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Submitted via mail and email on October 5, 2017

Dear Ms. Rotenberg:

Please take this letter as Food & Water Watch¹ (FWW)'s comments opposing the National Chicken Council ("NCC")'s September 1, 2017, petition to revoke the current line speeds applicable to NPIS poultry slaughter plants. FWW submits these comments in this manner in accordance with USDA Food Safety Inspection Service ("FSIS" or agency) staff instructions on how to do so, notwithstanding that this is the process for submitting comments on "petitions for rulemaking"² and NCC's "waiver" petition ostensibly calls for its approval without the public notice and opportunity for comment provided under the Administrative Procedure Act ("APA"). FWW interprets these staff instructions as an agency belief that it could not simply approve NCC's petition through an agency waiver under 9 C.F.R. § 381.3(b) (2017). Supporting this, FWW provides the following comments that demonstrate how approval of the petition without rulemaking would violate the APA. Moreover, even with adequate public notice and opportunity to comment, granting NCC's petition would violate the agency's waiver regulations and the Poultry Products Inspection Act ("PPIA"), as well as be arbitrary and capricious.³

FWW therefore respectfully requests that the agency DENY this petition. Should the agency deem any matter in NCC's petition worthy of consideration, at minimum it can only do so through notice and comment rulemaking under the APA. And, pursuant to 21 U.S.C. § 463(c) (2012), FWW hereby requests that the agency host a public hearing on the matter.

I. Granting NCC's Petition Through the Agency's Waiver Regulations, Without Public Notice and Opportunity to Comment, Would Violate the APA.

NCC's petition requests that the agency "implement a waiver system pursuant to 9 C.F.R. § 381.3(b)" that would allow young chicken slaughter establishments participating in the New Poultry Inspection System ("NPIS") and *Salmonella* Initiative Program ("SIP") to operate without having to comply with 9 C.F.R. § 381.69(a) (2017), which sets the line-speed limit for NPIS plants at 140 birds per minute ("bpm").

But granting the petition and implementing such a waiver system under § 381.3(b) would violate the APA. As the agency is undoubtedly aware, the APA generally requires that notice of

¹ Food & Water Watch is a national consumer organization that advocates for safe and sustainable food systems.

² 9 C.F.R. § 392.7.

³ FWW submits these comments without conceding that it or members of the public have, in fact, received adequate notice and opportunity to comment on the petition, as notice was not provided as required under the APA. Nor has the agency invited the public to comment on the petition.

proposed rule-makings be published in the Federal Register.⁴ 5 U.S.C. § 553(b) (2012). The APA further requires that all interested persons be provided the opportunity to participate in such rule-makings through submission of written comments. *Id.* § 553(c). The APA defines “rule making” as the “agency process for formulating, amending, or repealing a rule[.]” *id.* § 551(5), and a “rule,” as “an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy or describing the organization, procedure, or practice requirements of an agency” *Id.* § 551(4).

FSIS has been delegated the authority under the PPIA to engage in rule-making to “prescribe conditions under which poultry products capable of use as human food, shall be stored or otherwise handled . . . to assure that such articles will not be adulterated or misbranded when delivered to the consumer.” 21 U.S.C. § 463(a) (2012). And it is beyond cavil that, pursuant to this authority, FSIS’s establishment of a 140 bpm line-speed limit for NPIS slaughter plants under § 381.69(a) was a so-called legislative “rule.” It was a forward-looking provision that implemented and prescribed binding law applicable to all facilities opting into the NPIS program. There is no ambiguity or discretion as to the applicability of this provision, and violators are subject to Non-compliance Records (“NRs”).

If FSIS was to grant NCC’s petition and now establish a separate process whereby NPIS plants no longer are subject to this 140 bpm line-speed limit, it would likewise be a rule-making. After all, “[i]t is a maxim of administrative law that: “[i]f a second rule repudiates or is irreconcilable with [a prior legislative rule], the second rule must be an amendment of the first; and, of course, an amendment to a legislative rule must itself be legislative[.]” requiring APA public notice and opportunity to comment. *Nat’l Family Planning & Reprod. Health Ass’n v. Sullivan*, 979 F.2d 227, 235 (D.C. Cir. 1992) (quoting Michael Asimow, *Nonlegislative Rulemaking and Regulatory Reform*, 1985 *Duke L.J.* 381, 396 (1985)).

One need not look further than the NCC petition’s paltry conditions for the granting of “waivers” under its sought-after program to find proof that it is actually seeking a rule repudiating the existing NPIS line-speed limits. The requested criteria include a facility’s 1) participation in the NPIS program; 2) entrance into the SIP program; and 3) development of “a process for monitoring and ensuring it is maintaining process control at its chosen line speed, along with corrective actions to regain process control if lost.” But these are already applicable to poultry slaughter establishments subject to 9 C.F.R. § 381.69(a). All NPIS facilities must abide by the regulation’s speed limits. Most of the facilities that have had SIP waivers⁵ have already or are expected to enter the NPIS program.⁶ And all poultry slaughter facilities,

⁴ Publication is required in the Federal Register because all of the members of the public who are subject to this rulemaking cannot be named and personally served or otherwise have actual notice of the petition. 5 U.S.C. § 553(c).

⁵ This too is a rather insubstantial requirement, since all that the SIP program entails is an agency waiver of undetermined regulatory requirements with the condition that establishments perform microbiological testing and share all sample results with FSIS. If it were adopted by FSIS, NCC’s criteria that plants enter the SIP program before receiving the “waiver” from the NPIS line-speed limits also would amount to rules both revoking the agency’s present 5-facility limit for the number of poultry facilities that can obtain waivers increasing line speeds, *see* 76 Fed. Reg. 41,186 (July 13, 2011), and establishing new microbiological testing requirements for all such facilities.

⁶ 79 Fed. Reg. 49,566, 49,624 (Aug. 21, 2014) (indicating that FSIS would not count the effects of the NPIS rules on those poultry establishments with SIP waivers for the Regulatory Impact Analysis because such facilities were expected to join the program and the impacts are relatively small). *See also* 82 Fed. Reg. 41,392, 41,393 (Aug. 31,

regardless of their line-speed limits, are already required to have what could easily be construed as NCC's rather vapid requirement of "a process for monitoring and ensuring it is maintaining process control."⁷

Thus, far from seeking a regulatory "waiver"—applying only to "specific classes of cases" of facilities, as required by § 381.3—the NCC petition seeks a broad rule repudiating § 381.69(a)'s line-speed maximums.

Such a rule-making would not qualify for any of the APA's narrow notice-and-comment exceptions, either. Granting the petition would not be a "general statement of policy" under 5 U.S.C. § 553(b)(A), as the petition seeks to bestow upon slaughter facilities the right to disregard existing line-speed limits and instead follow the new, non-discretionary ones that they establish, and it does so based upon mandatory criteria, *i.e.*, the plants' entrance into the NPIS and SIP programs and establishment of "a process" for monitoring and ensuring they are maintaining and re-establishing process control—no matter how inadequate such a process is. The requested rule would thus be binding on both companies and the agency and not simply a statement of policy. *See Community Nutrition Institute v. Young*, 818 F.2d 943, 946 (D.C. Cir. 1987) (finding that binding action levels subjecting entities to agency enforcement were not mere general statements of policy).

Likewise, establishing the requested "waiver" program would not be a "rule of agency organization, procedure, or practice[.]" under § 553(b)(A), since it would be primarily directed at slaughter facilities' behavior and would have a substantial impact on them by lifting their line-speed limits. The NCC petition also seeks "a stamp of agency approval or disapproval on a given type of behavior[.]" by espousing that slaughter plants join the voluntary NPIS and SIP programs. This is enough to make the establishment of such a program subject to the APA's public-notice and opportunity-for-comment requirements. *Chamber of Commerce of the United States v. United States DOL*, 174 F.3d 206, 211 (D.C. Cir. 1999) (finding that the agency's establishment of a voluntary program without public notice-and-comment rulemaking violated the APA because the program incentivized and provided a normative stamp of approval on the adoption of certain work-place-safety compliance plans).

Plain and simple, to do what NCC's petition requests would be to engage in "rulemaking," subject to the APA's public-notice and opportunity-to-comment requirements, and would not simply be to granting a regulatory waiver. The petition should thus be rejected. Or, at minimum, the agency must provide notice in the Federal Register, take public comment, and host a public hearing pursuant to 21 U.S.C. § 463(c), as requested above.

2017) (noting a substantial decrease in the number of SIP approvals that "occurred as a result of the implementation of the New Poultry Inspection System").

⁷ For example, new rules finalized in 2014 required that all facilities incorporate process control measures to address the prevention of contamination by enteric pathogens and fecal material into the HACCP systems and to maintain ongoing documentation to demonstrate that the procedures are effective. 9 C.F.R. § 381.65(g).

II. FSIS's Granting of NCC's Petition Would Violate the Agency's Waiver Regulations.

Even if the agency were to provide adequate public notice and opportunity to comment on NCC's petition, FSIS has no authority to approve it under 9 C.F.R. § 381.3(b).

Granting NCC's petition would be contrary to § 381.3(b) for at least three reasons. First, (and in addition to it only applying to "specific classes of cases") this regulation only allows waivers for "limited periods" of time. NCC's petition, on the other hand, seeks no time limits whatsoever on the requested "waiver" program. NCC ostensibly seeks its indefinite establishment, rendering it unlawful.

Second, waivers under § 381.3(b) may only be granted for tests "to facilitate *definite improvements*" ⁸ (Emphasis added.) NCC offers no reason that their petition would even be aimed at "definite improvements" in food safety. Indeed, the petition's chief argument—which FWW disputes—is only that "Increasing Line Speeds *Would Not Impair* Food Safety." (Emphasis added.) In other words, increasing line-speed limits would not be *worse* for public health. And much of their supporting arguments, which would themselves be arbitrary and capricious grounds for granting the petition, as argued below, simply recite data from the agency's 2011 HIMP Assessment ⁹ that, *at best*, show how certain food-safety indicia are not worse in HIMP plants—but they certainly do not show definite improvements. For example, the petition's reliance on the 2011 HIMP Assessment's findings of an absence of statistical differences in fecal NRs and *Salmonella* positive rates based on line speeds simply show that FSIS did not find that increased line speeds were statistically related to these indicia of adulteration. The findings obviously did not demonstrate that there were definite improvements in food safety at HIMP plants, however, or that improvements would even be further facilitated by further increasing line speeds. ¹⁰

Moreover, the value of *Salmonella* data presented in the 2011 HIMP Assessment is now subject to serious doubt, as the neutralizing solution that the agency was using prior to July 2016 resulted in a far lower sample-positive rates compared to a new solution, demonstrating the prevalence of false negatives in the agency's prior verification testing. And other parts of the 2011 HIMP Assessment show that HIMP plants still had major problems, such as having significantly higher NRs for entire years for certain public-health-related inspection tasks. ¹¹

This is a far cry from *definite improvements*. Indeed, it appears as if true thrust of NCC's arguments is that granting the petition will simply improve profits, by "leveling the playing field within the U.S. chicken industry," and "eliminating competitive barriers between the U.S. and international chicken producers." This is not permissible grounds for granting slaughter plants a regulatory waiver under § 381.3(b).

⁸ These comments assume *arguendo* that the petition's requested new line-speed limits amount to "new procedures, equipment, and processing technique," under § 381.3(b)—itself a highly dubious proposition.

⁹ USDA, FSIS, *Evaluation of HACCP Inspection Models Project (HIMP)* (Aug. 2011) ("2011 HIMP Assessment"), https://www.fsis.usda.gov/shared/PDF/Evaluation_HACCP_HIMP.pdf.

¹⁰ The petition's reliance on the 2001 RTI study is hardly relevant for the NPIS program which was finalized and implemented in 2014.

¹¹ Given this and that the agency does not know the plants in which the flawed neutralizing solution was used, any study of the benefits of NPIS would have to start anew and could not simply build on FSIS's 2011 HIMP Assessment.

Third and finally, § 381.3(b) only allows the granting of waivers when it does not conflict with the purposes or provisions of the PPIA. The act provided that the FSIS “shall cause to be made by inspectors post-mortem inspection of the carcass of each bird processed” 21 U.S.C. § 455(b) (2012). The D.C. Circuit has ruled that the ordinary, common meaning of the term “inspection” means that each carcass must receive a “critical appraisal” by a government inspector. *See AFGE v. Glickman*, 215 F.3d 7, 11 (D.C. Cir. 2000) (“[A] critical appraisal . . . is what the[] statute[] demand[s].”)

Nothing in NCC’s petition demonstrates that inspectors will be able to provide the “critical appraisal” of poultry carcasses, as is required under the PPIA. This is true of plants that are currently operating at increased line-speed limits under NPIS, and it certainly would be true in those plants operating even faster under NCC’s desired “waiver” program. For example, there is nothing in the petition that demonstrates that federal inspectors are able to appraise the exterior backsides of carcasses or the inside of the birds, either in NPIS facilities or those operating at faster speeds.

Thus, FSIS has no authority under § 381.3(b) to grant NCC’s petition, and it must be denied.

III. FSIS’s Granting of NCC’s Petition Would Be Unreasonable and Arbitrary and Capricious.

Finally, NCC’s petition should be rejected because granting it would be simply unreasonable and arbitrary and capricious.

It is well established administrative law that “[a]n agency changing its course must supply a reasoned analysis indicating that prior policies and standards are being deliberately changed, not casually ignored. Failing to supply such analysis renders the agency’s action arbitrary and capricious.” *Lone Mountain Processing, Inc. v. Secretary of Labor*, 709 F.3d 1161, 1164, 9 (D.C. Cir. 2013) (internal quotation marks and citation omitted).

Here, FSIS already considered and rejected industry requests like NCC’s to increase line-speed limits when it finalized the NPIS rules:

After considering the comments, FSIS agrees that it is important to assess establishments’ ability to maintain process control as they implement changes to operate under the NPIS. Data from the HIMP pilot demonstrate that establishments operating under HIMP are able to maintain process control at line speeds of up to 175 bpm. However, as noted above, although they are authorized to do so, most HIMP establishments do not operate at 175 bpm. The average line speed under HIMP is 131 bpm. It is also the case that non-HIMP establishments have been operating successfully at line speeds of 140 bpm or less.

Therefore, under this final rule, the maximum line speed for young chickens will be 140 bpm for establishments operating under the NPIS instead of 175 bpm, as was proposed. Limiting the maximum line speed for young chickens under the NPIS to 140 bpm also addresses the concern raised in some of the industry comments that establishments permitted to implement the NPIS first during a staggered implementation will be able to

increase their line speeds while other establishments will be economically harmed as they wait for their implementation date.

After the NPIS has been fully implemented on a wide scale, and the Agency has gained at least a year of experience under the new system, FSIS intends to assess the impact of changes adopted by establishments operating under the NPIS by evaluating the results of the Agency's *Salmonella* and *Campylobacter* verification sampling, reviewing documentation on establishments' OCP performance, and other relevant factors. FSIS will consider these results in assessing whether establishments operating under the NPIS have implemented measures that are effective in maintaining process control.

79 Fed. Reg. at 49,591.

NCC's petition offers no reasonable grounds to reverse this course,¹² as several of the agency's stated criteria for re-evaluation of the 140 bpm line-speed limit have not yet occurred. For example, NPIS has not been "fully implemented on a wide scale," for at least a year, since only 60 or so plants have entered the program. And this sparse participation alone cannot be grounds for re-evaluating and repudiating the NPIS line-speed limits because the agency was well-aware of the industry's argument that lower line-speed limits might stymie some participation, but it adopted the 140 bpm limit anyways, based on the following rationale:

The Agency's experience under HIMP demonstrates that young chicken establishments have incentives to participate and remain in the HIMP pilot for reasons other than the ability to operate faster line speeds. Experience from the HIMP pilot shows that HIMP establishments operate with an average line speed of 131 bpm, and that although they are authorized to do so, most of the young chicken HIMP establishments do not operate line speeds at 175 bpm. Thus, the faster line speeds authorized under HIMP do not appear to be the primary incentive for establishments to participate in the pilot because the average line speed of establishments operating under the HIMP inspection is slower than the 140 bpm maximum line speed authorized under the existing inspection systems.

79 Fed. Reg. at 49,615.

Therefore, the agency still estimated that 219 poultry plants—all but the smallest—would volunteer for the NPIS program. And while this has not been the case thus far, NCC offers no reason for the agency to reject its assumption and reverse course at the NPIS program's infancy.

Nor does the petition offer new data for the agency to reasonably "assess the impact of changes adopted by establishments operating under the NPIS by evaluating the results of the Agency's *Salmonella* and *Campylobacter* verification sampling, reviewing documentation on establishments' OCP performance, and other relevant factors[,]"¹³ as the agency contends it would do prior to reconsidering its 140 bpm line-speed limit.

¹² It should not go unnoticed that the NCC petition does not even request that the agency adopt the 175 bpm line-speed limits the FSIS originally proposed with NPIS. Facilities under the petition's program could be operating *even faster than this*, provided that they are in the NPIS and SIP program and have a system to monitor, maintain, and re-establish process control, whatever that means. So, an even greater showing would be needed to justify that such new line-speed limits are reasonable.

¹³ *Id.* at 49,591.

Rather, NCC simply offers the results from a plant survey, which is shockingly bad in its discussion of details, if not its methodology. The survey ostensibly compares *Salmonella* and *Campylobacter* testing results from a very small sample of 20 NPIS and non-NPIS plants over a very short six-month period. The petition does not, however, detail the manner in which the surveyed plants were selected, suggesting likely bias, and the petition fails to reveal other plant characteristics demonstrating that the non-NPIS and NPIS comparators were similar.¹⁴ The petition does not present the *Campylobacter* and *Salmonella* data, even in summary form, instead solely listing the survey participants' total rates and then contending that the NPIS participants' rates were "as good as if not better than their non-NPIS counterparts."¹⁵ The petition simply states that NR rates for non-NPIS and surveyed NPIS facilities "were statistically the same" and the public-health NR rates in NPIS plants were "less than" in non-NPIS plants, again failing to reveal these rates.

For poultry parts, the petition does provide a tad more data, saying that NPIS plants had 21 and 9% lower *Salmonella* and *Campylobacter* rates than non-NPIS plants, respectively, but it does not present other key statistics necessary to evaluate this data's meaning, including the number of samples, standard deviations, and whether these differences were significant at a given *p* value, as opposed to simply being a product of sampling error. Nor does the petition attempt to evaluate whether there is any relationship between line speeds and *Campylobacter* and *Salmonella* rates, simply noting more generally that NPIS plants had higher line speeds and greater production.

Finally, the supposed public-health benefits from NPIS ostensibly were to come from an increase in *unscheduled* verification tasks—tasks that FSIS's HIMP risk assessment correlated to lower *Campylobacter* and *Salmonella* rates.¹⁶ NCC's petition does not indicate how many more of this type of public-health-related verification tasks were done in NPIS plants compared to non-NPIS plants, if any. Thus, its conclusion that NPIS and HIMP show that "increased line speed and corresponding production volume can result in robust food safety outcomes and subsequent public health protection[]"¹⁷ is completely unfounded.

Clearly, NCC's proffered survey is not a serious evaluation of NPIS facilities in order to compare them to non-NPIS facilities, no less a reasoned "evaluat[ion of] the results of the Agency's *Salmonella* and *Campylobacter* verification sampling, review[of the] documentation

¹⁴ The petition does admit that the-NPIS plants had 6% more production than non-NPIS facilities.

¹⁵ And of course, it matters little that the *Campylobacter* and *Salmonella* rates are lower in the surveyed NPIS plants than in the industry-wide data that the petition presents, since the former is based on only six-months of data and the latter is based on data from an entire year. Moreover, the survey data comes from the time of year when *Salmonella* rates are typically their lowest.

¹⁶ See *FSIS Risk Assessment for Guiding Public Health-Based Poultry Slaughter Inspection: An Implementation Scenario-Based Approach*, 17 (July 2014), <http://www.fsis.usda.gov/wps/wcm/connect/5eab5fe5-e113-491c-afc7-c4d351443679/PSRA+++2014-07-30++Final.pdf?MOD=AJPERES>

¹⁷ Further, since HIMP was designed as quasi-experiment, where the application of the inspection system was anticipated to result in desired public-health outcomes such as lower *Salmonella* rates, the NCC survey does not bolster the results of the HIMP pilot, as it fails to compare the *Salmonella* rates at the facilities subject to the NPIS "treatment" and compare them to when they were not within the program (just as the FSIS's 2011 HIMP Assessment failed to do).

on establishments' OCP performance, and other relevant factors[,]" that the agency indicated it would need to do in order to re-evaluate NPIS's 140 bpm line-speed limits.¹⁸

In sum, the NCC petition provides anything but a reasoned analysis for the agency to reverse course and increase NPIS's line-speed limits, and FSIS should accordingly reject it. A failure to do so would be unreasonable and arbitrary and capricious.

IV. Conclusion

As demonstrated, approval of NCC's petition without notice-and comment rulemaking would violate the APA. The petition, which seeks a broad-brush repudiation of FSIS's existing rules limiting NPIS line speeds using the agency's waiver provisions, thus should be rejected. Moreover, even with adequate public notice and opportunity to comment, FSIS's granting of the petition would violate the agency's waiver regulations, the PPIA, and be unreasonable arbitrary and capricious. FWW therefore respectfully requests that the agency DENY this petition. Alternatively, pursuant to 21 U.S.C. § 463(c), FWW hereby requests that the agency host a public hearing on the matter. FWW appreciates your consideration of the comments. Please feel free to contact our Senior Staff Attorney, Zach Corrigan, zcorrigan@fwwatch.org, if you have any questions.

Sincerely,



Wenonah Hauter,
Executive Director

cc: Paul Kiecker, paul.kiecker@fsis.usda.gov,
Mary Porretta, mary.porretta@fsis.usda.gov.

¹⁸ It is ridiculous for the petition to argue that "were there any reason to believe" that increased line speed and corresponding production volume would not result in "robust food safety outcomes and subsequent public health protection," "FSIS certainly would not have continued to allow the former HIMP plants the option of operating at speeds up to 175 bpm." Not only was there substantial information demonstrating that HIMP plants had serious problems, including that, over ten years, 14 out of 20 plants had higher *Salmonella* rates when they were part of the HIMP pilot than when they weren't, but also, FSIS ultimately set the 140 bpm line-speed limit for NPIS facilities based on the fact that the HIMP plants were in fact only operating at a rate of 131 bpm, which is far lower than the limits the NCC petition would ostensibly allow.