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MEMORANDUM

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RE: FSIS Releases Final Poultry Slaughter Rule

The Food Safety and Inspection Service (FSIS) will soon publish in the *Federal Register* its long-anticipated final rule modernizing the poultry slaughter inspection system. The final rule generally tracks the Agency's January 2012 proposal with some modifications, most notably a lower line speed than proposed for chicken establishments. 1/ The new system, dubbed the New Poultry Inspection System (NPIS), is modeled after the Agency's long-running HACCP Based Inspection Models Project (HIMP) pilot program and is designed to give establishments more control over their slaughter and processing operations.

The final rule will require establishments that opt into the voluntary NPIS to conduct initial carcass sorting and pathogen sampling and will place a greater emphasis on plans and procedures. There will be a greater emphasis on offline verification inspection by FSIS inspection personnel, but NPIS will retain carcass-by-carcass inspection. Maximum line speed under NPIS will be 140 birds per minute (bpm) for chicken and 55 bpm for turkeys, although young chicken slaughter establishments currently participating in HIMP will be allowed to continue operating at up to 175 bpm.

NPIS will be voluntary, and the existing inspection systems—Streamlined Inspection System (SIS), New Line Speed Inspection System (NELS), and New Turkey Inspection System (NTIS)—will remain. FSIS plans to implement NPIS across groups of establishments in stages, and establishments will have six months from the date of publication to opt into the initial implementation sequence. The rule also makes several changes to the existing inspection systems. Those changes will become effective 90 days from the date of publication for large establishments. The rule also includes discussion aimed at promoting worker safety.

In a briefing announcing the rule, FSIS Administrator Al Almanza heralded the rule as one of the "biggest changes in generations" to the Agency's inspection systems and described it as promoting a modernized, science-based approach to poultry slaughter inspection. The Agency projects that the final rule will save the Agency several million dollars per year in operating costs while improving food safety and public health. The preamble to the final rule also includes a forceful defense of the food safety benefits of the HIMP program. 2/

1/ *See* Hogan Lovells Memorandum, *FSIS Issues Proposed Rule Revamping Poultry Slaughter Inspection* (Jan. 27, 2014).

2/ FSIS has also released a questions and answers document explaining the benefits of the rule, available on its website at http://www.fsis.usda.gov/wps/wcm/connect/3b7e7781-c17e-4f73-810f-f66a904f66f3/Poultry-Slaughter-FAQ_073114.pdf?MOD=AJPERES.

This memorandum explains the key features of the NPIS as well as general changes to all poultry inspection programs. An advance copy of the final rule is attached.

New Poultry Inspection System (NPIS) Framework

The final rule establishes the framework for NPIS. NPIS is based largely on HIMP, although with some changes. Establishments will have primary responsibility for sorting and trimming carcasses before presenting them to an online inspector stationed before the chiller. FSIS will continue carcass-by-carcass inspection but will increase focus on offline verification activities. The following features will apply to establishments that opt into NPIS.

Inspector Staffing. Under NPIS, each evisceration line will be staffed with a total of two inspectors—one online carcass inspector (CI) and one offline verification inspector (VI)—as well as an inspector in charge (IIC) for the establishment. The CI will be responsible for conducting carcass-by-carcass inspection and will be stationed immediately before the chiller. The VI will conduct verification sampling as well as other inspection tasks.

Inspectors will continue to issue noncompliance records (NRs) for observed regulatory violations. FSIS advises that the VI will issue NRs for fecal matter observed during offline verification checks, and the CI will issue NRs for visible fecal contamination on the line, citing a failure of the establishment's procedures to prevent the fecal contamination of product during processing as the basis for the NR.

Inspection Stations and Facility Requirements. Establishments must locate the CI's inspection station at a point on the line before the chiller and after all sorting, trimming, and reprocessing steps. The station must be height adjustable, must have continuous or foot-activated hand-rinse stations, and must have access to a line-stop button and a notification buzzer, among other design requirements. Establishments must also provide an offline verification inspection station before and after the chiller, built to Agency specifications. Young chicken establishments must also provide an inspection station after evisceration to conduct the avian leukosis check (described below).

The rule also requires that a trough or similar drainage device must extend beneath the conveyor at all places where processing is conducted from the point the carcass is opened through the trimming step. FSIS disagreed with comments that drainage should be addressed through sanitation procedures alone.

Carcass Sorting and Presentation. Establishments will be responsible for sorting and trimming carcasses for presentation to the online CI. Establishments will be required to develop procedures (incorporated into their HACCP plans, SSOPs, or other prerequisite programs) to ensure that carcasses contaminated with septicemic and toxemic conditions do not enter the chiller and that parts other than those identified as "major portions" are available for offline inspection as reprocessing or salvage.

Carcasses must be presented to the online CI for inspection before entering the chiller. Both hocks must be held by the shackle, the back side of the carcass must face the inspector, there must be minimum swinging, and the establishment must be able to identify parts and viscera associated with a carcass sufficiently to allow the parts and viscera to be condemned if the carcass is condemned.

Viscera and Avian Leukosis Inspection. The rule finalizes the proposal to relax but not eliminate avian leukosis inspection. Rather than requiring carcass-by-carcass inspection of birds for avian leukosis, the offline inspector will observe the viscera from the first 300 birds slaughtered from each chicken flock for signs of avian leukosis. FSIS believes that 300 birds is a sufficient sample size to

allow inspectors to identify avian leukosis if it is present in the flock. Although the term "flock" is not formally defined in regulations, FSIS explained that it interprets a "flock" to be "birds that have been raised under similar circumstances on the same premises, [and that] arrive at slaughter together" and notes that it believes industry can appropriately designate flocks. If avian leukosis is identified in the flock, an inspector will inspect the viscera of each carcass. If avian leukosis is not identified in the flock, inspectors will not inspect viscera after the first 300 birds. The avian leukosis check will not apply to turkeys.

Responding to comments, FSIS explained that, although avian visceral leukosis is not a disease transmissible to humans, it may nonetheless render poultry "unwholesome or otherwise unfit for human food."

Line Speed. The maximum line speed under NPIS will be 140 bpm for chickens and 55 bpm for turkeys. This represents a reduction from the 175 bpm proposed for chickens. The 55 bpm line speed for turkeys represents a slight increase from the current maximum of 51 bpm under NTIS. Chicken establishments participating in the HIMP pilot will be allowed to continue operating at up to 175 bpm.

IICs will have the authority to order a reduction in line speed when, "in their judgment," carcass-by-carcass inspection cannot be performed due to presentation, health conditions of that flock, or factors that indicate a loss of process control. Line speeds are also explicitly subject to workplace safety laws administered by the Occupational Safety and Health Administration (OSHA).

In discussing the reduction in line speed from that proposed for chickens, the Agency noted that HIMP establishments operated at an average line speed of 131 bpm and that most did not operate at the maximum line speed available. FSIS also noted that it believed limiting the line speed to 140 bpm addressed competitive concerns about permitting some establishments temporarily to operate at a greater line speed than competitors while NPIS is being implemented. The Agency reasoned that 140 bpm, which is the fastest line speed allowed under the existing (non-HIMP) inspection systems, provides an appropriate line speed for NPIS. FSIS rejected with little explanation comments supporting the 175 bpm line speed or advocating for removing the fixed limit on line speed.

Ready-to-Cook (RTC) Standard. All poultry produced under NPIS must meet the standard for RTC poultry. 3/ NPIS establishments will be expected to develop procedures for controlling Other Consumer Protection (OCP) defects that are best suited to the establishment's specific operations. FSIS has indicated that an establishment operating under NPIS may use the Finished Product Standards (FPS) from SIS or NELS or the OCP performance standards from HIMP to demonstrate it is meeting the RTC standard.

Establishments must maintain records documenting that products meet the RTC standard. FSIS expects that these records will include the establishment's records system (e.g., statistical process control, HACCP records); the points in the process at which the establishment monitors for RTC criteria; the frequency of monitoring; the definition of the OCP and processing and trim defects being monitored; the criteria used to evaluate RTC compliance; and corrective actions.

3/ FSIS defines ready-to-cook poultry as "any slaughtered poultry free from protruding pinfeathers and vestigial feathers (hair or down) from which the head, feed crop, oil gland, trachea, esophagus, entrails, and lungs have been removed, and from which the mature reproductive organs and kidneys may have been removed, and with or without giblets, and which is suitable for cooking without need for further processing." 9 C.F.R. § 381.1.

FSIS will review records and inspect product to determine whether an establishment is meeting the RTC standard. The Agency will view the presence of persistent, unattended trim and dressing defects at the end of the process as indication that the establishment is not producing RTC poultry and possibly that the establishment may lack control over its process.

For establishments operating under NPIS, the RTC standard will replace the current FPS, although FPS will remain in place for establishments operating under SIS, NELS, and NTIS.

Workplace Safety Attestation. All establishments operating under NPIS (or HIMP) must submit annually to FSIS an attestation that the establishment maintains a program to monitor and document any work-related conditions that arise among establishment workers. The monitoring program includes encouraging reporting of illness and injuries, informing employees of the symptoms of workplace illness and injuries, and monitoring injury and illness logs and other data for injury information. 4/

Changes Applicable to All Poultry Inspection Systems

The final rule also implements several changes applicable to all poultry inspection, including NPIS:

Fecal and Enteric Pathogen Contamination and Sampling. Poultry establishments must develop written procedures to ensure that poultry carcasses contaminated with visible fecal material do not enter the chiller. Establishments must also develop written procedures to prevent the contamination of carcasses and parts by enteric pathogens or fecal contamination throughout the entire slaughter and dressing operation. These procedures must be incorporated into the establishment's HACCP plan, sanitation standard operating procedures (SSOPs), or other prerequisite programs.

Moreover, the procedures to prevent fecal or enteric pathogen contamination throughout slaughter and dressing must include sampling. At a minimum, establishments must take samples for microbial organisms at pre-chill and post-chill points. 5/ FSIS notes that, because most establishments apply interventions between the pre- and post-chill sampling points, it expects that a reduction in microbiological contamination between these two points would indicate the effectiveness of these controls. The pre-chill sampling location will be before the chiller at the end of the evisceration process. The post-chill sampling location will be after the establishment has completed all interventions and will be the sample point at which FSIS collects *Salmonella* and *Campylobacter* verification samples. 6/

Establishments may sample directly for enteric pathogens or may choose to sample for indicator organisms. Establishments may use generic *E. coli* as an indicator organism provided the establishment can demonstrate that this is an appropriate indicator organism.

4/ This provision also includes a severability clause stating that, if this provision is held invalid by a court, the rest of the regulation is to remain in place.

5/ FSIS explains that it believes sampling data from the pre-chill location "to be a valuable source of data about how well an establishment is minimizing contamination with fecal material and enteric pathogens on live birds coming to slaughter and on carcasses throughout the evisceration and dressing process." FSIS believes that the post-chill sampling provides valuable information about "how well an establishment is minimizing contamination during chilling and the overall effectiveness of any antimicrobial interventions" applied during processing.

6/ FSIS concluded that a third sampling point at re-hang, contemplated in the proposed rule, would not be worth the additional costs.

Establishments must collect samples at the following rates, at a minimum:

- For chickens: once per 22,000 carcasses, but at least once each week of operation;
- For turkeys, ducks, geese, guineas, and squabs: once per 3,000 carcasses, but at least once each week of operation.

The rule also specifies that establishments must sample at a frequency that is adequate to monitor the establishment's ability to maintain process control for enteric pathogens, although the rule does not explicitly indicate when this requirement may necessitate more than the minimal level of sampling. FSIS anticipates that most establishments will adopt sampling frequencies similar to those used under the current generic *E. coli* sampling requirements and notes that establishments using infrequent sampling will be at greater risk of missing early indications of process control issues.

Establishments will be responsible for maintaining scientific and technical documentation supporting the sampling plans. Establishments must also maintain daily records documenting the implementation and monitoring of these procedures. Records must be kept for at least one year.

Exceptions apply for very small establishments or very low-volume establishments, as defined in the final rule, operating under traditional inspection. These establishments must collect samples from only the post-chill location and face a reduced mandatory testing frequency.

Chiller Performance Standards. The rule will eliminate the defined chilling standards for poultry (except ratites) and instead require that establishments ensure that poultry is chilled "immediately after slaughter" such that "there is no outgrowth of pathogens," unless the product is to be frozen or cooked immediately at that establishment. Previously chilled poultry must be kept chilled such that there is no outgrowth of pathogens. The establishment must develop chilling procedures that address the potential for pathogen outgrowth, conditions affecting carcass chilling, and when the chilling process is completed. These procedures must be part of the establishment's HACCP plan, SSOPs, or other prerequisite programs.

Establishments will be expected to develop scientific support for their chilling processes. FSIS advises that this support should include scientific documentation as well as repeated tests of the adequacy of the chilling process.

The rule eliminates the current requirements in 9 C.F.R. § 381.66(b) specifying how quickly poultry of certain sizes must be chilled and specifying 40°F as the target temperature. The rule also eliminates the requirement that giblets be chilled to 40°F within two hours. These requirements are all replaced by the more general performance standard. But FSIS also confirms that the current time and temperature chilling requirements will be accepted as a safe harbor. The Agency indicates it intends to incorporate those parameters into a compliance guideline document.

Air Chilling. The rule expands the agency's treatment of air-chilled poultry, defining "air chilling" as "the method of chilling raw poultry carcasses and parts predominantly with air." In response to comments, FSIS revised the rule to make clear that an antimicrobial intervention may be applied with water at the beginning of the air chilling process, provided that its use does not result in any net pickup of water or moisture during chilling. The rule also clarifies that the antimicrobial intervention may result in "some temperature reduction" provided that the majority of the temperature reduction is accomplished "exclusively by chilled air." The rule states that only poultry chilled in this manner may be labeled as "air chilled."

Carcass Contamination and Reprocessing. The rule will allow online reprocessing of all carcasses using an antimicrobial intervention after evisceration and before the chiller to remove digestive tract contamination from carcasses. The rule will continue to allow offline reprocessing of contaminated inner surfaces that are not cut using any method that will remove the contamination, including

vacuuming, washing, and trimming. If the inner surfaces are reprocessed by means other than trimming, all surfaces of the carcass must be treated with chlorinated water containing 20 to 50 parts per million (ppm) available chlorine or another approved antimicrobial.

E. coli Sampling. The rule will eliminate the generic *E. coli* sampling requirement for all poultry except ratites. 7/

Other Issues

In addition to the specific regulatory changes, the Agency's discussion of its final rule addresses several other issues related to implementing NPIS.

Implementation Process. Adopting NPIS will be voluntary and, unlike in the proposal, establishments not wishing to participate in NPIS may continue operating under their existing inspection systems. Establishments will have six months from the date the rule is published to notify their district office that they wish to opt into NPIS. FSIS has committed to implementing NPIS eventually in all establishments that wish to use the system, but establishments that opt in after the initial six-month period will not be part of the initial implementation process. FSIS rejected comments requesting that the different aspects of NPIS be phased in gradually, instead opting to implement NPIS all at once on a plant-by-plant basis.

FSIS will assign scores to establishments to determine the order in which NPIS is implemented. Scores will be based on the number of FSIS employees to be affected and the food safety performance history of the establishment. Scores will be adjusted to group establishments into geographic clusters and to ensure establishments are evenly distributed among different corporate owners. FSIS will implement NPIS in establishments with higher scores first, working in geographic clusters and taking into account corporate ownership to ensure no one company is overly represented in the transition process. Higher-ranked establishments that are not ready to transition may opt to transition later.

FSIS contemplates that it may begin transitioning establishments to NPIS before the six-month period ends, possibly starting as early as 60 days after the rule is formally published in the *Federal Register*, and encourages establishments to notify the Agency as soon as possible if they wish to opt into the new system. FSIS anticipates transitioning about twelve establishments per month to NPIS. 8/ In its economic analysis, FSIS assumes that the full transition process to NPIS will take about five years.

The changes to the procedures for controlling visible fecal contamination, the changes to procedures for controlling contamination throughout slaughter and dressing (including sampling), and the accompanying recordkeeping requirements will take effect 90 days after publication in the *Federal Register* for large establishments, 120 days after publication for small establishments, and 180 days after publication for very small establishments.

7/ The final rule also formally removes the pathogen reduction performance standards, which have not been enforced as binding regulations following the *Supreme Beef* decision holding that requirement invalid. Note that the Agency will continue to implement its technically non-binding performance standards.

8/ Details about the establishment scoring system are available on FSIS's website at http://www.fsis.usda.gov/wps/wcm/connect/b2dfd66d-f6a6-489e-be99-c000d1136f2a/PSR-Scheduling-Plants_073114.pdf?MOD=AJPERES.

Training. FSIS is not requiring specific training for carcass sorters under NPIS, but the Agency has prepared guidance documents to assist in training establishment sorters. The guidance documents are based on training that FSIS provides to its inspectors responsible for carcass sorting. 9/

Existing HIMP Establishments. Chicken establishments currently participating in the HIMP program will be permitted to continue operating under most aspects of the HIMP program, including running at line speeds of up to 175 bpm. FSIS will modify other portions of the *Salmonella* Initiative Program (SIP) waivers applicable to those establishments to remove other inconsistencies between HIMP and NPIS (e.g., the OCP performance standard). FSIS has committed to maintaining the same number of HIMP establishments. If an establishment participating in HIMP closes or decides to drop out of the program, its place will be offered to another establishment.

One-Year Assessment. FSIS explained that it intends to assess the impact of changes adopted by establishments operating under NPIS after one year of experience with the system. The Agency will evaluate the results of FSIS *Salmonella* and *Campylobacter* verification sampling, OCP performance, and other factors.

Workplace Safety. FSIS incorporated workplace safety considerations into the final rule and its discussion of the rule in response to comments expressing concern for workplace safety. 10/ The rule makes clear that NPIS line speeds are subject to OSHA requirements that workplaces be "free from recognized hazards that are causing or are likely to cause death or serious physical harm to [establishment] employees" and that workplaces satisfy OSHA regulatory requirements.

FSIS indicates that it remains committed to working with the National Institute for Occupational Safety and Health (NIOSH) and to disseminating guidance from the recent NIOSH study of the effects of line speed on worker safety. FSIS also indicates it continues to work with OSHA and FSIS's own Occupational Safety and Health Division, which is intended to promote safe working conditions for federal inspectors. FSIS reports it is in the process of developing a Safety and Health Committee made up of program representatives and members of the National Joint Council of Food Inspection Locals (the federal inspectors' union). FSIS also reports that it is working with OSHA to improve the ability of FSIS inspectors to identify and report to OSHA unsafe working conditions in federally inspected establishments. FSIS recently released FSIS Notice 37-14, *Procedures for Notifying the Occupational Safety and Health Administration (OSHA)*, which provides instructions for inspectors to notify OSHA of workplace safety issues affecting FSIS inspectors or establishment employees.

In addition, although FSIS recognizes it lacks the authority to mandate worker safety requirements, the Agency strongly encourages establishments to adopt several recommendations from OSHA to promote worker safety:

- Develop policies to encourage prompt reporting of injuries and illnesses;
- Evaluate existing programs to ensure that they do not discourage such reporting;
- Implement training programs on injury identification and prevention;
- Review workplace illness and injury logs and workplace conditions to identify potential hazards;
- Develop an employee complaint procedure;

9/ The Agency indicates it will post this guidance to the Compliance Guides Index portion of its website at http://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/compliance-guides-index.

10/ FSIS reports that the "vast majority" of comments received on the proposal were on the issue of worker safety in relation to increased line speeds.

- Request employee feedback on workplace modifications; and
- Implement mitigating measures to address job hazards.

FSIS advises that OSHA "will be paying close attention to poultry slaughter establishments, including those that elect to operate under the NPIS."

Animal Welfare. FSIS reports receiving thousands of comments expressing concern for animal welfare in the context of NPIS. The Agency indicates that its good commercial practice requirements would continue to apply and that it has no basis to believe that NPIS would adversely affect animal welfare.

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We will continue to monitor FSIS's implementation and enforcement of the new requirements and NPIS. Please do not hesitate to contact us if you have any questions.