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DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

[Docket No. FSIS-2018-0014]

Petition to Permit Waivers of Maximum Line Speeds for Young Chicken Establishments Operating under the New Poultry Inspection System; Criteria for Consideration of Waiver Requests for Young Chicken Establishments to Operate at Line Speeds of up to 175 Birds Per Minute

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Response to comments and information on waiver criteria.

SUMMARY: The Food Safety and Inspection Service (FSIS) is responding to public comments on a petition submitted by the National Chicken Council (NCC) on September 1, 2017, and is also providing information on the criteria applicable to line speed waivers for young chicken establishments. The NCC submitted a petition to FSIS requesting that the Agency establish a waiver program to permit young chicken slaughter establishments to operate without line speed limits if they participate in the New Poultry Inspection System (NPIS) and the FSIS *Salmonella* Initiative Program (SIP) and develop a system for monitoring and responding to loss of process control. FSIS issued a response denying the petition on January 29, 2018. The response explained

that instead of establishing a separate line speed waiver program under the conditions requested in the petition, FSIS would make available criteria that it will use under its existing waiver procedures to consider individual waiver requests from young chicken establishments to operate at line speeds of up to 175 bpm.

FSIS published these criteria in the February 23, 2018, *Constituent Update*. This notice provides additional information on the criteria that FSIS will use to evaluate new line speed waiver request submissions. Additionally, FSIS is announcing that the 20 young chicken establishments already operating under line speed waivers must meet the new criteria to remain eligible for the waiver. FSIS will issue these establishments new waiver letters that reflect the eligibility criteria described in this document. Failure by establishments already operating under line speed waivers to meet the new criteria within 120 days of receipt of these letters may result in the revocation of the waivers.

FOR FURTHER INFORMATION CONTACT: Roberta Wagner, Assistant Administrator, Office of Policy and Program Development, FSIS, USDA; Telephone: (202)205-0495.

SUPPLEMENTARY INFORMATION:

Background

On August 24, 2014, FSIS published a final rule that, among other things, established the NPIS as an additional inspection system for young chicken and all turkey slaughter establishments (79 FR 49566). The NPIS did not replace FSIS's other poultry slaughter inspection systems, and young chicken and turkey slaughter establishments that do not choose to operate under the NPIS may continue to operate under their current inspection system.¹ Under the inspection systems other than the NPIS, FSIS online inspectors positioned along the slaughter line are responsible for identifying unacceptable carcasses and parts, examining carcasses for visual defects, and directing establishment employees to take appropriate corrective actions if the defects can be corrected through trimming and reprocessing. The maximum line speeds authorized under these inspection systems reflect the time it takes for an inspector to effectively perform the online carcass inspection procedures required for the system. The fastest line speed authorized for a non-NPIS young chicken inspection system is 140 birds per minute (bpm) with four online inspectors, i.e., 35 bpm per inspector, under the Streamlined Inspection System (SIS) for young chickens.

¹ Poultry slaughter inspections systems other than the NPIS include the Streamlined Inspection System (SIS), New Line Speed Inspection System (NELS), the New Turkey Inspection System (NTIS), and Traditional Inspection.

Under the NPIS, establishment employees sort carcasses and remove unacceptable carcasses and parts before the birds are presented to an online inspector located at the end of the line before the chiller. Because the online inspector under the NPIS is presented with carcasses that have been sorted, washed, and trimmed by establishment employees, and are thus much more likely to pass inspection, the inspector is able to conduct a more efficient and effective online inspection of each bird processed.

The NPIS was informed by the Agency's experience under the Hazard Analysis and Critical Control Point (HACCP)-Based Inspection Models Project (HIMP) pilot study. FSIS's experience under the HIMP pilot showed that online inspectors in HIMP young chicken establishments were able to conduct an effective online inspection of each carcass when operating at a line speed of up to 175 bpm and that HIMP establishments were able to maintain process control at the line speeds authorized under HIMP. Based on FSIS's experience under HIMP, the Agency initially proposed 175 bpm as the maximum line speed for NPIS young chicken establishments (77 FR 4408). However, after considering the public comments submitted on the proposed rule, FSIS concluded that it was important to assess young chicken establishments' ability to maintain process control as they implement changes to operate under the NPIS (79 FR 49591). Therefore, the final rule

that established the NPIS provided for a maximum line speed of 140 bpm for young chicken establishments, instead of 175 bpm as was proposed, with an exception for the 20 young chicken establishments that participated in the HIMP pilot study.

In the preamble to the final rule, FSIS explained that it decided to grant waivers to the 20 young chicken HIMP establishments to permit them to continue to operate at line speeds of up to 175 bpm after they convert to NPIS because data from the HIMP pilot demonstrated that these establishments were capable of consistently producing safe, wholesome and unadulterated product and meeting pathogen reduction and other performance standards when operating under line speeds authorized under HIMP (79 FR 49591). The preamble to the final rule also explained that if an NPIS establishment operating under a line speed waiver goes out of business or decides to give up its waiver, FSIS will select another establishment to take its place (79 FR 49583). Thus, when it published the final rule, FSIS planned to continue to provide waivers for up to 20 young chicken establishments to operate at up to 175 bpm under the NPIS.

In the preamble to the final rule, FSIS also explained that "[a]fter 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' [other consumer protection] performance, and other relevant factors" (79 FR 49591). The preamble also stated that "once the NPIS is fully implemented at most establishments, data from these establishments can be used to compare against data from the [former HIMP] young chicken establishments operating under the [line speed] waivers" (79 FR 49591). Thus, when FSIS published the final rule establishing NPIS, it made clear that the Agency would continue to consider line speeds at which establishments are capable of consistently producing safe, wholesome, and unadulterated product and are meeting pathogen reduction and other performance standards.

National Chicken Council Petition and FSIS Response

Petition. On September 1, 2017, NCC petitioned² FSIS to implement a waiver system to exempt young chicken slaughter establishments from the regulation that prescribes 140 bpm as the maximum line speed under the NPIS (9 CFR 381.69(a)). As conditions for the waiver, the petition requested that establishments be required to opt into the NPIS, participate in

² NCC petition available at:
<https://www.fsis.usda.gov/wps/wcm/connect/7734f5cf-05d9-4f89-a7eb-6d85037ad2a7/17-05-Petition-National-Chicken-Council-09012017.pdf?MOD=AJPERES>

SIP³, and develop a system for monitoring and responding to loss of process control. According to the petition, the 140 bpm maximum line speed for the NPIS has deterred many young chicken establishments from opting into the NPIS. The petition stated that FSIS has the authority to implement such a waiver program under 9 CFR 381.3(b), which provides that "[t]he Administrator may, in specific cases, waive for limited periods ... any provision of the regulations ... to permit experimentation so that new procedures, equipment, and processing techniques may be tested to facilitate definite improvements: *Provided*, [t]hat such waivers ... are not in conflict with the purposes or provisions of the [Poultry Products Inspection Act (PPIA)]."

The petition asserted that the requested waiver program will encourage more establishments to opt into the NPIS and will promote and enhance Agency and industry efficiency without compromising food safety, worker safety, or animal welfare. The petition referenced information from the 2011 HIMP pilot study⁴, a 2001 published study, a report from the Department of Labor (DOL) Bureau of Labor Statistics (BLS), and an unpublished industry survey conducted by NCC in 2017 to support the

³ Under SIP, FSIS grants establishments a waiver of the regulation under the condition that the establishment collects and analyzes samples for microbial organisms and shares the results with FSIS.

⁴ The 2011 HIMP Report is available at:
https://www.fsis.usda.gov/wps/wcm/connect/fcd9ca3e-3f08-421f-84a7-936bc410627c/Evaluation_HACCP_HIMP.pdf?MOD=AJPERES

requested action. The petition also stated that the current line speed regulation imposes costs on the industry, creates competitive disparities among U.S. poultry establishments, and places U.S. poultry establishments at a competitive disadvantage with international competitors. The petition said that allowing establishments to operate without line speed limits is consistent with Executive Order (EO) 13771 on "Reducing Regulation and Controlling Regulatory Costs."

Consistent with its regulations on petitions, FSIS posted the NCC petition on the FSIS website and received comments from interested persons on the petition (9 CFR 392.6 and 392.7). FSIS also announced the availability of the petition in the October 13, 2017, *Constituent Update*⁵ and explained that, based on communications with stakeholders, the Agency anticipated that it would receive a significant number of additional comments on the petition. Therefore, to facilitate submission and public posting of comments on the petition, FSIS announced that interested persons could submit comments online through the Federal eRulemaking Portal at: <https://www.regulations.gov>. Comments were accepted online until December 13, 2017, and FSIS

⁵ The October 13, 2017 Constituent Update is available at: https://www.fsis.usda.gov/wps/wcm/connect/a54d5331-372e-4df3-ac4d-8c2953969039/ConstiUpdate101317.pdf?MOD=AJPERES&CONVERT_TO=url&CACHEID=a54d5331-372e-4df3-ac4d-8c2953969039.

considered all timely comments on the petition as part of its review of the petition (9 CFR 392.7).

FSIS Response to Petition. On January 29, 2018, FSIS sent a response to the NCC denying the petition.⁶ In its response, FSIS explained that it had decided to deny the petition because the Agency already has detailed procedures for the submission of new technology notifications and protocols and requests for waivers from regulatory requirements. The response noted that these procedures include a process for submitting requests for the use of alternative procedures, such as faster line speeds, that would require regulatory waivers under the SIP. The response further stated that because FSIS has already implemented procedures for establishments to request regulatory waivers, the Agency determined that it was not necessary to establish a separate system to provide line speed waivers to young chicken establishments operating under the NPIS.

In addition to denying the request to establish a line speed waiver program, the January 2018 response also stated that FSIS was denying NCC's request to permit waivers that would allow NPIS young chicken establishments to operate without a maximum line speed. As noted in the response, the preamble to the final rule that established the NPIS stated that, based on

⁶ FSIS's January 29, 2018, response to the petition is available at: <https://www.fsis.usda.gov/wps/wcm/connect/235092cf-e3c0-4285-9560-e60cf6956df8/17-05-FSIS-Response-Letter-01292018.pdf?MOD=AJPERES>.

its experience under the HIMP pilot, FSIS found that inspectors are able to conduct an effective online inspection of each carcass at line speeds of up to 175 bpm (79 FR 49592). The response noted that the petition did not include data to demonstrate that online inspectors can conduct an effective carcass-by-carcass inspection at line speeds faster than those authorized under HIMP.

In addition to denying the petition, the response noted that FSIS now has over a year of documented process control history for many young chicken establishments operating under the NPIS. The response explained that based on this history, FSIS has decided to consider requests for waivers from young chicken establishments in addition to the current 20 HIMP establishments, to operate at line speeds of up to 175 bpm. The response also explained that in the near future, FSIS intends to make available criteria that it will use to consider these waiver requests.

Criteria for FSIS to Consider Line Speed Waivers

On February 23, 2018, in the *Constituent Update*, FSIS announced the criteria that the Agency will use to consider requests from NPIS young chicken slaughter establishments to operate at line speeds of up to 175 bpm and outlined the

submission requirements.⁷ As provided in that document, to be eligible for a line speed waiver, a young chicken establishment:

- Must have been operating under the NPIS for at least one year, during which time it has been in compliance with all NPIS requirements;
- Must be in *Salmonella* performance standard category 1 or 2 for young chicken carcasses;
- Must have a demonstrated history of regulatory compliance. More specifically, the establishment has not received a public health alert⁸ for the last 120 days; has not had an enforcement action as a result of a Food Safety Assessment (FSA) conducted in the last 120 days; and has not been the subject of a public health related enforcement action in the last 120 days; and
- Must be able to demonstrate that the new equipment, technologies, or procedures that allow the establishment to operate at faster line speeds will maintain or improve food safety.

⁷ The February 23, 2018, *Constituent Update* is available at: https://www.fsis.usda.gov/wps/wcm/connect/ee977696-7f87-4b87-8717-15a824ce0a81/ConstiUpdate022318.pdf?MOD=AJPERES&CONVERT_TO=url&CACHEID=ee977696-7f87-4b87-8717-15a824ce0a81

⁸ This refers to a public health alert issued through the Public Health Information System for non-compliance with public health regulations (see FSIS Notice 15-08, *Public Health Regulations and Alerts for Use in Determining Inspection Program Personnel Actions and Public Health Risk Evaluation Scheduling in Meat and Poultry Establishments* (March 20, 2018)).

In addition to outlining the criteria that FSIS will consider to determine whether to grant a line speed waiver, the February 23, 2018 *Constituent Update* also describes the documentation that establishments will need to include with their waiver request submissions. As stated in the *Constituent Update*, the waiver request submission will need to include documentation that:

- Provides details about the establishment's HACCP system, including how the establishment addresses the inhibition and reduction of *Salmonella*;
- Demonstrates that the establishment has effective process control by submitting one year of microbial data, methodology for evaluating that microbial data (e.g., indicator organism data in a process control chart identifying upper and lower control limits), correlation of that microbial data to the establishment's sanitary dressing process control data, correlation of that microbial data to FSIS's *Salmonella* data, and interventions to address seasonality;
- Describes how existing or new equipment, technologies, or procedures will allow for the operation at a faster line speed (e.g., descriptions or names of the equipment, line

configuration, and verification activities that will be used);

- Provides support on how the increased line speed will not negatively impact FSIS employee safety nor interfere with inspection procedures (e.g., information about safety protocols or line configuration);
- Supports how the modifications to its food safety system to operate at the faster line speed will maintain or improve food safety (e.g., a statement that explains how the new equipment will provide the same as or cleaner evisceration processes, or how an improved line configuration will continue to prevent cross contamination); and
- Indicates the type of records that will be maintained in the new process, including the collection of information that will assist FSIS in performing appropriate rule-making analysis (e.g., laboratory results, weekly or monthly summary production reports, or evaluations from inspection program personnel).

Because FSIS intends to use the data collected from young chicken establishments to evaluate their ability to maintain process control at higher line speeds, the *Constituent Update* explained that the Agency will limit the additional line speed

waivers to establishments that have the ability and intend to operate at line speeds higher than 140 bpm.

In addition, after reviewing comments submitted in response to the NCC petition, FSIS is adding compliance with good commercial practices (GCPs) to the criteria that the Agency will use to consider line speed waiver requests submitted by NPIS young chicken slaughter establishments. The regulations require that poultry be slaughtered in accordance with GCPs, in a manner that will result in thorough bleeding of the poultry carcass and will ensure that breathing has stopped before scalding (9 CFR 381.65(b)). In a *Federal Register* notice published on September 28, 2005, FSIS explained that poultry products are more likely to be adulterated if, among other circumstances, they are produced from birds that have not been treated humanely because such birds are more likely to be bruised or to die other than by slaughter (70 FR 56624).

If an establishment is not following GCPs, and birds are dying other than by slaughter, FSIS inspection program personnel (IPP) will document a non-compliance record (NR) citing 9 CFR 381.65(b). If birds are being mistreated, but can still be fully bled and are not breathing when they enter the scalding, IPP are instructed to discuss the mistreatment with the establishment and document the discussion and any planned action by the establishment in a Memorandum of Interview (MOI). IPP will

forward a copy of the MOI to the FSIS District Veterinary Medical Specialist (DVMS) for review (FSIS Directive 6100.3, *Ante-Mortem and Post-Mortem Poultry Inspection*, April 11, 2011).

As discussed below, some comments raised issues related to line speeds for NPIS young chicken establishments and compliance with GCPs. Under all poultry inspection systems, including the NPIS, establishments are required to slaughter poultry in accordance with GCPs. Therefore, in addition to the criteria described above, the Agency will consider compliance with GCPs as part of an establishment's demonstrated history of regulatory compliance. Thus, consistent with the above regulatory compliance criteria, to be eligible for a line speed waiver, establishments must also have not had an NR for violation of GCPs (9 CFR 381.65(b)) in the past 120 days.

Finally, FSIS also will be requiring establishments with line speed waivers to conduct daily Aerobic Plate Count (APC) testing, instead of weekly testing for indicator organisms, and to make the results available to FSIS. This testing will provide additional data for consideration by FSIS when it determines whether rulemaking for young chicken slaughter line speeds is supported.

Conditions for Operating Under a Waiver and FSIS Verification

Establishments that are eligible for a line speed waiver and that have assembled the documentation that needs to be

included in their waiver request described above should submit their line speed waiver requests to the FSIS Office of Policy and Program Development (OPPD) Risk Innovations and Management Staff (RIMS). After FSIS receives a line speed waiver request, the Agency will follow the procedures in FSIS Directive 5020.2, *The New Technology Review Process* (October 24, 2017), to verify that the establishment meets the criteria to be eligible for the waiver and to evaluate the establishment's waiver request submission.

As noted in the *Constituent Update*, if an establishment is granted a waiver, RIMS will provide the establishment with a waiver letter that specifies the required conditions for operating under the waiver. To ensure consistency in data collection and analysis, when FSIS issues the waiver letter, the Agency will also include a template for the establishment to use to record and report to FSIS the data that the establishment will be required to collect as a condition for its waiver. This template will provide for the reporting of data on the daily Aerobic Plate Count (APC) testing described above. FSIS will require that all young chicken establishments with line speed waivers use the template to submit their data to facilitate data aggregation and analysis.

As also noted in the *Constituent Update*, one of the conditions for operating under a line speed waiver will be that

establishments notify the FSIS inspector-in-charge (IIC) when they are operating at line speeds higher than 140 bpm and when they reduce their line speeds to 140 bpm or below to allow FSIS to evaluate the establishment's ability to maintain process control at a given line speed. Young chicken establishments that are granted a line speed waiver will routinely need to operate at least one line at speeds above 140 bpm on average, but not higher than 175 bpm. Establishments with multiple lines may operate more than one line above 140 bpm and up to 175 bpm, but if they do, they will need to collect separate data for each individual line. While FSIS recognizes that establishments may need to occasionally reduce line speed during the course of operations, the average speed for each line used to collect data under the waiver will need to be higher than 140 bpm. Establishments consistently unable to maintain process control at line speeds higher than 140 bpm or consistently operating at line speeds lower than 140 bpm will be subject to waiver revocation.

Consistent with the waivers granted to the 20 HIMP young chicken establishments to operate at up to 175 bpm, any additional NPIS establishments that are granted a line speed waiver will need to participate in the SIP as a condition of their waivers. Under the SIP, FSIS grants establishments a waiver of a regulation with the condition that the establishment

collects and analyzes samples for microbial organisms including both *Salmonella* and indicator organisms, and shares the results with FSIS. As discussed above, FSIS will require establishments with line speed waivers to conduct daily APC testing, instead of weekly testing for indicator organisms, as a condition of their waivers. Establishments operating under a line speed waiver will need to identify the line speed they were operating under when they collected the microbial data required under the SIP and include the line speed when they submit their SIP data to FSIS. FSIS intends to use a six-month moving window approach to determine the establishment's average line speed based on the line speeds recorded as part of the SIP data.

In addition to participating in the SIP, young chicken establishments that have been granted a line speed waiver will need to continue to meet the criteria outlined in the February 23, 2018, *Constituent Update* described above to remain eligible for a waiver. The Agency will follow the procedures in FSIS Directive 5020.1, *Verification Activities for the Use of New Technology in Meat and Poultry Establishments, and Egg Products Plants* (October 6, 2016), to verify that establishments that have been granted waivers remain eligible for their waivers and are following the process control procedures agreed to as a condition for the waivers.

Under Directive 5020.1, FSIS IPP verify, among other things, that the establishment is effectively implementing its process control procedures as documented in its waiver letter and collecting SIP microbial data to monitor its ability to maintain process control. IPP will review the results of the establishment's microbial sampling program and verify that the establishment takes appropriate corrective actions in response to its testing results, including slowing the line when needed to maintain process control.

Additionally, FSIS will review the results of the Agency's *Salmonella* sampling to verify that the establishment continues to meet the performance standards for Category 1 or 2 for young chicken carcasses when operating at faster line speeds. FSIS will also evaluate process control by reviewing the results of the Agency's 10-bird offline verification checks to verify that the establishment is meeting the zero tolerance standard for fecal contamination and septicemia/toxemia, and that it is not producing product with persistent, unattended non-food safety trim and processing defects when operating at higher line speeds.

Directive 5020.1 provides that FSIS may revoke a waiver of regulatory requirements when an establishment fails to meet or follow its alternative procedures associated with the waiver. Thus, if FSIS finds that an establishment that has been granted

a line speed waiver is unable to meet the conditions of its waiver agreement, the Agency will consider whether to allow the establishment to implement corrective actions and resume operating under the waiver or whether the waiver needs to be revoked. If the waiver is revoked, the establishment will be required to comply with the 140 bpm maximum line speed for the NPIS (9 CFR 381.69(a)).

FSIS currently posts a table of all establishments that have been granted regulatory waivers under the SIP on the FSIS web site at: https://www.fsis.usda.gov/wps/wcm/connect/188bf583-45c9-4837-9205-37e0eb1ba243/Waiver_Table.pdf?MOD=AJPERES. The 20 former HIMP young chicken establishments now operating under the NPIS that have been granted line speed waivers are included in the table. These establishments are the only NPIS young chicken establishments that have been granted line speed waivers under the SIP. FSIS intends to update this table if the Agency grants additional SIP waivers or revokes existing waivers.

Former HIMP Young Chicken Establishments' Line Speed Waivers

As noted above, when FSIS implemented the NPIS, the Agency granted waivers to allow the 20 young chicken establishments that participated in the HIMP pilot to operate at line speeds up to 175 bpm after they converted to the NPIS because data from the HIMP pilot showed that these establishments were able to maintain process control when operating at the line speeds

authorized by HIMP (79 FR 49591). A preliminary review of the SIP data that these establishments have submitted to FSIS as a condition of their waivers shows that most of them have operated at line speeds higher than 140 bpm since they converted to the NPIS, and over half report that they have operated between 170 and 175 bpm. Thus, the data collected under these waivers has allowed FSIS to continue to evaluate the ability of the former HIMP young chicken establishments to maintain process control when operating at higher line speeds after they convert to the NPIS.

As discussed above, FSIS now has over a year of documented process control history for many young chicken establishments operating under the NPIS.⁹ Therefore, the Agency intends to consider additional waiver requests to allow NPIS young chicken establishments that meet the criteria described above to operate at line speeds of up to 175 bpm. FSIS intends to use the data collected from young chicken establishments that are granted these additional waivers, along with data collected from the 20 former young chicken HIMP establishments that have been granted waivers, to assess the ability of NPIS establishments to maintain process control at higher line speeds and to inform future rulemaking, if supported.

⁹ As of August 21, 2018, 67 young chicken establishments were operating under the NPIS, including the 20 former HIMP establishments.

So that the data collected from all NPIS establishments with line speed waivers will be comparable, the 20 former HIMP young chicken establishments granted line speed waivers and establishments applying for new line speed waivers will have to meet the new, additional line speed waiver criteria. FSIS intends to issue new waiver letters containing the eligibility criteria described above to the 20 former HIMP establishments and grant them 120 days from receipt to meet the criteria. If an establishment is unable to meet any of the criteria within 120 days of receipt, FSIS may revoke its line speed waiver.

Comments

As noted above, FSIS made the NCC petition available to the public on the FSIS website and the Federal eRulemaking Portal at <https://www.regulations.gov>. FSIS received over 100,000 comments and signatures on the NCC petition, most of them identical comments or form letters submitted as part of organized write-in campaigns. FSIS received comments from poultry slaughter establishments and their employees, companies that own poultry slaughter establishments, trade associations representing the poultry industry, consumer advocacy organizations, animal welfare advocacy organizations, worker advocacy organizations, civil rights advocacy organizations, environmental advocacy organizations, labor unions, members of Congress, poultry establishment employees, and individuals. The

comments also included a petition from an animal welfare advocacy organization with over 53,000 signatures and a petition from a consumer advocacy organization with over 17,000 signatures. FSIS also received approximately 7,900 identical postcards from individuals employed by poultry slaughter establishments urging the Agency to deny the petition. In addition, several employees from various poultry slaughter companies submitted comments on company letterhead in support of the petition.

Comments from poultry slaughter establishments and their employees, companies that own poultry slaughter establishments, trade associations representing the poultry industry, and a few individuals supported granting the petition. Comments from consumer advocacy organizations, animal welfare advocacy organizations, worker advocacy organizations, civil rights advocacy organizations, labor unions, members of Congress, poultry establishment employees, and several individuals urged FSIS to deny the petition. All of the comments submitted in response to organized write-in campaigns urged FSIS to deny the petition.

A summary of the general issues raised by the comments received in response to the NCC petition and FSIS's responses are presented below. Several of the issues have been addressed by FSIS's denial of the NCC petition.

Support for Petition

Comment: Poultry slaughter establishments, companies that own poultry slaughter establishments, and trade associations representing the poultry industry said that granting the NCC petition would enhance FSIS inspection procedures and increase industry efficiency while ensuring safeguards are in place to promote worker safety and bird welfare. The comments stated that line speeds should be based on an establishment's ability to maintain process control rather than regulatory line speed limits. The comments noted that the NPIS was intended to improve food safety outcomes and generate cost efficiencies for both establishments and FSIS. According to the comments, without the incentive of higher line speeds, the 140 bpm line speed cap established in the final NPIS rule has discouraged many establishments from opting into the NPIS and has caused the industry and FSIS to forego potential cost savings associated with making better use of resources. The comments asserted that allowing establishments to increase line speeds will enhance food safety by encouraging more establishments to participate in the NPIS and SIP.

Response: As stated in FSIS's response to the NCC petition, the Agency has determined that it is not necessary to establish a separate system to provide line speed waivers to young chicken establishments operating under the NPIS because FSIS has already

issued regulations and implemented procedures for establishments to request regulatory waivers. Establishments that meet the criteria to be eligible for a line speed waiver may use the existing procedures to submit a waiver request.

FSIS established 140 bpm as the maximum line speed for the NPIS, with an exception for the 20 former HIMP young chicken establishments, because FSIS concluded that it is important to assess each young chicken establishment's ability to maintain process control as they implement changes to operate under the NPIS (79 FR 49591). In the final rule that established the NPIS, FSIS made clear that it would continue to evaluate the line speeds at which establishments are capable of consistently producing safe, wholesome, and unadulterated product, as well as meeting *Salmonella* and other performance standards.

Although FSIS has denied NCC's request to establish a waiver program that would provide for unlimited line speeds, the Agency will consider granting individual waivers to allow young chicken establishments that meet the criteria described above to operate at line speeds of up to 175 bpm. The data collected from establishments that are granted these waivers will allow FSIS to evaluate the ability of NPIS establishments that did not participate in the HIMP pilot to maintain process control at line speeds of up to 175 bpm. The waivers do not provide for unlimited line speeds, as requested in the NCC petition, because

the Agency's experience under the HIMP pilot showed that online inspectors are able to conduct an effective online inspection of each bird processed at line speeds of up to 175 bpm.

Waiver Regulations

Comment: Comments from consumer advocacy organizations, animal welfare advocacy organizations, worker safety advocacy organizations, civil rights advocacy organizations, labor unions, and members of Congress stated that FSIS must deny the NCC petition because the requested action does not meet any of the criteria to qualify for a waiver under 9 CFR 381.3(b). The waiver regulations in 9 CFR 381.3(b) provide that "[t]he Administrator may, in specific cases, waive any provision of the poultry inspection regulations in order to permit appropriate and necessary action in the event of a public health emergency or to permit experimentation so that new procedures, equipment, and processing techniques may be tested to facilitate definite improvements: *Provided*, That such waivers ... are not in conflict with the purposes or provisions of the Act."

The comments stated that the petition does not identify a public health emergency, does not provide for experimentation, does not identify a new technology, would not be for a limited period of time, and does not describe any definite improvements as required under the regulation. Specific issues raised in the comments received follow:

- *Public health emergency*. The comments stated that the requested waiver system does not meet the first basis for granting a waiver under 9 CFR 381.3(b) because providing for faster line speeds is not "an appropriate or necessary action in the event of a public health emergency."
- *"Specific classes of cases" and "limited periods"*. The comments noted that 9 CFR 381.3(b) only authorizes FSIS to grant waivers in "specific classes of cases" for "limited periods." The comments said that the NCC petition does not identify any specific classes of cases because the line speed waiver requested in the petition would apply to any slaughter establishment that participates in the NPIS or the SIP. The comments also asserted that the petition does not provide for time limits for the requested waiver system. The comments stated that granting the petition would establish an indefinite waiver program in violation of the regulation.
- *"Experimentation with new technology"*. The comments stated that the petition asks that FSIS allow establishments participating in the NPIS to operate without any line speed limitations without identifying any new procedures, equipment, or processing techniques. A worker rights advocacy organization and a labor union commented that in

FSIS's 2003 notice regarding procedures for notification of new technology, the Agency acknowledged that line speeds are not a new technology when it explained that "a new technology that changed the line speeds for poultry would require a waiver to the regulations for a limited time to test the new technology" (68 FR 6874). According to the comments, a change in line speed may be the result of a new technology, but is not a new technology itself.

- "*Definite improvements*". The comments stated that the NCC petition does not include any information to show how a waiver of the maximum line speed authorized under the NPIS would "facilitate definite improvements" consistent with the purposes or provisions of the PPIA. Several comments stated that rather than describe how the requested waiver system would facilitate definite improvements in food safety, the petition asserts that allowing faster line speeds would not be worse for public health or worker safety than the current line speeds. Several comments stated that the economic considerations identified in the petition, such as cost savings, profitability, and competitiveness are not valid criteria for granting a waiver because they do not qualify as "definite improvements" under 9 CFR 381.3(b).

FSIS Response: For the reasons specified below, FSIS believes that line speed waivers are consistent with its regulations under 9 CFR 381.3(b) and has developed criteria that the Agency intends to use to consider these waiver requests and has specified the documentation that establishments will need to include in their waiver request submissions.

"Specified classes of cases" and "limited periods."

Any individual waivers that FSIS may grant using the aforementioned criteria will comply with the regulatory requirements for waivers in 9 CFR 381.3(b) because the waivers will apply to specific classes of cases, i.e. young chicken establishments that meet the criteria described above. Further, the waivers are time limited in that if the data generated under the waivers support regulatory changes, i.e., the establishments are able to consistently maintain process control at the higher line speeds, the waivers will be in effect only until the rulemaking process is complete. If the data generated do not support regulatory changes, the waivers will be terminated.

"Experimentation with new technology."

FSIS broadly defines "new technology as new, or new applications of, equipment, substances, methods, processes, or procedures affecting the slaughter of livestock and poultry or processing of meat, poultry, or egg products. (68 FR 6873, February 11, 2003). At a minimum, increasing line speeds is a

new application of existing technology in facilities that have never operated at these higher speeds in the past. Further, it is expected that some facilities that request waivers would have to install new equipment or reconfigure existing equipment in order to accommodate higher line speeds. In the same *Federal Register* notice cited above, FSIS noted that technology changes that could adversely affect product safety, interfere with FSIS inspection procedures, or jeopardize the safety of inspection program personnel, including changes in line speeds, would require regulatory waivers (68 FR 6874). Therefore, FSIS believes that the line speed waivers contemplated in this document are consistent with past Agency policy and the regulations at 9 CFR 381.3(b).

“Definite improvements.”

FSIS interprets “definite improvement” to mean *any* improvement of equipment, substances, methods, processes, or procedures affecting the slaughter of livestock and poultry or processing of meat, poultry or egg products, (83 FR 4782, February 1, 2018). FSIS believes that if an establishment were able to increase efficiency in poultry production by operating at higher line speeds, while consistently maintaining process control, with no diminution in the food safety profile of the finished product, it would constitute a “definite improvement” within the meaning of 9 CFR 381.3(b). As previously noted, an

establishment's waiver submission request will need to explain how food safety system modifications undertaken to operate at faster line speeds will maintain or improve food safety.

Comment: In addition to the criteria for granting waivers described above, the comments also noted that under the regulation, FSIS may only grant waivers that are not in conflict with the purposes or provisions of the PPIA (9 CFR 381.3(b)). Comments from consumer advocacy organizations, animal welfare organizations, members of Congress, and worker advocacy organizations stated that the requested waiver system, if implemented, would be inconsistent with the fundamental purpose of the PPIA because eliminating maximum line speeds has the potential to increase the risk that adulterated product will enter commerce. A consumer advocacy organization stated that the potential for human error increases with an increase in line speed, and workers forced to perform the same repetitive activities at a faster pace will become increasingly fatigued, making them more likely to make mistakes that result in product contamination or failure to notice and address safety risks. Consumer advocacy organizations, worker advocacy organizations, and an environmental advocacy organization commented that higher line speeds may also affect the accuracy of the equipment on the evisceration and cause carcasses to become contaminated with fecal material.

Several comments stated that faster line speeds give company sorters less time to identify carcasses affected with food safety defects, such as septicemia/toxemia and visible fecal contamination. An animal welfare advocacy organization commented that NCC's requested action would increase the risk that poultry meat would become adulterated from inhumane handling of chickens because faster line speeds are correlated with loss of process control that results in birds being intentionally mistreated by workers, improperly hung in shackles, insufficiently cut and bled, and scalded alive.

FSIS Response: Because FSIS has denied the NCC petition, the Agency will not be establishing a waiver program that the comments state will conflict with the purposes or provisions of the PPIA. Instead, as noted throughout this document, the Agency will use its existing waiver procedures to consider granting line speed waivers to individual establishments that meet the criteria described above to operate at line speeds of up to 175 bpm. Under these criteria, establishments will only be eligible for a waiver if, among other things, they have been operating under the NPIS for at least one year with a demonstrated ability to maintain process control and demonstrated history of regulatory compliance. After an establishment has been granted a waiver, it will need to submit microbial data and other records, such as statistical process control charts, to FSIS to

demonstrate that it is able to maintain process control when operating at faster line speeds. FSIS will monitor the establishment's ability to maintain process control by evaluating the results of the Agency's *Salmonella* verification sampling, performing carcass verification checks, performing sanitation verification activities, and reviewing the records that the establishment maintains to demonstrate process control, including the establishment's microbiological testing data. Finally, in regard to the handling of live chickens, as discussed above, compliance with GCP regulations will be a condition of operating under a line speed waiver for both waiver applicants and establishments already operating under waivers.

Comment: Several comments asserted that, in addition to the potential for increased contamination, the petition's requested waiver system would conflict with the purposes or provisions of the PPIA because high line speeds would make it difficult for FSIS inspectors to conduct an effective online carcass-by-carcass inspection. Comments from consumer and animal welfare advocacy organizations noted that the PPIA requires FSIS inspectors to inspect "the carcass of each bird processed" (21 U.S.C. 455(b)) and that "inspection" means that the inspector gives a "critical determination whether [a carcass or part of a carcass] is adulterated or unadulterated" (*AFGE v. Glickman*, 215 F.2d 7 (D.C. Cir., 2000)). According to the comments, NCC's

request to allow poultry slaughter establishments to operate at line speeds greater than 175 bpm would make it extremely difficult, if not impossible, for FSIS to inspect the carcass of each bird processed. A consumer advocacy organization stated that faster line speeds will also reduce the percentage of carcasses assessed through offline inspections because the number of assigned offline carcass verification checks does not vary with line speed, meaning a smaller percentage of birds will be inspected offline for fecal contamination as line speeds increase.

FSIS Response: Because FSIS has denied the NCC petition, young chicken NPIS establishments will not be granted waivers to operate without line speed limits. FSIS's experience under the HIMP pilot showed that online inspectors in HIMP young chicken establishments were able to conduct an effective online inspection of each carcass when operating at a line speed of up to 175 bpm. As discussed above, FSIS intends to grant individual waivers to allow certain young chicken NPIS establishments to operate at line speeds up to 175 bpm. To ensure that online inspectors are able to conduct an effective online inspection of each bird processed, FSIS inspectors-in-charge (IICs) in all NPIS establishments, including those operating under waivers, are authorized to direct establishments to operate at a reduced line speed when in the IIC's judgment a carcass-by-carcass

inspection cannot be performed within the time available, due to the manner in which the birds are presented to the online carcass inspector, the health conditions of a particular flock, or factors that may indicate a loss of process control (9 CFR 381.69(d)).

With respect to the comment that faster line speeds will reduce the percentage of carcasses assessed through offline inspections, as stated in the preamble to the rule that established the NPIS, under the NPIS, the offline carcass verification checks will be more risk-based than under the HIMP pilot to reflect the performance of the establishment (79 FR 49587). As under the HIMP pilot, FSIS continues to conduct eight 10-bird verification checks per line per shift under the NPIS. However, as noted in the final NPIS rule, FSIS monitors and analyzes the ongoing results of its offline carcass verification activities to assess the effectiveness of the establishment's sorting and other process control procedures (79 FR 49587). FSIS conducts additional verification activities in all NPIS establishments, including those operating under waivers, as needed to respond to the Agency's verification findings (FSIS Directive 6500.1, *New Poultry Inspection System: Post-Mortem Inspection and Verification of Ready-to-Cook Requirement*, February 1, 2017).

Comment: A worker rights advocacy organization stated that even if the requirements of the waiver regulations are met, the NCC is not authorized to submit a waiver request under CFR 381.3(b). The organization stated that FSIS's Procedures for Notification of New Technology (68 FR 6873) allow official establishments and companies that manufacture and sell technology to official establishments to submit new technology notifications to the Agency. The comment noted that the NCC is not an official establishment or a company that manufactures or sells new technologies.

FSIS Response: Nothing in the regulations at 9 CFR 381.3(b) limits the submission of waiver requests to the regulated industry or companies that manufacture or sell new technologies. FSIS has denied the NCC petition, but will continue to consider waiver requests from official establishments, companies that manufacture or sell new technologies, and other interested parties.

NPIS Line Speed Regulation

Comment: Comments from consumer advocacy organizations, animal welfare advocacy organizations, worker rights advocacy organizations, civil rights advocacy organizations, and members of Congress asserted that the NCC petition is an attempt to bypass the maximum line speed for the NPIS prescribed in the regulations without going through the rulemaking process in

violation of the Administrative Procedure Act (APA) (5 U.S.C. 553). These comments stated that the 140 bpm maximum line speed is a legislative rule established through notice-and-comment rulemaking and, therefore, can only be modified through notice-and-comment rulemaking. A consumer advocacy organization stated that the SIP waiver process is intended to facilitate experimentation, not implement industry-wide changes.

FSIS Response: Because FSIS has denied the NCC petition, the Agency will not be establishing a line speed waiver system for all young chicken establishments and will not allow all young chicken NPIS establishments to operate at line speeds faster than the maximum 140 bpm prescribed by the regulation (9 CFR 381.69(a)). The Agency will consider individual line speed waiver request submissions through its existing procedures using the criteria described above. It should be noted that the existing waiver regulations were promulgated by notice-and-comment rulemaking pursuant to the APA. FSIS's decision to grant individual regulatory waivers under 9 CFR 381.3(b) will not apply to all young chicken slaughter establishments nor establish a new maximum line speed under NPIS and, therefore, would not be subject to the APA's notice-and-comment rulemaking provisions.

Comment: Comments from consumer advocacy organizations, animal welfare advocacy organizations, worker rights advocacy

organizations, civil rights advocacy organizations, and members of Congress stated that granting waivers from the line speed limits established for the NPIS would be an arbitrary reversal of Agency position. The comments asserted that FSIS considered and rejected requests to allow for faster line speeds under the NPIS when the Agency finalized the rule that established the NPIS in 2014 (79 FR 49566). The comments noted that the 2014 final rule was the result of a comprehensive, two-and-a-half year rulemaking process during which FSIS received and considered more than 250,000 public comments. A worker safety advocacy organization noted that the question of the maximum allowable line speed was the single most commented-upon aspect of the NPIS rulemaking. Several comments also noted that in the fall of 2013, a network of worker safety groups petitioned the Occupational Safety and Health Administration (OSHA) and USDA to regulate and reduce assembly line speeds in meat and poultry processing establishments. The comments stated that OSHA ultimately denied the petition due to "a lack of resources," but in the 2014 NPIS final rule, FSIS chose not to increase the current maximum line speed limits for poultry slaughter establishments.

Comments from consumer advocacy organizations, animal welfare advocacy organizations, worker rights advocacy organizations, civil rights advocacy organizations, and members

of Congress stated that in FSIS's 2014 NPIS rulemaking, the Agency acknowledged that line speeds should not increase without further research "to assess establishments' ability to maintain process control as they implement changes to operate under the NPIS" (79 FR 49615). The comments noted that FSIS intended to conduct this assessment "[a]fter 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" (79 FR 49615). The comments noted that at the time the NCC petition was submitted, approximately 60 establishments had converted to the NPIS while in the final rule that established the NPIS, FSIS had estimated that 219 establishment would convert. Therefore, the comments asserted, the NPIS has not yet been fully implemented on a wide scale. According to the comments, FSIS has not accrued the necessary experience to evaluate the NPIS establishments' ability to maintain process control at any given line speed.

A consumer advocacy organization noted that FSIS granted SIP waivers to allow the 20 former young chicken HIMP establishments to continue to operate at line speeds of up to 175 bpm after they converted to the NPIS because these establishments have demonstrated that they are able to maintain process control under the line speeds authorized by HIMP. The comment said that in granting these SIP waivers, FSIS stated that it would compare the data from the former HIMP young

chicken establishments to data from other non-HIMP NPIS establishments as a means of evaluating the new program (79 FR 49591). The comment stated that FSIS has not made any efforts to conduct such an assessment that is available to the public.

FSIS Response: As noted above, FSIS has denied the NCC petition and thus, will not be implementing the line speed waiver program requested in the petition. FSIS's decision to consider individual waiver requests to allow certain young chicken NPIS establishments to operate at line speeds of up to 175 bpm does not affect the regulation that prescribes 140 bpm as the maximum line speed for NPIS young chickens establishments (9 CFR 381.69(a)) and is consistent with the Agency's position on line speeds as stated in the final rule that established the NPIS.

Also as discussed above, when FSIS published the final rule that established the NPIS, the Agency made it clear that it would continue to evaluate the line speeds at which establishments are capable of consistently producing safe, wholesome, and unadulterated product, as well as meeting pathogen reduction and other performance standards (79 FR 49591). The data collected from establishments that are granted new line speed waivers will allow FSIS to evaluate the ability of NPIS establishments that did not participate in the HIMP pilot to maintain process control at line speeds up to 175 bpm.

FSIS intends to use these data, along with the data from establishments currently operating under line speed waivers, to inform future rulemaking, if warranted, with respect to line speeds under the NPIS.

Comment: An animal welfare advocacy organization commented that the PPIA requires a hearing be held for "oral presentation of views" for interested parties when the Agency engages in rulemaking related to its subject matter (21 U.S.C. 463(c)). The organization stated that FSIS has not held such a public hearing, and the public comment period that FSIS provided on regulations.gov is not a lawful substitute for the hearing requirement.

FSIS Response: FSIS's regulations on petitions provide for interested persons to submit comments on a petition (9 CFR 392.7). The public comment period that FSIS provided on regulations.gov is consistent with this regulatory provision. Under 21 U.S.C. 463(c), FSIS is required to provide interested persons an opportunity for the oral presentation of views after the Agency has initiated informal rulemaking. FSIS has not initiated informal rulemaking in response to the petition. In addition, 21 U.S.C. 463(c) does not require that FSIS hold public hearings to receive oral presentation of views as part of the rulemaking process.

NPIS Line Speed Data

Comment: As discussed earlier in this document, the NCC petition cited data in support of its position, including information from the 2011 HIMP pilot study, a 2001 published study on the HIMP pilot, and a 2017 unpublished survey of NCC member companies operating under the NPIS with and without line speed waivers. Comments from poultry slaughter establishments and trade associations representing the poultry industry stated that the available data demonstrate that young chicken NPIS establishments are able to operate at line speeds above 140 bpm without compromising food safety. The comments stated that FSIS's experience with the HIMP pilot upon which the NPIS is based demonstrates that establishments can safely operate at higher line speeds. The comments referenced data from the 2011 HIMP Report that shows that establishments operating under the line speeds authorized by HIMP perform as well as or better than comparable non-HIMP establishments. A trade association representing the poultry industry referenced the 2001 study cited in the petition and claimed that this study reinforces the conclusions in the HIMP Report. The comments also referenced a preliminary analysis of data from NPIS and non-NPIS establishments that FSIS presented to stakeholders in October 2017. The comments asserted that this analysis further confirms that establishments permitted to operate at line speeds greater than 140 bpm had comparable *Salmonella* and *Campylobacter* percent

positives for both whole chicken carcasses and chicken parts, and that both were below the FSIS performance standards for these pathogens. The comments also stated that an NCC analysis of FSIS performance standards sampling data, NR rates, and other key food safety performance indicators submitted in support of the petition shows that NPIS establishments, including former HIMP establishments operating with higher line speeds, are performing at least as well as non-NPIS establishments.

Consumer advocacy organizations, animal welfare advocacy organizations, and worker advocacy organizations asserted that the petition does not include any data to demonstrate that the NPIS establishments would be able to maintain process control at faster line speeds. The comments stated that although the petition discusses the results of an unpublished industry survey, the discussion does not provide sufficient detail for FSIS to consider the data. The comments noted that the petition does not include any information on how establishments were chosen for the survey, the methodology used to conduct the survey, or how the results are statistically sound or valid. Comments from a consumer advocacy organization and an animal welfare advocacy organization noted that the petition did not present the *Campylobacter* and *Salmonella* data, even in summary form. The comments stated that the petition only lists the survey participants' total *Salmonella* and *Campylobacter* percent

positives and that the petition states that the NPIS participants' percent positives were "as good as if not better than their non-NPIS counterparts."

The comments also noted that the NCC survey results were not peer reviewed. A consumer advocacy organization stated that the survey also did not include a pre-specified analysis plan, which could allow for selective reporting, and that the survey relied upon data collected in the winter months, a time period when *Salmonella* positives are typically lower. Another consumer advocacy organization stated that the NCC seeks to draw conclusions on line speeds beyond the range of actual line speeds studied in its survey.

Two consumer advocacy organizations noted that the petition also referenced data from the 2011 HIMP Report to support the requested action. The comments asserted that data in the 2011 HIMP Report does not establish that food safety will be maintained should line speed caps be lifted. The comments noted that the 2011 HIMP Report stated that the average line speed under HIMP was 131 bpm, well below the maximum line speed of 175 bpm authorized under HIMP. The comments also asserted that line speed information from former HIMP establishments does not provide insight into operation at unlimited line speeds. The organizations also commented that the petition does not address the concern that other young chicken establishments might behave

differently than the 20 former HIMP establishments. One comment stated that the 2011 HIMP Report findings of no statistical difference in fecal NRs and *Salmonella* positives based on line speed show that FSIS did not find that increased line speeds were statistically related to these indicia of contamination. The comment stated that this is not a "definite improvement."

FSIS Response: Although FSIS considered the supporting data in the petition and the comments on these data when evaluating the NCC petition, the supporting data were not the primary basis for denying the petition. FSIS denied the NCC petition because the Agency has already implemented procedures for establishments to request regulatory waivers and therefore, FSIS determined that it is not necessary to establish a separate waiver system to provide line speed waivers to young chicken establishments operating under the NPIS. FSIS reviews submissions for the use of procedures or processes that require regulatory waivers on a case-by-case basis to determine whether the waiver request submission includes a method to document the performance of the new technology, so the resulting data can be monitored and analyzed.

As noted above, FSIS has established criteria that the Agency intends to use under its existing waiver process to consider waiver requests by young chicken establishments to operate at line speeds of up to 175 bpm. FSIS will consider

individual waiver requests on a case-by-case basis and will base its decision on whether to grant a waiver on the information included in an establishment's waiver request submission, not on the data submitted in support of the petition.

Worker Safety

Comment: Comments from poultry slaughter establishments, trade associations representing the poultry industry, and individuals stated that permitting NPIS young chicken establishments to run at line speeds faster than 140 bpm would not be expected to have a significant impact on worker safety because the waivers would only apply to a specific highly automated part of the processing line with little direct employee interaction with the equipment or the birds. The comments stated that the "further processing lines" where workers debone and cut up chicken parts are separate from the evisceration line and do not run at the same speed as the evisceration line. The comments stated that even under the current NPIS system, these further processing lines run at slower speeds appropriate for the type of work being done and this would not change if FSIS were to grant the petition.

Poultry establishments and trade associations representing the poultry industry commented that the available data show that increased line speeds do not present greater risks for worker safety. The comments asserted that worker safety in poultry

establishments has improved in the past two decades, with worker illness and injury rates reported by the Bureau of Labor Statistics (BLS) decreasing by more than 80 percent since 1994. The comments stated that the incidence of non-fatal occupational injuries and illnesses in the poultry sector, which includes slaughter and processing, remains at an all-time low. The comments further stated that the total recordable poultry processing illness and injury rate for 2016 was 4.2 cases per 100 full-time workers per year, down from 4.3 in 2005. The comments also stated that the poultry industry's rate of 4.2 was below the rate of 6.9 for similar agricultural industries in terms of injuries per 100 full-time workers and lower than the rate of 4.7 for the entire food manufacturing sector. In addition to these statistics, the comments noted that the NCC's industry survey of establishments that have recently opted into the NPIS and those that had been former HIMP establishments revealed that all plants surveyed, on average, were operating well below the industry's total DART (days away, restricted, or transferred) rates. According to the comments, this provides evidence that the increased line speeds have not resulted in an increase in worker injuries.

Comments from worker and civil rights advocacy organizations, poultry establishment employees, consumer advocacy organizations, labor unions, members of Congress, an

environmental advocacy organization, and private citizens asserted that establishing a line speed waiver system as requested in the NCC petition would increase risks to worker health and safety in establishments that operate under such waivers and would expose workers to hazards that have not been studied. The comments referenced studies, reports, and other data on work-related injuries in the meat and poultry processing industry. The most commonly referenced information sources included:

- Studies published by the National Institute for Occupational Safety and Health (NIOSH) that found high rates of carpal tunnel syndrome among workers in the poultry industry. One study found that 34 percent of workers in poultry processing establishments had carpal tunnel syndrome, and 76 percent had evidence of nerve damage in their hands and wrists. Another study found that 42 percent of workers at a poultry processing establishment had carpal tunnel syndrome.
- 2016 BLS data showing that employer reported injury rates for poultry workers were 60 percent above the national average for all private industry, and illness rates were more than five times as high.

- Reports published by the Government Accountability Office (GAO) in 2005, 2016, and 2017 that concluded, among other things, that injury rates in the meat and poultry slaughter industries continue to be higher than the rates for others in the manufacturing industry, that meat and poultry workers may under-report illnesses and injuries because they fear losing their jobs, and that employers may underreport worker injuries because of concerns about potential costs.
- Various reports from worker advocacy organizations on worker safety in meat and poultry processing establishments. These reports include surveys of poultry workers that have suffered illnesses and injury from the fast-paced repetitive tasks associated with the current line speeds.
- OSHA citations of poultry processing establishments for failure to record injuries and illnesses requiring more than first aid.

The comments stated that the available studies, reports, and data contradict NCC's assertion that worker illness and injury are at an all-time low, and, according to the comments, the statistics that NCC relied on are based on a potentially biased self-reporting system. Several comments noted that in the

preamble to the final rule that established the NPIS, FSIS recognized that the systemic underreporting of the poultry industry work-related injuries and illness "could make it difficult to accurately assess the extent to which poultry workers suffer from work related injuries and musculoskeletal diseases and disorders." Comments from a civil rights organization, members of Congress, and a labor union expressed concern that increased line speeds will disproportionately hurt women and people of color. The labor union commented that nearly 40 percent of those who work in animal slaughtering and processing are women and 67 percent are people of color.

FSIS Response: While FSIS agrees that working conditions in poultry slaughter establishments is an important issue, the Agency has neither the authority nor the expertise to regulate issues related to establishment worker safety. FSIS has been delegated the authority to exercise the functions of the Secretary of Agriculture under the Federal Meat Inspection Act (FMIA) (21 U.S.C. 601 *et seq.*), the PPIA (21 U.S.C. 451 *et seq.*), and the Egg Products Inspection Act (EPIA) (21 U.S.C. 1301 *et seq.*) (the Acts). Under the Acts, FSIS protects the public by verifying that meat, poultry, and egg products are safe, wholesome, not adulterated, and properly marked, labeled, and packaged. The Acts authorize FSIS to administer and enforce laws

and regulations solely to protect the health and welfare of consumers.

The DOL's OSHA was created by the Occupational Safety and Health Act of 1970 (29 U.S.C. 651 *et seq.*) to assure safe and healthful working conditions for men and women by setting and enforcing standards and by providing training, outreach, education, and assistance. As was noted in the preamble to the final rule that established the NPIS, OSHA is the Federal agency with statutory and regulatory authority to promote workplace safety and health (79 FR 49600). FSIS's authority with respect to working conditions in poultry slaughter establishments extends only to FSIS inspection personnel. While FSIS is prepared to address worker safety within the bounds of its authority, as noted above, FSIS has neither the legal authority nor the expertise to regulate or enforce workplace standards for establishment employees.

During the development of the final rule that established the NPIS, FSIS collaborated with OSHA and NIOSH, to address issues related to worker safety raised by the public comments. OSHA and NIOSH are the government agencies with the expertise and authority to address worker safety issues in private industry workplaces. As a result of this collaboration, the final NPIS regulations include provisions to remind establishments of their existing legal obligations to comply

with the worker safety laws administered by OSHA (9 C.F.R. 381.69(d)). The final regulations also provide for establishments operating under the NPIS to submit on an annual basis an attestation to the management member of the local FSIS circuit safety committee stating that the establishment maintains a program to monitor and document any work-related conditions of establishment workers (9 CFR 381.45). Because OSHA is the Federal agency with statutory and regulatory authority to promote workplace safety and health, FSIS forwards the annual attestation to OSHA for use in its own enforcement program. All establishments operating under the NPIS are subject to the attestation regulation, including the NPIS establishments operating under regulatory waivers. However, FSIS employees are not responsible for determining the merit of the content of the attestation or for enforcement of non-compliance with the attestation provision.

Animal Welfare

Comment: Comments from animal welfare advocacy organizations and individuals concerned about animal welfare asserted that granting the petition and allowing NPIS establishments to operate at faster line speeds would have adverse effects on the humane handling of poultry. The comments expressed concern about worker frustration over faster line speeds and the potential for workers to take these frustrations

out on the birds; the potential for increased injuries that may occur from shackling birds at faster line speeds; the potential for worker injuries from birds vigorously flapping their wings while in shackles; and the potential for ineffective stunning and throat cutting of birds at faster line speeds. The comments noted that for over 12 years, FSIS has recognized that "poultry products are more likely to be adulterated if, among other circumstances, they are produced by birds who have not been treated humanely, because such birds are more likely to be bruised or to die other than by slaughter" (79 FR 49590). The comments referenced FSIS NRs for cadavers, birds entering the scalders alive or not fully bled out, and birds exhibiting severe bruising primarily caused by dislocated legs and broken wings. According to the comments, faster line speeds will exacerbate these conditions. Two animal welfare advocacy organizations asserted that setting policy for poultry slaughter that promotes better animal handling practices would further compliance with the PPIA and ensure more effective and efficient inspections.

FSIS Response: Because the Humane Methods of Slaughter Act (HMSA) (7 U.S.C. 1901-1907) does not apply to poultry, FSIS does not have direct authority to regulate the humane handling of live poultry in connection with slaughter. As noted above, under all poultry inspection systems, including the NPIS, establishments are required to slaughter poultry in accordance

with GCPs, in a manner that results in thorough bleeding of the poultry carcasses and ensures that breathing has stopped before scalding (9 CFR 381.65(b)). As noted in the comments, in September 2005, FSIS published a *Federal Register* notice to explain that poultry products are more likely to be adulterated if, among other circumstances, they are produced from birds that have not been treated humanely because such birds are more likely to be bruised or to die other than by slaughter (70 FR 56624). Under both the PPIA and its implementing regulations, poultry carcasses showing evidence of having died from causes other than by slaughter are considered adulterated and as such must be condemned (21 U.S.C. 453(g)(5) and 9 CFR 381.90). Establishments operating under the NPIS have always been, and will continue to be, subject to these requirements regardless of their line speed, including establishments that have been granted waivers to operate at line speeds of up to 175 bpm. As outlined in FSIS Directive 6300.1, *Ante-mortem and Post-mortem Poultry Inspection*, FSIS verifies GCPs as part of a daily, per-shift inspection task performed by the public health veterinarian (PHV). Any non-compliances are documented under 9 CFR 381.65(b) and reviewed weekly as one of many measures of process control. However, in response to these comments, as discussed above, FSIS has decided to add compliance with the GCP regulation to the criteria that the Agency will consider when

evaluating an establishment's line speed waiver request submission. Also, as discussed above, FSIS will now consider compliance with the GCP regulations as a condition for existing line speed waivers.

Comment: Two animal welfare advocacy organizations commented that if FSIS grants NCC's petition, it should require multi-stage controlled atmosphere killing (CAK) as a condition of increasing line speeds. According to the comments, faster line speeds will likely result in more frequent loss of process control, and FSIS is unlikely to be able to provide a rational explanation on how removing line speed limits will result in similar or better process control than is currently achieved with the line speed limit for the NPIS. The comments asserted that multi-stage CAK systems would help maintain process control because birds stunned while in transport cages do not need to be removed from their cages, dumped onto conveyor belts, and shackled upside down while still conscious. The organizations stated that this would facilitate proper handling.

FSIS Response: FSIS does not prescribe specific methods that establishments must use to stun or kill poultry in connection with slaughter. Establishments are required to maintain process control and comply with requirements for GCPs regardless of the methods they use to stun or kill the birds. Establishments may use CAK stunning if they choose to do so.

National Environmental Policy Act

Comment: Comments from animal welfare advocacy organizations and an environmental advocacy organization stated that if FSIS grants the NCC petition, the Agency must prepare an Environmental Impact Statement (EIS) as required under the National Environmental Policy Act (NEPA) (42 U.S.C. 4321 *et seq.*) because the requested action to allow poultry slaughterhouses to increase line speeds would result in significant environmental impacts. The comments stated that faster line speeds would mean more birds slaughtered per shift. According to the comments, more birds slaughtered would mean more waste, more water use, and more fossil fuels required to transport the birds from farm to slaughterhouse. The comments asserted that these are all significant environmental impacts, with both individual and cumulative effects at the local, state, and national levels. The comments also stated that if FSIS grants NCC's petition, FSIS cannot claim the categorical exclusion from the preparation of an Environmental Assessment (EA) or an EIS under 7 CFR part 1b of the USDA regulations.

FSIS Response: Because FSIS has denied the NCC petition, it will not be implementing the waiver system that these commenters believe could result in significant environmental impacts and thus is not required to analyze potential

environmental impacts resulting from the waiver system proposed by NCC as suggested by the comments.

With respect to the Agency's decision to consider granting waivers to additional NPIS establishments to operate at line speeds of up to 175 bpm, that decision is categorically excluded from NEPA requirements. Federal agencies may identify classes of actions that normally do not require the preparation of either an EA or EIS because such actions do not have a significant effect on the human environment, either individually or cumulatively (40 CFR 1507.3(b)(2)). Such classes of actions are "categorically excluded" from NEPA requirements (40 CFR 1508.4). Under 7 CFR 1b.4, all FSIS actions, including inspection functions, are categorically excluded from preparation of an EA or EIS unless the Agency head determines that a particular action may have a significant environmental effect. Accordingly, FSIS is not required to prepare an EA or EIS unless it anticipates that granting additional line speed waivers may have a significant environmental effect.

The Agency does not anticipate that its decision to consider granting waivers to additional NPIS establishments to operate at line speeds of up to 175 bpm will have individual or cumulative effects on the environment. Expected sales of poultry products to consumers will determine the total number of birds that a poultry establishment slaughters, not the maximum line

speed under which it operates. The Agency has no authority to determine a poultry establishment's production levels. An establishment may decide to increase production hours to slaughter more birds in response to market demand, regardless of its maximum line speed. Granting an establishment a waiver to operate at up to 175 bpm will allow that establishment to slaughter birds more efficiently, but will not affect consumer demand for the establishment's poultry products. In some instances, an establishment that is granted a waiver may be able to reduce its hours of operation while maintaining production at a rate necessary to meet market demand for its poultry products. Thus, granting waivers to allow additional NPIS establishments to operate at up to 175 bpm is not expected to affect the number of birds slaughtered or result in more waste, more water use, or require more fossil fuels to transport the birds from farm to slaughterhouse, as suggested by the comments. In addition, all poultry slaughter establishments, regardless of line speed, are required to meet all local, State, and Federal environmental requirements.

Economic Issues and Regulatory Reform

Comment: Comments from poultry slaughter establishments and an individual stated that granting the NCC petition would be consistent with Executive Order (EO) 13771, which requires that for each new regulation issued, at least two existing

regulations must be eliminated to offset the cost of the new regulations. The comments noted that a line speed waiver program would be a deregulatory action under EO 13771 because it would expand production options and provide for cost savings to industry.

Comments from consumer advocacy organizations and animal welfare advocacy organizations noted that the petition states that the requested waiver system would be consistent with the Administration's emphasis on reducing regulatory burdens on the industry and assuring competitiveness with other countries. Comments from consumer advocacy and animal welfare advocacy organizations stated that enhanced competitiveness and reduced regulatory burden are not justifications for FSIS to take an action that is inconsistent with its regulatory authority and that, according to the comments, could potentially compromise food safety. Animal welfare advocacy organizations stated that the petition exaggerates the regulatory burden of the maximum authorized line speed under the NPIS. According to the organizations, the petition does not identify any clear cost savings or decreases in FSIS administrative burden and does not include any explanation of how the administration of the requested action would be cost-effective or even financially neutral to FSIS.

FSIS Response: The purpose of the waiver process is to allow establishments to experiment with new equipment, technologies, or procedures to facilitate definite improvements, not to initiate regulatory changes across the industry, as some of the comments seem to suggest. FSIS evaluates the data generated by establishments operating under regulatory waivers to inform future rulemaking, if warranted. FSIS would consider the costs, benefits, and other economic impacts associated with implementing a new technology, including new technologies that would permit faster line speeds, if, based on the data collected under regulatory waivers, the Agency decided to initiate rulemaking to provide for the use of the new technology in the regulations.

Comment: Comments from poultry establishments, trade associations representing the poultry industry, and an individual asserted that allowing the 20 former young chicken HIMP establishments to operate under line speed waivers after they convert to the NPIS gives these establishments a competitive advantage over the other NPIS establishments. The comments stated that all facilities operating under the same inspection system should be regulated under identical criteria, and that the granting of waivers should be done equitably as well. According to the comments, limiting line speed waivers to the 20 former young chicken HIMP establishments has no

justification and puts the Agency in the position of apparently granting financial favors to select poultry processing operations.

Several worker advocacy organizations stated that, in the final rule establishing the NPIS, after FSIS considered the extensive comments from affected stakeholders on all sides, and in light of evidence that young chicken establishments authorized to operate up to 175 bpm under the HIMP pilot were in fact operating at an average speed of 131 bpm, FSIS determined that a maximum line speed of 140 bpm would meet the economic needs of poultry slaughter establishments.

A consumer advocacy organization stated that lifting line speed caps across NPIS establishments will lead to new competitive pressures that could undermine food safety in ways not predictable from currently available data. According to the organization, it is conceivable that lifting line speed caps across the industry would create competitive pressure to push line speeds even higher than observed previously, potentially compromising food safety.

FSIS Response: FSIS disagrees that the line speed waivers granted to the former HIMP establishments to operate at line speeds up to 175 bpm after they converted to the NPIS created a new competitive advantage over other NPIS establishments subject to the 140 bpm maximum line speeds prescribed in the final NPIS

regulations. The 20 former HIIMP young chicken establishments had been authorized to operate at line speeds up to 175 bpm for over 20 years during the time they were participating in the HIMP pilot. Under the final NPIS rule, these establishments were permitted to run at the line speeds that were authorized before FSIS established the NPIS.

Although FSIS has denied NCC's request to establish a waiver program to allow young chicken NPIS establishments to operate without line speed limits, the Agency will consider granting individual waivers to allow young chicken establishments that meet the criteria described above to operate at line speeds of up to 175 bpm. Under these criteria, line speed waivers will no longer be limited to the 20 former HIMP establishments, and thus, will be equitably distributed to eligible establishments. Because FSIS is not removing the maximum line speed for all NPIS establishments, FSIS has no reason to believe that granting additional individual waivers will create competitive pressure for establishments to increase line speeds. Establishments will not submit line speed waiver requests if their current line speeds meet their business needs.

Comment: Comments from poultry establishments, trade associations representing the poultry industry, and individuals commented that the current system places the U.S. chicken industry at a disadvantage compared to global competitors in

South America, Asia, Canada, and Europe that are allowed to operate at line speeds in excess of 200 bpm using the same equipment as processors in the United States. An individual commented that animal welfare is important, and countries in Europe have shown that poultry can be slaughtered humanely under faster line speeds.

Comments from worker advocacy organizations asserted that the evidence points to clear problems with the faster line speeds permitted in foreign countries. According to the comments, certain foreign countries are not permitted to export poultry products to the United States because their poultry inspection systems have not been found equivalent to the U.S. system. The comments also stated that the poultry processed in certain foreign establishments have high levels of pathogens that continue to be of concern to European food safety officials. However, the comments did not indicate what the maximum line speeds permitted in these countries were and did not explain how maximum line speeds affected the countries' pathogen levels.

Response: As noted above, the purpose of the waiver process is to allow establishments to experiment with new equipment, technologies, or procedures, not to initiate regulatory changes across the industry. Regulatory waivers are not the appropriate vehicle to address the poultry industry's global competition

issues. Additionally, countries that currently export poultry to the United States require that establishments that process poultry for export comply with maximum line speeds regulations similar to those in the United States.

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Paul Kiecker,

Acting Administrator.

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