who are interested in participating voluntarily to do so.

Once an establishment is participating in SIP, it must implement additional, tighter controls, conduct additional testing, and provide information to FSIS. Moreover, it is widely known throughout the industry that an establishment's *Salmonella* performance levels are associated with FSIS enforcement actions and heightened scrutiny. Lastly, companies participating in SIP will have to change their processing operations to achieve the target standards. The consequences incurred by not complying with SIP underscore the legislative nature of the agency action.

Second, if an agency "document is couched in mandatory language, or in terms indicating that it will be regularly applied, a binding intent is strongly evidenced." 10/ The Notice speaks in terms of "standards," which is not a discretionary label. 11/ The *Federal Register* Notice discusses the Agency's plans to "implement" (*i.e.*, enforce) the standards 12/, using language underscoring the standards' and the program's binding nature. Additionally, FSIS states in the Notice that SIP

5/ *Jerri's Ceramic Arts, Inc. v. Consumer Product Safety Comm'n*, 874 F.2d 205, 207 (4th Cir. 1989).

6/ *Center for Auto Safety v. Nat'l Highway Traffic Safety Admin.*, 452 F.3d 798, 806 (D.C.Cir.2006).

7/ *General Motors Corp. v. Ruckelshaus*, 742 F.2d 1561, 1565 (D.C. Cir. 1984) (en banc).

8/ *General Elec. Co.*, 290 F.3d at 383 (quoting Anthony, *Interpretive Rules*, 41 Duke L. J. at 1328-29).

9/ 76 Fed. Reg. 41186, 41192; s*ee also id.* at 41189 ("[E]stablishments will have 120 days from publication of this notice to decide whether they will continue to operate under the waiver by complying with the provisions of SIP or else operate without a waiver.").

10/ *General Elec. Co. v. Envtl. Protect. Agency*, 290 F.3d 377, 383 (D.C. Cir. 2002) (quoting Robert A. Anthony, *Interpretive Rules, Policy Statements, Guidances, Manuals, and the Like-Should Federal Agencies Use Them to Bind the Public?*, 41 Duke L. J. 1311, 1328-29 (1992)).

11/ *E.g.*, 76 Fed. Reg. at 41187 ("[T]he standards for *Salmonella* positives in young chicken and turkey will become 7.5 and 1.7 percent, respectively.").

12/ *E.g.*, *id.* at 41191.

"offers incentives to meat and poultry slaughter establishments to control *Salmonella* in their operations." 13/ Using lowered standards as a means of controlling levels of *Salmonella* is indicative of the Agency's intent to require companies to meet these standards. Companies operating under waivers realistically have no option but to comply with the regulation and FSIS does not provide them with an opportunity not to do so. Accordingly, SIP is a legislative rule.

Through its failure to comply with the APA's requirements, FSIS has circumvented the numerous protections that must be afforded to the public when agencies promulgate legislative rules. 14/ Because FSIS's Notice was not subject to review by the Office of Management and Budget, there was no determination of the rule's economic impact 15/ or its impact on small entities (for which a regulatory flexibility analysis is required). 16/ Additionally, FSIS is evading the APA's requirement that agencies "give interested persons an opportunity to participate in the rulemaking" and consider comments before issuing a final rule. 17/ By using a mere notice, FSIS averts the legal safeguards afforded for legislative rules despite promulgating a new rule that will materially affect all establishments operating under waivers and all establishments otherwise participating in SIP. 18/

II. Failing to Use Notice and Comment Rulemaking Creates Legally and Scientifically Infirm Rules

Failing to follow notice and comment rulemaking procedures when implementing substantive rules creates a legally infirm and scientifically unsound regulatory environment. As explained above, the APA requires agencies to provide notice and opportunity to comment before promulgating rules that substantively affect persons' rights and obligations. By not availing itself of this well-established mechanism, the Agency has created a regulatory scheme that is legally suspect. This situation increases cost to both the industry and the Agency. The industry must expend time and resources understanding the mandatory nature of the new regulations and has no established process by which to work with the Agency to resolve legal and technical concerns with the rules. The Agency, in turn, must expend its limited resources addressing after the fact regulated parties' concerns and possibly defending challenges. Moreover, the regulated industry is forced to operate under rules of uncertain legal legitimacy, which breeds considerable uncertainty. An uncertain regulatory environment affects whether and how companies invest

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13/ *Id.* at 41186.

14/ Congress enacted the APA's requirements in part to "afford adequate safeguards to private interests." *Chamber of Commerce v. Occupational Safety and Health Admin.*, 636 F.2d 464, 470 (D.C. Cir. 1980) (quoting H.R. 1203, 79th Cong., 1st Sess. (Comm. Print June 1945)).

15/ Exec. Order No. 12866 – Regulatory Planning and Review.

16/ Regulatory Flexibility Act, 5 U.S.C. § 601-612.

17/ 5 U.S.C. § 553(c).

18/ In an earlier Notice regarding the Agency's new *Salmonella* and *Campylobacter* performance standards, FSIS attempted to justify its circumvention of the notice and comment rulemaking process on the ground that "notice establishing standards against which to measure establishment performance has been accomplished before through Federal Register notices." 76 Fed. Reg. at 15283. This is of no consequence. Whether the regulated industry has tolerated the Agency's failure to use the proper notice and comment rulemaking in the past is irrelevant to whether the Agency must comply with its legal obligations under the APA when promulgating substantive regulations.

capital, structure transactions, organize supplier relationships, and operate their production processes.

Second, by not availing itself of the notice and comment process, the agency deprives itself of significant scientific and technical data needed to inform its decision making process. Not only does this leave regulations vulnerable to challenge as being arbitrary and capricious, it also leads to rules and policies that may not be as effective as they would had the Agency requested and considered additional information from interested parties. For example, there is concern that, given current performance standards, further reducing *Salmonella* levels in raw poultry products is not as efficient or effective in improving public health as would be increasing consumers' understanding of proper cooking and handling practices. The APA requires the notice and comment process for substantive rules to ensure agencies can use information such as this to craft efficient rules that materially advance agencies' objectives. Sidestepping this process leads to regulations that may be as unsound scientifically as they are legally.

Conclusion

SIP imposes significant new requirements on establishments, especially those operating under waivers who might not opt into the program but for a need to maintain their waivers. NCC objects to the Agency imposing requirements such as these, as well as the performance standards on which they are based, without properly availing itself of the notice and comment rulemaking process. By using mere notices, the Agency is creating a regulatory scheme vulnerable to challenge developed without meaningful consideration of all relevant information. Such an infirm regulatory scheme advances neither regulatory certainty nor food safety. NCC therefore urges FSIS to follow the notice and comment procedures required by the APA for this and future substantive rulemakings.

Please do not hesitate to contact us if we may be of assistance in developing an alternative approach. Thank you for your consideration.

Respectfully submitted,

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