

Sandra Eskin
Deputy Under Secretary
U.S. Department of Agriculture
Office of Food Safety
Room: 210-W, Jamie Whitten Building
1400 Independence Ave.
Washington, DC, 20250

February 11, 2022

Dear Deputy Under Secretary Eskin:

We write to share our concerns about the new trial line-speed program that FSIS recently announced for New Swine Inspection System (“NSIS”) establishments. As many of our organizations have written in formal comments, the agency’s NSIS rule lacks adequate safeguards to protect consumers from foodborne illness threats that are likely to emerge as a result of higher line speeds, a reduced inspection force, and the elimination of microbiological testing standards. For these reasons, we continue to oppose implementation of the NSIS rule and the trial program that would increase line speeds for participating plants. Should the agency nevertheless move forward with the proposed trial, we recommend you adopt additional safeguards to better protect consumers from the NSIS program’s deficiencies and better ensure compliance with the agency’s waiver regulations.

We continue to be greatly concerned about the Trump administration’s NSIS rule, which transfers a number of critical federal inspectors’ responsibilities to slaughter-plant employees, with no mandatory training or education, and no applicable pathogen performance standards by which to evaluate establishments. We were buoyed by the Biden administration’s decision last year not to appeal a federal district court decision that found the rule’s lifting of line-speed limits unlawful. The agency’s new trial program could reverse this progress, however, lifting line-speed limits again and reinstating the program championed by the prior administration. As you are undoubtedly aware, between 2014 and 2017, the slaughter plants that piloted the NSIS operated only 12.5% faster than comparably sized traditional plants but had nearly *twice* the violation rates for contamination with fecal matter, digestive contents, and milk.¹

According to FSIS, its new line-speed trial program is designed in part to facilitate experimentation to protect food safety, but the program’s requirements do not adequately advance that objective. The trial program merely requires that establishments not receive a public health alert and enforcement action as a result of a Food Safety Assessment (“FSA”) in the last 120 days, but much more is needed to protect public health. Indeed, a number of the establishments requesting permission to enter the trial program have had serious issues, even though they did not result in a public health alerts or FSA-generated enforcement action. For example, the most recent establishment-specific data for *salmonella* in pork show that 36% of the comminuted product in

¹ Kimberly Kindy, *Pork Plants in a USDA Test Program Had Higher Contamination Rates Than Traditional Plants*, Washington Post, Feb. 18, 2021, www.washingtonpost.com/politics/pork-plants-contamination/2021/02/18/8d90c986-7133-11eb-93be-c10813e358a2_story.html.

Clemons Food Group's Hatfield NSIS plant tested positive in the last fiscal year.² This was substantially higher than the average large establishment's rate (19%) over the same time period.³ It bears emphasis that the public does not have a complete picture of the true performance of any of the plants seeking to enter FSIS's trial program, since in the past the agency evaluated the NSIS-pilot slaughter plants based on now-abandoned, whole-carcass-verification tests as well as exploratory sampling of *cuts* of pork (presumably because not every slaughter facility produces comminuted product). In the last fiscal year, the agency only tested cuts of pork for *two* of the NSIS plants applying to the trial program, so the public cannot easily evaluate and compare these NSIS plants to each other or to other large slaughter plants.

Further, we are aware that a number of NSIS plants, including some that are seeking to enter the trial program, have had serious problems with plant-employee sorters not being able to perform sorting, including critical tasks such as incising and palpating animals' lymph nodes. Accompanying this letter are some agency summaries of Memoranda of Interview and Noncompliance Reports that document these problems, many of which occurred long after the plants had been approved to operate under NSIS.⁴ These problems appear to stem from establishments' decisions to reduce the numbers of sorters and not provide training for their employees under NSIS.⁵ This is perhaps not surprising as the NSIS rule had no requirements that establishments train their plant employees on these tasks, notwithstanding that they are vital for the detection of serious food safety issues like *septicemia*.⁶

Given this, the agency should only grant waivers to establishments that can demonstrate an established track record of exceptional food safety performance under NSIS. Specifically, plants should meet the following criteria—which are additional to those detailed in the agency's recent letter inviting NSIS plants to join the trial. Plants must:

- have a substantially lower non-compliance rate for fecal matter, digestive matter, and milk contamination (9 C.F.R. 310.18) than plants with comparable production volumes;
- not have a substantially higher non-compliance rate for failing to incise lymph nodes than other NSIS plants (9 C.F.R. 310.25(b));

² USDA, Raw Pork Products Sampling Data (current), Samples collected from October 1, 2020 to September 30, 2021, https://www.fsis.usda.gov/sites/default/files/media_file/2022-01/FSIS_Pork_Data_FY21Q4.xlsx. (data for Est. Id. "6408").

³ USDA, Quarterly Sampling Reports on Salmonella, <https://www.fsis.usda.gov/science-data/data-sets-visualizations/microbiology/microbiological-testing-program-rte-meat-and-7> (combined comminuted data for First through Fourth Quarters October 1, 2020 to September 30, 2021).

⁴ Attached at Exhibit A.

⁵ See e.g., *id.* at A-7, A-10, A-13 (showing that the problems stemmed from stationing only one sorter at the head station for an extended periods of time).

⁶ As the agency has indicated: "[c]arcasses and parts . . . that exhibit signs of septicemia, toxemia, pyemia, or cysticercosis during post-mortem examination are likely to contain infectious agents, such as bacteria, virus, rickettsia, fungus, protozoa, or helminth organisms, which can be transmitted to humans. For this reason, they present a food safety risk if they are permitted to enter the cooler." 83 Fed. Reg. 4780, 4793 (Feb. 1, 2018).

- have substantially lower *salmonella* positive rates than plants of similar production volumes and not have a substantially higher positive rates than other NSIS plants;
- show the increased line speed will not negatively impact FSIS employee safety or interfere with inspection procedures (*e.g.*, information about safety protocols or line configuration); and
- document how they obtained this minimal level of performance under NSIS, identifying concrete measures they have taken to address each issue, such as training measures or standards employed to ensure adequate sorter performance; wherever feasible, establishments should incorporate these concrete measures as actions they will take to implement their HACCP plans.

Fulfilling these criteria will help protect public health and establish a baseline of procedures that establishments have employed to avoid problems at NSIS facilities (particularly now, when line speeds have presumably been lower). This will allow the agency to test the effects of line-speed increases alone and ensure that the agency complies with its regulations, which only allow waivers to test new procedures, equipment, or processing techniques to “facilitate definite improvements.”⁷ This is particularly important if the agency were to adopt the Trump administration’s interpretation that the regulation’s “definite improvement” requirement is met if there is an increase in line speeds and “no diminution in the food safety profile of the finished product.”⁸ To the extent there are any industry-wide data-collection or performance limitations that would prevent the agency from evaluating plants’ compliance with the above criteria, the agency should correct these issues before the program begins.

Prior to approving any waiver application, FSIS should ensure that adherence to all waiver criteria is fully documented, consistent with the recommendation of the USDA Office of Inspector General’s (“OIG”) March 2021 audit of the agency’s regulatory-waiver program.⁹ Moreover, the agency should regularly monitor admitted plants’ compliance with these criteria after the trial program begins. Like it has done with some of the plants granted line-speed waivers in the past, such as the Clemons Food Group plant in Coldwater, the agency should increase the frequency of its verification tasks relevant to the waiver for at least the first 90 days after implementation. Thereafter, the agency should periodically assess whether the admitted establishments are adhering to the above criteria—at least every 90 days—and revoke their line-speed waivers if they are not.

Our recommended criteria and implementation processes are no surrogate for more comprehensive reforms to the agency’s hog slaughter inspection—including updated, enforceable, microbial testing standards—that the agency should work to develop and implement as soon as possible. Should the agency choose to go forward with its proposed line speed waiver program, the

⁷ 9 C.F.R. § 303.1(h) (2021).

⁸ 83 Fed. Reg. 49,048, 49,053 (Sept. 28, 2018).

⁹ Office of Inspector General Report, *FSIS Waiver of Regulatory Requirements*, at 6, OIG Report 24601-0007-31 (Mar. 26, 2021).

adoption of these recommendations would help to better protect consumers from the food safety risks posed by deficiencies in the NSIS program. Thank you for your consideration.

Sincerely,

/s/ Zach Corrigan
Senior Staff Attorney
Food & Water Watch

Thomas Gremillion
Director of Food Policy
Consumer Federation
of America

Jaydee Hansen
Policy Director
Center for Food Safety

Mitzi D. Baum
Chief Executive Officer
Stop Foodborne Illness

Exhibit A

| District | EstNbr | EstName | MOINbr | Date | Task Code | TaskName | Status | MOI_Agenda |
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| 60 | M791 | Clemens Food Group, LLC | MXL09071 12430G | 30NOV2018 | | | Finalized | <p>Present: Agency Representatives: (b) (6)</p> <p>Establishment Representatives: (b) (6)</p> <p>Following was discussed at approximately 1000 hours on Friday, November 30, 2018 in FSQA conference room: USDA/FSIS has not been able to hold meetings on 11/16/2018 and 11/23/2018 because of staffing issues. Therefore there is no weekly meeting documentation in PHIS for dates previously mentioned. (b) (6) inquired about any consumer complaints or returned product. (b) (6) informed us that there has been a complaint received. It was received on Thursday from (b) (4). The complaint involved a metal concern. (b) (6) said the plant was starting the investigation and would keep us informed. (b) (6) reviewed available SIP records all negative. A few weeks ago, (b) (6) discussed that request for OT that was just an hour for a shift may not be honored. Since that time you, the establishment, have made requests for OT for about 4 hours on second shift on Sunday. On Nov 18 and Nov 25 the written email request to the inspector was requesting OT for a few hours for second shift, but then the first shift inspector was informed that coverage was not needed on Sunday after 5 pm. If there is a change to the request for OT that change needs to be communicated in writing. It would not be sufficient to inform the first shift inspector verbally of that change. Any change to OT request needs to be made when the inspector covering that OT is on duty, otherwise there is no way for the inspector to become aware of the change. The inspector was informed that they are to work the original OT request until we receive a new request in writing. Therefore, you, the establishment, would be charged for the original request for OT hours. FSIS has an obligation to assure effective and efficient use of Inspection. Therefore, if the plant management request OT inspection, we would assume that you reasonably need that inspection time and our inspectors would be utilized to verify your process. On Nov 18 and 25 you requested second shift OT but failed to utilize it. Management needs to note that OT is a request and if the inspectors are not being utilized during OT we may consider denying the requests for overtime in the future. (b) (6) inform the plant of the outcome of the Robust Systemic Approach task. On Friday the 30th weekly meeting I reviewed the written RSA and the daily records. I confirm that what the establishment 00791 Clemens Food Groups LLC. state in the program is exactly what it is happening. The task has been completed in the PHIS</p> |

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| | | | | | | | | <p>System. MOI about my review is completed and discussed today Friday the 30th with the management at the weekly meeting. A copy of the MOI that indicate the monthly RSA task has completed and evaluated will be sent to the DVMS. (b) (6) informed the plant management that I will not sign any export certificates unless it is completely filled accurately and No abbreviations is allow. Furthermore (b) (6) emphasized that the product name must be written the same way as it is on the label of the product. (b) (6) and (b) (6) met with (b) (6) on November 27, 2018 to observe the establishment perform its pre shipment review process. She explained her process to us and all looks ok so far but the final paper work which shows all CCPs have met and SSOP records have been reviewed is on establishment internal electronic program which is not available for review when IPPs review records. Therefore, establishment needs to provide the document for review by the IPP. Some of the metal nipples in the pens need attention. There is a work order in for pen 30 and 31 the water nipples slide towards the wall and at times animals struggle to get water. (b) (6) stated a work order has been submitted and should be completed this weekend. Establishment did install additional nipples and plans to remove the ones on the wall. Last couple of weeks (b) (6) and (b) (6) covered the line multiple times and observed employees are not properly incising (cutting) the lymph nodes at the head drop area. This issue has already been brought to the attention of (b) (6) and (b) (6). Establishment stated it is required to have one cut as per HIMP program. IPP will verify. Kidneys are not being popped properly. They are still incased in fat or its thin white shell. This issue has already been brought to the attention of (b) (6) and (b) (6). When inspector goes to perform Zero Tolerance Check at the end of the line, there are two individuals that stop trimming fat from inside the belly (which establishment has a SOP for) and start inspecting carcass prior to inspectors inspection, Why? This is the same issue (b) (6) brought to establishments' attention when he first joined. Establishment collects lard (leaf lard) on the clean side. Two conveyors which carry lard down a chute also include kidneys going down the same chute. According regulation 319.702(a) lard is the fat rendered from clean and sound edible tissues from swine. The tissues may be fresh, frozen, cooked, or prepared by other processes approved by the Administrator in specific cases, upon his determination that the use of such processes will not result in the adulteration or misbranding of the lard. The tissues shall be reasonably free from blood, and shall not include</p> |

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| | | | | | | | | <p>forthcoming had FSIS judged that the establishment was not successfully implementing required corrective actions (CA's). At this point, and relating to CA's, (b)(6) indicated one very important reason for M791C to have notified FSIS immediately upon discovery of the problem. He indicated that FSIS, even though product was still under control by the establishment and had not passed its pre-shipment review, FSIS should be afforded the opportunity to verify observing corrective actions as they are in process and not merely by record review, especially since FSIS Inspectors were on hand and available to do so. Randy Zorn indicated that in the future, FSIS notification would occur after an initial investigation, process control, and facts are understood by the CFG team.</p> |
| 50 | M791C | Clemens Food Group, LLC | QCF02060 21808G | 08FEB2018 | | | Finalized | <p>At 0618, (b)(6) observed the establishment's sorting procedures of the viscera at the pans station. At this time, we observed that only one sorter was sorting at the pans station. The line speed was (b)(4). The sorter was observed only palpating every other viscera. Immediate actions were taken and the line was stopped. Management (b)(6) was notified of our findings. Management decided to add an additional sorter to the pan station. Management was informed to reduce the line speed until it could be verified that corrective actions taken by the establishment would be affective to insure that the establishments sorting procedures were properly implemented. (b)(6) was informed that a MOI would be documented as to the findings and the actions taken.</p> |

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| | | | | | | | | <p>of the exhaust fan louvers on the west side of the barn near pen 13? Ice has been seen to form near the entry into this pen presumably due to the continually open louvers and has been observed to be appropriately FSQA tagged when ice is present to prevent hogs from slipping. M791C INSPECTION/SORTING PROCEDURES: There are three main provisions of M791C's SIP-Waiver: a) elimination of line speed limitations, b) alternative microbial testing procedures to verify sanitary dressing, and c) the establishments inspection and sorting activities. During the visit on 2/5/18 by acting FSIS Administrator Paul Kiecker and Chicago District Manager Paul Wolseley, both individuals noted and had concerns about the consistency and thoroughness of your head inspection procedure. On 2/8/18 (b)(6) noted deficiencies in the viscera sorting procedures and his observations were documented in an MOI. It is imperative that this important, basic, and fundamental provision of the waiver (inspection/sorting) be diligently adhered to. There have been no subsequent similar observations by IPP since at either heads or viscera. PRODUCER SPECIFIC FSIS or MDARD LAB RESULTS: Michigan Department of Agriculture and Rural Development (MDARD), (b)(6) (b)(6) noted to (b)(6) in a phone conversation that anytime a source producer is known, lab results, other than to regulatory officials, because of privacy concerns, will only be reported to the producer involved. Should the plant wish to learn of the lab results they would need to contact the producer, and if approved by the producer, his/her veterinarian. MDARD will however still generally notify the plant if the hogs and/or product can be released. OCP: All OCP checks thus far this week by FSIS have given SIP Waiver compliant results. OLD BUISNESS Slaughter Is there a possibility of creating an area in the cooler for USDA retained carcasses? How will USDA retained carcasses be handled in the future? - There is currently a rail and procedures available to retain hog carcasses. - (b)(6) is still working on a better way to accomplish this than is currently available. - PO will be cut next week for a manual rail out off of rail #1 for any USDA retained carcasses There is flaking paint on the walls in the harvest floor room and in the offal room and other areas. Establishment management has a work order to address this issue. This issue needs prompt attention. - The company that painted the floor is scheduled to fix the problem on 1/6. -The company that painted the walls has not responded to a recent inquiry as to when they will be making repairs. - Paint representative was here to look at the walls and no fix date has been set yet. - Large peeling pieces are being removed. If they scrape too much it just keeps peeling. - (b)(6) met with the</p> |

Ex. A-6

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| 50 | M791C | Clemens Food Group, LLC | QCF58140 20113G | 13FEB2018 | | | Finalized | <p>An exit meeting was conducted in (b)(6) office from approximately 1045 to 1134 hours following Chicago District, Deputy District Manager, (b)(6) visit to M791 this morning (02/13/2018). Present at this meeting were (b)(6) Randy Zorn (b)(6) (b)(6) Discussed were (b)(6) findings and observations made 1) in the Clean Harvest at the M791C Head (incising) Sorting area, 2) at the viscera sorting area, 3) in the bleed rail area, 4) at the shackle conveyor, 5) at the CO2 stunning area and 6) in the ante-mortem areas generally including truck unloading and at the "subject" pen. Head (mandibular lymph node) incising and sorting - (b)(6) observed that at (b)(4) hogs per hour that there were two M791 head sorting employees incising mandibular lymph nodes. When one of these two employees stopped to steel his knife the other employee attempted to perform the head sorting procedure on all heads by himself. (b)(6) stated that during this short period of time when only one employee was incising heads this employee missed one or two heads and those lymph nodes he did incise were done in a more chopping manner instead of a smooth rolling slicing manner. Other than this brief period when there was only one person incising, all heads were incised as per the SIP Waiver. Also noted was an observation that although incisions were being made into the mandibular lymph nodes, the approach of the cuts was such that in order to visualize the lymph node after the cut had been made, FSIS on-line personnel at the pan/head inspection area would have to lift or reflect the mandibular salivary gland out of the way to visualize the underlying mandibular lymph node and its incisions. (b)(6) noted that the establishment had been required by FSIS to turn the heads in the head halo-ring so that FSIS IPP could visualize these incised lymph nodes and other structures, but the covering of the lymph nodes by the salivary glands still obstructs visualization of the incised lymph nodes. (b)(6) did ask what written training program M791C had for its sorters – for both ante- and post-mortem sorting (b)(6) said that they had a PCP (written Process Control Program) that addressed A.M and P.M. sorting, as well as an on-line alchemy for ante-mortem inspection authored by their veterinarian (b)(6) which ante-mortem sorters are required to take. She also mentioned correlations sessions with more experienced supervisors from both their Coldwater and Hatfield plants. (b)(6) indicated that they were working on or obtaining a risk analysis for a possible justification for an alternate method of head inspection based upon the prevalence of avian TB in their and contract grower/finisher confinement raised herds. Viscera Sorting Area – (b)(6) did not note any</p> |

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| | | | | | | | | <p>deficiencies in sorting procedures at this location. Bleed rail area – in the area of the bleed rail, particularly at the head/neck thumping area, (b)(6) (b)(6) had concerns, although not necessarily regulatory concerns at this time, regarding blood dripping from hogs at this location directly to the floor and coagulating. She noted that in the summer this might become an issue with odors and or insects. She primarily was interested as to why this was the practice here even though there was a blood collection trough after the stickers and prior to the two lines joining back as one line. At the shackle conveyor, (b)(6) had concerns about hogs being contorted/bent/twisted as they exited from the CO2 stunner. This was not a humane handling concern but rather a process control concern as it might relate to the production of defects such as bruises and or broken bones, etc. (b)(6) indicated that FSIS OCP verification tasks throughout the day have never revealed any defects that would relate back to this practice and therefore considered this area compliant. CO2 stunning area – (b)(6) observed a non-egregious humane handling noncompliance at the staging area for the CO2 stunning area when a horizontal bar gate was closed upon the snout of a hog. Although (b)(6) had informed (b)(6) that an NR would be issued for this, he reiterated this to those present inasmuch as they were unaware.</p> <p>Ante-mortem sorting – as with post-mortem sorting, (b)(6) wanted to know what method of training was used in training post-mortem sorters at the four post-mortem areas (head, viscera and carcass and lead sorting). (b)(6) indicated that the PCP and correlations were used as mentioned in item 1. above.</p> |

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| | | | | | | | | <p>Rate November: 11.76% December: 50.00% January: 30.77% This last week 22.22%, was 50% Last 2 weeks 30.77, was 50% Oct 19-Jan(to date) 31.11%, was 32.10% Your Public Health Risk Noncompliance rate for November 1 to January 31 is 4.29% (was 3.90%). The cut point for Public Health Risk Enforcement/FSA scheduling is 8.73%. Sampling No KIS tests run thus far this week. One exploratory pork sample sent in 02/12/2018 Post Evisceration Salmonella Sampling Results since 12/22: Doc reviewed APC results since 12/22: Doc reviewed Slaughter Head Sorting: (b)(6) today (2/16/18) observed a head sorter missing for a short period at the head sorting station leaving only one employee to incise heads at 1100 head an hour. While he did not observe this employee miss any heads or incisions he did think this observation was noteworthy as it related to item 2. below in OLD BUSINESS for Slaughter. OCP: All OCP checks thus far this week by FSIS have given SIP Waiver compliant results. OLD BUSINESS Slaughter BARN EXHAUST FAN LOUVERS: What is the status of the exhaust fan louvers on the west side of the barn near pen 13? Ice has been seen to form near the entry into this pen presumably due to the continually open louvers and has been observed to be appropriately FSQA tagged when ice is present to prevent hogs from slipping. M791C INSPECTION/SORTING PROCEDURES: There are three main provisions of M791C's SIP-Waiver: a) elimination of line speed limitations, b) alternative microbial testing procedures to verify sanitary dressing, and c) the establishments inspection and sorting activities. During the visit on 2/5/18 by acting FSIS Administrator Paul Kiecker and Chicago District Manager Paul Wolseley, both individuals noted and had concerns about the consistency and thoroughness of your head inspection procedure. On 2/8/18 (b)(6) noted deficiencies in the viscera sorting procedures and his observations were documented in an MOI. It is imperative that this important, basic, and fundamental provision of the waiver (inspection/sorting) be diligently adhered to. There have been no subsequent similar observations by IPP since at either heads or viscera. Is there a possibility of creating an area in the cooler for USDA retained carcasses? How will USDA retained carcasses be handled in the future? - There is currently a rail and procedures available to retain hog carcasses. (b)(6) is still working on a better way to accomplish this than is currently available. - PO will be cut next week for a manual rail out off of rail #1 for any USDA retained carcasses - few months out on rail out. fabrication company needs to design yet. Tentative install date is by May 1st. There is flaking paint on the walls in the harvest floor room and in the offal room and other areas. Establishment management has a</p> |

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| 50 | M791C | Clemens Food Group, LLC | QCF4914033309G | 09MAR2018 | | | Finalized | <p>Clemens FSIS Weekly Meeting MOI 1300 hour 03/09/2018 FSIS inspection personnel: (b)(6)</p> <p>(b)(6) Plant Personnel: Facilities Manager Randy Zorn, (b)(6)</p> <p>(b)(6)</p> <p>(b)(6)</p> <p>(b)(6) NEW BUSINESS General</p> <p>USDA, AMS will be here next week to conduct a Process Verified Program annual review. (b)(6) – wrapping up 90 day review program; no date from RIMS on their in-plant review; they will be reviewing data next week. (b)(6) – Daily tasks will continue until RIMS is finished with their review. (b)(6) – The primary issue so far during the SIP Waiver verification period has revolved around M791C’s sorting activities which appear to have been resolved. (b)(6) will be here next week. The two new inspectors which will join (b)(6) are due to report to M791C on 4/2/18. M791C will not be operating on Good Friday (3/30/18). They will work Saturday 3/24/18. Baseline Salmonella spp. testing has thus far returned negative results for all samples taken. Noncompliance Records OPEN Slaughter HACCP noncompliance QCF2212022806N/1, dated 02/05/2018, describes the slaughtering of a hog that did not receive Ante-Mortem inspection. Discussing with team to – possible appeal Rescinded and replaced with NR# QCF3112032205N/1 per supervisor instructions. Discussing with team – possible appeal of replacement NR QCF3112032205N/1. OPEN Slaughter HACCP noncompliance QCF2212022806N/2, dated 02/05/2018, describes a Hazard Analysis noncompliance for not adequately identifying the reasonably likely to occur hazards or the preventative measures needed to control those hazards. Discussing with team to – possible appeal Rescinded and replaced with NR# QCF3112032205N/1 per supervisor instructions. Discussing with team – possible appeal of replacement NR QCF3112032205N/1. OPEN Operational SSOP Review and Observation NR# QCF2014032306N/1, dated 03/05/2018, by (b)(6) which describes 10 or more carcasses on the floor in the transition room where carcasses enter the snap chill and also the dragging of carcasses across the floor. M791C still reviewing NR Open SPS NR#QCF1415030305N/1, dated 03/05/2018, by (b)(6) which describes a sour odor coming from a drain in the enclosed area between the double doors that lead to the offal area. This NR also describes liquid flowing down the north wall from the seal at the top of the wall. Temporary repair not holding; will fully repair this</p> |

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| 50 | M791C | Clemens Food Group, LLC | QCF2514103726G | 26OCT2018 | | | Finalized | <p>Clemens - FSIS Weekly Meeting MOI 10/26/2018, ~1300- 1330 hours Plant Personnel: Plant Manager Randy Zorn, (b)(6) (b)(6) (b)(6) FSIS inspection personnel: (b)(6) (b)(6) I. NEW BUISNESS APPEALED Noncompliance Records OPEN Noncompliance Records (NR's not completed in PHIS)</p> <p>1. Open General Labeling noncompliance QCF2206100411N/1; dated 10/11/2018, describes the use of "RFD" without a corresponding label approval (b)(6) - establishment just received the noncompliance and will file an appeal to (b)(6) - establishment corporate office working on appeal</p> <p>2. Open Livestock Zero Tolerance noncompliance QCF4509101117N/1, dated 10/17/2018, describes a yellowish ingesta-like substance on cheek meat in Offal A. (b)(6) (b)(6) - response will be available the beginning of next week</p> <p>3. Open Livestock Zero Tolerance noncompliance QCF1511105618N/1, dated 10/18/2018, describes yellowish ingesta-like substance no the back of the right side of a carcass. (b)(6) - response will be available the beginning of next week</p> <p>4. Open Slaughter HACCP noncompliance QCF4711103119N/1, dated 10/19/2018, describes yellowish ingesta-like substance on the front of the left side of the brisket. This was located after the establishments zero tolerance critical control point. (b)(6) - response will be available the beginning of next week</p> <p>5. Open Livestock Zero Tolerance noncompliance QCF1616101424N/1, dated 10/24/2018, describes a greenish, sticky fecal-like substance on the leading side belly lard. (b)(6) - response will be available the beginning of next week</p> <p>6. Open Other Inspection Requirements noncompliance QCF4108101426N/1, dated 10/26/2018, describes a swine carcass railed out for veterinary disposition presented without abdominal viscera to examine. (b)(6) (b)(6) - just received NR today. Have not started working on</p> <p>8. "Associated noncompliance findings can lead to further regulatory or administrative action."</p> <p>9. % noncompliant rates for SPS, Pre-op & Operational SSOP tasks performed</p> <table border="1"> <thead> <tr> <th></th> <th>Jul</th> <th>Aug</th> <th>Sep</th> <th>Oct</th> <th>last 90 days</th> <th>SPS</th> </tr> </thead> <tbody> <tr> <td>Pre-Op</td> <td>17.30 (4/23)</td> <td>18.1 (4/22)</td> <td>4.35 (1/23)</td> <td>25.0 (5/20)</td> <td>13.89 (10/72)</td> <td></td> </tr> <tr> <td>Operational</td> <td>57.14 (4/7)</td> <td>52.63 (20/38)</td> <td>7.14 (1/14)</td> <td>27.78 (5/18)</td> <td>26.67 (4/15)</td> <td>6.67 (1/15)</td> </tr> <tr> <td></td> <td></td> <td></td> <td></td> <td>18.52 (10/54)</td> <td></td> <td></td> </tr> </tbody> </table> <p>10. Your Public Health Risk Noncompliance rate for July 1st to Sep 30th is 4.67% (for</p> | | Jul | Aug | Sep | Oct | last 90 days | SPS | Pre-Op | 17.30 (4/23) | 18.1 (4/22) | 4.35 (1/23) | 25.0 (5/20) | 13.89 (10/72) | | Operational | 57.14 (4/7) | 52.63 (20/38) | 7.14 (1/14) | 27.78 (5/18) | 26.67 (4/15) | 6.67 (1/15) | | | | | 18.52 (10/54) | | |
| | Jul | Aug | Sep | Oct | last 90 days | SPS | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Pre-Op | 17.30 (4/23) | 18.1 (4/22) | 4.35 (1/23) | 25.0 (5/20) | 13.89 (10/72) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Operational | 57.14 (4/7) | 52.63 (20/38) | 7.14 (1/14) | 27.78 (5/18) | 26.67 (4/15) | 6.67 (1/15) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | | | | 18.52 (10/54) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |

| District | EstNbr | EstName | MOINbr | Date | Task Code | TaskName | Status | MOI_Agenda | | | | | | | | | | | | | | | | | | | | | | | | | |
|--------------|-----------------|------------------|-----------------|-----------|-----------|----------|--------|--|--------------|-----------------|------------------|-----------------|--|-------|------|------|-------|-----------|-------|------|------|-------|------|-------|------|------|------|-------|-------|------|------|------|-----------|
| | | | | | | | | <p>Jun-Aug was 4.34%). The noncompliance cut point for an early warning is now 5.64% (for Jun-Aug was 5.38%). The cut point for Public Health Risk Enforcement/FSA scheduling is now 9.4% (for Jun-Aug was 8.73%).</p> <p>Sampling 1. No KIS tests this week. 2. 1 NRP collected on 10/25/2018 by (b)(6) 3. (b)(6) has collected all Raw-Intact Exploratory samples for the month of October. Sample Requests for the month of November have not loaded in the system. 4. (b)(6) provided Post Evisceration Salmonella and APC Sampling results. APC/Salmonella spp. results since the last reporting date of 10/05:</p> <table border="1"> <thead> <tr> <th>Harvest Date</th> <th>Pre-Chill (log)</th> <th>Post-Chill (log)</th> <th>Salmonella spp.</th> <th></th> </tr> </thead> <tbody> <tr> <td>10/12</td> <td>2.81</td> <td>1.11</td> <td>10/15</td> <td>1.85 1.54</td> </tr> <tr> <td>10/16</td> <td>1.74</td> <td>1.08</td> <td>10/17</td> <td>2.04</td> </tr> <tr> <td>10/18</td> <td>0.70</td> <td>2.04</td> <td>1.69</td> <td>10/19</td> </tr> <tr> <td>10/22</td> <td>1.75</td> <td>3.76</td> <td>0.95</td> <td>Office 1.</td> </tr> </tbody> </table> <p>Keys to the outside (hall) door to USDA office are needed for (b)(6) - (b)(6) will follow up on key today Processing New Business 1. Processing opportunities this week - Employees entering through double doors instead of entering through the hand wash stations - Hairnets/beard nets not properly worn. Lots of mustaches hanging out. - Cryovac's A and B are still removing boxes off the chutes and throwing them all over the floor. At approximately 1020 hours today there were approximately 20 boxes at Cryovac A and 25 boxes at Cryovac B on the floor. - Exports have received approval for stickers and have received the stickers to use. Currently they are waiting on a printer for the stickers. Whether it has been ordered or being ordered (b)(6) is unsure. Slaughter New Business Slaughter Inspection 1. FSIS inspection personnel have noticed that there are extended periods of time (40 plus carcasses) when only one Clemens employee is incising mandibular lymph nodes. FSIS inspection personnel question whether one person performing this task for extended periods of time can perform quality work that effectively sorts food safety and other consumer protection condition.</p> <p>a. Adjusted line speed down during rotation 2. Online inspection personnel are regularly noticing that heads are not in the correct halo at start up, after breaks, and when there are gaps. This is a presentation issue. Sorters and inspection personnel should be notified when the reason for an isolated head in a halo is owing to a carcass that has fallen on the floor. Proper head presentation requires both mandibular lymph nodes to be displayed for inspection personnel to view at the pan station.</p> <p>Humane Handling 1. Where are you at with the testing of alternative restraint methods for captive bolt stunning? Have you updated the</p> | Harvest Date | Pre-Chill (log) | Post-Chill (log) | Salmonella spp. | | 10/12 | 2.81 | 1.11 | 10/15 | 1.85 1.54 | 10/16 | 1.74 | 1.08 | 10/17 | 2.04 | 10/18 | 0.70 | 2.04 | 1.69 | 10/19 | 10/22 | 1.75 | 3.76 | 0.95 | Office 1. |
| Harvest Date | Pre-Chill (log) | Post-Chill (log) | Salmonella spp. | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 10/12 | 2.81 | 1.11 | 10/15 | 1.85 1.54 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 10/16 | 1.74 | 1.08 | 10/17 | 2.04 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 10/18 | 0.70 | 2.04 | 1.69 | 10/19 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 10/22 | 1.75 | 3.76 | 0.95 | Office 1. | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |

| Dist rict | EstNbr | EstName | MOINbr | Date | Task Code | TaskName | Status | MOI_Agenda | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|-----------|---------------|-------------------------|----------------|--------------|-----------|----------|-----------|---|--|-----|-----|-----|--------------|-----|-----|--|------|--|--|--|--|--|--------|-------------|--------------|-------------|-------|--|--|---------|--------|--------------|--------------|--------------|-------|--|-------|---------------|-------------|--------------|--------------|------|--|--------|-------------|--------------|--|--|--|--|
| 50 | M791C | Clemens Food Group, LLC | QCF4806114610G | 10NOV2018 | | | Finalized | <p>Clemens - FSIS Weekly Meeting MOI 11/09/2018, ~1300 - 1330hours Plant Personnel: Plant Manager Randy Zorn, (b)(6) (b)(6) (b)(6) (b)(6) FSIS inspection personnel: (b)(6) I. NEW BUISNESS APPEALED Noncompliance Records 1. Open General Labeling noncompliance QCF2206100411N/1; dated 10/11/2018, describes the use of "RFD" without a corresponding label approval. (b)(6) (b)(6) - establishment just received the noncompliance and will file an appeal to (b)(6) - establishment corporate office working on appeal OPEN Noncompliance Records (NR's not completed in PHIS) 1. Open Other Inspection Requirements noncompliance QCF4108101426N/1, dated 10/26/2018, describes a swine carcass railed out for veterinary disposition presented without abdominal viscera to examine. (b)(6) - in process 2. Open SPS verification noncompliance QCF1915103330N/1, dated 10/30/18 describe pans exiting the pan washing machine that still had fat, blood, and ingesta on them. (b)(6) - ready for inspector review 3. Open General Labeling noncompliance QCF3411112202N/1, dated 10/31/2018 describes both wording on the label approval that is not on the final label and wording on the label approval that is not on the final label. (b)(6) (b)(6) 4. "Associated noncompliance findings can lead to further regulatory or administrative action." 5. % noncompliant rates for SPS, Pre-op & Operational SSOP tasks performed</p> <table border="1"> <thead> <tr> <th></th> <th>Sep</th> <th>Oct</th> <th>Nov</th> <th>last 90 days</th> <th>SPS</th> <th>Aug</th> </tr> </thead> <tbody> <tr> <td></td> <td>18.1</td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>(4/22)</td> <td>4.35 (1/23)</td> <td>25.93 (7/27)</td> <td>33.33 (3/9)</td> <td>17.57</td> <td></td> <td></td> </tr> <tr> <td>(13/74)</td> <td>Pre-Op</td> <td>63.64 (7/11)</td> <td>50.00 (7/14)</td> <td>54.55 (6/11)</td> <td>50.00</td> <td></td> </tr> <tr> <td>(2/4)</td> <td>58.82 (20/34)</td> <td>Operational</td> <td>27.78 (5/18)</td> <td>26.67 (4/15)</td> <td>5.88</td> <td></td> </tr> <tr> <td>(1/17)</td> <td>25.00 (1/4)</td> <td>17.65 (9/51)</td> <td></td> <td></td> <td></td> <td></td> </tr> </tbody> </table> <p>6. Your Public Health Risk Noncompliance rate for August 1st to October 31st is 3.85% (for Jul-Sep was 4.67%). The noncompliance cut point for an early warning is now 5.38% (for Jun-Aug was 5.64%). The cut point for Public Health Risk Enforcement/FSA scheduling is now 8.73% (for Jul-Sep was 9.4%). Sampling 1. One KIS test on Monday the 5th. Negative. Tissues from this retained carcass also sent to the FSIS Eastern Lab for histopathology to rule out toxemia. Results pending. (b)(6) said a report strongly indicative of a toxemia would result in a Non-compliance Record being issued. This carcass was U5 Retained at the pans by (b)(6) 2. 1 NRP</p> | | Sep | Oct | Nov | last 90 days | SPS | Aug | | 18.1 | | | | | | (4/22) | 4.35 (1/23) | 25.93 (7/27) | 33.33 (3/9) | 17.57 | | | (13/74) | Pre-Op | 63.64 (7/11) | 50.00 (7/14) | 54.55 (6/11) | 50.00 | | (2/4) | 58.82 (20/34) | Operational | 27.78 (5/18) | 26.67 (4/15) | 5.88 | | (1/17) | 25.00 (1/4) | 17.65 (9/51) | | | | |
| | Sep | Oct | Nov | last 90 days | SPS | Aug | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | 18.1 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| (4/22) | 4.35 (1/23) | 25.93 (7/27) | 33.33 (3/9) | 17.57 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| (13/74) | Pre-Op | 63.64 (7/11) | 50.00 (7/14) | 54.55 (6/11) | 50.00 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| (2/4) | 58.82 (20/34) | Operational | 27.78 (5/18) | 26.67 (4/15) | 5.88 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| (1/17) | 25.00 (1/4) | 17.65 (9/51) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |

| District | EstNbr | EstName | MOINbr | Date | Task Code | TaskName | Status | MOI_Agenda | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|----------|-----------------|--------------|-----------------|-----------------------|-----------|----------|--------|--|-------|-----------------|--------------|-----------------|------------|--|--|-------|------|--|------|---|-------|------|------|-------|------|------|-------|------|------|-------|------|------|---|-------|------|---------|--------|-----------------------|
| | | | | | | | | <p>collected on 10/25/2018 by (b)(6) 3. 2 NRP and 2 NARMS samples scheduled for November. Other requests for the month of November have not loaded in the system. 4 (b)(6) provided Post Evisceration Salmonella and APC Sampling results. APC/Salmonella spp. results since the last reporting date of 11/02:</p> <table border="1"> <thead> <tr> <th>(log)</th> <th>Salmonella spp.</th> <th>Harvest Date</th> <th>Pre-Chill (log)</th> <th>Post-Chill</th> </tr> </thead> <tbody> <tr> <td></td> <td></td> <td>10/29</td> <td>2.41</td> <td></td> </tr> <tr> <td>1.15</td> <td>0</td> <td>10/30</td> <td>3.76</td> <td>1.49</td> </tr> <tr> <td>10/31</td> <td>2.04</td> <td>2.11</td> <td>11/01</td> <td>3.76</td> </tr> <tr> <td>0.90</td> <td>11/02</td> <td>2.96</td> <td>1.40</td> <td>0</td> </tr> <tr> <td>11/05</td> <td>3.76</td> <td>pending</td> <td>Office</td> <td>1. Nothing this week,</td> </tr> </tbody> </table> <p>thank you Processing New Business 1. Processing opportunities this week - Containers need to be marked as to identify their contents once product is placed into them. This includes both cardboard and plastic combos. Product code is sufficient either written directly on them or the use of a label. Slaughter New Business Slaughter Inspection</p> <p>1. (b)(6) has noted significantly fewer heads that have not had their mandibular lymph nodes incised when checking dropped heads at the head dropping station, but has also noted that occasionally the wrong set of lymph nodes (not the mandibular) and occasionally also the mandibular salivary gland being incised instead of the mandibular lymph node. He believes this may be because plant employees are incising the heads while they are in the halo with the snouts facing down instead of the normal on-line incising when it is pointing up. Also occasionally heads are presented without lymph nodes present and were most likely left with the jowls. 2. The new un-eviscerated carcass documentation protocol has gone well this week. As a reminder though, un-eviscerated carcasses passed by CFG and put back on the line without FSIS inspection of the viscera will involve a non-compliance and tagging of carcasses in the cooler until the carcass can be found so that it can be condemned.</p> <p>Humane Handling 1. So far this week, all VP items have been verified as compliant by (b)(6) Thus far this week (VP week 2) 34 stuns have been observed to be compliant with the CFR as well as M791C's CA's/PM's provided as a result of the Suspension held in Abeyance. Eighty four (84) have cumulatively been observed in weeks 1 through 3 thus far.</p> <p>2. VP Item 8. Verify that the FSQA Management-Supervision, Animal Welfare Manager or designee tests alternative designs for physical barriers/enclosures/restraint methods over the next 60 days and updates the Animal Welfare Program Reassessment Page and CAW SOP 2 after testing is completed. Verification frequency is weekly. Where are you at with the testing of alternative restraint methods for captive bolt</p> | (log) | Salmonella spp. | Harvest Date | Pre-Chill (log) | Post-Chill | | | 10/29 | 2.41 | | 1.15 | 0 | 10/30 | 3.76 | 1.49 | 10/31 | 2.04 | 2.11 | 11/01 | 3.76 | 0.90 | 11/02 | 2.96 | 1.40 | 0 | 11/05 | 3.76 | pending | Office | 1. Nothing this week, |
| (log) | Salmonella spp. | Harvest Date | Pre-Chill (log) | Post-Chill | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | | 10/29 | 2.41 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 1.15 | 0 | 10/30 | 3.76 | 1.49 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 10/31 | 2.04 | 2.11 | 11/01 | 3.76 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 0.90 | 11/02 | 2.96 | 1.40 | 0 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 11/05 | 3.76 | pending | Office | 1. Nothing this week, | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |

| District | EstNbr | EstName | MOINbr | Date | Task Code | TaskName | Status | MOI_Agenda |
|----------|--------|-------------------------|----------------|-----------|-----------|----------|-----------|--|
| 50 | M791C | Clemens Food Group, LLC | QCF5804120926G | 26DEC2018 | | | Finalized | <p>Clemens -FSIS Weekly Meeting MOI 12/21/2018, ~1300 – hours Plant Personnel: (b)(6) (b)(6) (b)(6) FSIS inspection personnel: (b)(6) (b)(6) I. NEW BUISNESS APPEALED Noncompliance Records 1. Open General Labeling noncompliance QCF341112202N/1, dated 10/31/2018. a. Noncompliance was appealed and denied by (b)(6) (b)(6) b. On 12/14/2018 (b)(6) stated that the appeal has ben furthered to (b)(6) c. 2. Open Livestock Zero Tolerance noncompliance QCF3510110426N/1, dated 11/26/2018 describes fecal in the bung area. (b)(6) received a written appeal from (b)(6) on 12/01/2018 and he will answer this appeal within two weeks of 12/01/2018. OPEN Noncompliance Records (NR's not completed in PHIS) 1. Open SPS noncompliance QCF 2907111521N/2, dated 11/20/2018 describes the pushbar entering into the hallway kept in an un-clean state. a. 12/14 (b)(6) stated the establishment will be appealing this noncompliance b. 12/21 establishment still in the process of appealing 2. Open Pre-Operational Review and Observation noncompliance QCF3505114827N/1, dated 11/27/2018 describes in Offal rooms B & C which involved the lid to the stomach blancher and the fans above the drying tunnel in Offal B, and the casing cutting wheels all with various amounts and types of debris. (b)(6) a. c/a is on file. (b)(6) said she would close this NR after the meeting 3. Open General Labeling noncompliance QCF3909110329N/1, dated 11/29/2018, describes three partial pallets of product in Offal A with no label as to their contents. (b)(6) (b)(6) a. Appeal has been denied, establishment considering further appeal 4. Open Livestock Zero Tolerance noncompliance QCF2113124710N/1, dated 12/10/2018 describes yellowish ingesta-like substance on the left side of the leaf lard of the 10th carcass checked. (b)(6) (b)(6) a. Appeal has been denied, establishment considering further appeal 5. Open Pre-Op SSOP Review and Observation noncompliance QCF0414125712N/1, dated 12/12/2018 describes un-clean conditions on the south side of dehair 1-4, Zone B in Clean harvest on the floor behind the split saws, and Offal C with fat like debris under vats on the floor. (b)(6) (b)(6) a. c/a is on (b)(6) office, Carston closed NR on Saturday 6. Open Pre-Op SSOP Review and Observation noncompliance QCF1806122914N/1, dated 12-14-2018 describes un-clean conditions in Zones 5 and 15. (b)(6) a. (b)(6) reviewed the noncompliance that was in the USDA desk, no corrective actions were</p> |

Ex. A-16

| District | EstNbr | EstName | MOINbr | Date | Task Code | TaskName | Status | MOI_Agenda | | | | | | | | | | | | | | | | | | | | | | | | |
|-------------|--------------|--------------|--------|------|-----------|----------|--------|--|--|-----|-----|-----|-----|--------------|-------------|--------------|--------------|--------|--------------|--------------|---------|-------------|--------------|-------|-------------|-------------|------------|--------------|--------------|-------|-------|------|
| | | | | | | | | <p>attached with the noncompliance report. Report was given back to (b)(6) for completion. b. Corrective actions are now available for review 7. Open Pre-Op SSOP Review and Observation noncompliance QCF3107125617N/1, dated 12-17-2018, describes un-clean conditions at the Leaf Lard station and PPE. (b)(6) a. Corrective Actions in progress 8. Open Pre-Op SSOP Review and Observation noncompliance QCF1006124819, dated 12-19-2018 describes un-clean conditions in Zones 4 and 11 of the processing floor. (b)(6) a. Corrective actions in progress 9. Open Other Inspection Requirements noncompliance QCF5513123420N/1, dated 12-20-2018 describes the presentation of heads, more specifically the mandibular lymphnodes, were not being properly presented to inspection personnel. (b)(6) a. Corrective actions in progress 12. "Associated noncompliance findings can lead to further regulatory or administrative action." 13. % noncompliant rates for SPS, Pre-op & Operational SSOP tasks performed</p> <table border="1"> <thead> <tr> <th></th> <th>Aug</th> <th>Sep</th> </tr> </thead> <tbody> <tr> <td>Oct</td> <td>Dec</td> <td>last 90 days</td> </tr> <tr> <td>4.35 (1/23)</td> <td>25.93 (7/27)</td> <td>15.38 (2/13)</td> </tr> <tr> <td>Pre-Op</td> <td>63.64 (7/11)</td> <td>50.00 (7/14)</td> </tr> <tr> <td>(15/30)</td> <td>Operational</td> <td>27.78 (5/18)</td> </tr> <tr> <td>(0/8)</td> <td>8.51 (4/47)</td> <td>5.88 (1/17)</td> </tr> <tr> <td>5.00 (3/4)</td> <td>50.00 (7/14)</td> <td>54.55 (6/11)</td> </tr> <tr> <td>5.29%</td> <td>5.64%</td> <td>9.4%</td> </tr> </tbody> </table> <p>5. Your Public Health Risk Noncompliance rate for September 1st to November 30th is 5.29%. The noncompliance cut point for an early warning is now 5.64% The cut point for Public Health Risk Enforcement/FSA scheduling is now 9.4%. Sampling 1. One residue sample was taken this week. 5. APC/Salmonella spp. results since results last provided on 12/01: Harvest Date Pre-Chill (log) Post-Chill (log) Salmonella spp. 12/7 2.79 2.20 12/10 1.82 0.48 0 12/11 3.76 3.76 12/12 3.76 2.46 12/13 3.76 1.60 12/14 2.72 Office 1. Nothing to report this week. Processing New Business 1. (b)(6) was informed on 12-17-2018 that a few individuals on the Loin Boning line have been chewing gum or candy on the line. (b)(6) informed (b)(6) and (b)(6) in Zone 12. 2. Ham Line still has trash combos every day without the USDA Inspection Legend removed or defaced. 3. Overheads during Pre-Operational inspection. What is the plan going forward as they continue to be found in noncompliance when inspected? The previous corrective actions of supervisors/leads inspecting them is apparently not effective enough. a. Increased inspection by</p> | | Aug | Sep | Oct | Dec | last 90 days | 4.35 (1/23) | 25.93 (7/27) | 15.38 (2/13) | Pre-Op | 63.64 (7/11) | 50.00 (7/14) | (15/30) | Operational | 27.78 (5/18) | (0/8) | 8.51 (4/47) | 5.88 (1/17) | 5.00 (3/4) | 50.00 (7/14) | 54.55 (6/11) | 5.29% | 5.64% | 9.4% |
| | Aug | Sep | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Oct | Dec | last 90 days | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 4.35 (1/23) | 25.93 (7/27) | 15.38 (2/13) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Pre-Op | 63.64 (7/11) | 50.00 (7/14) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| (15/30) | Operational | 27.78 (5/18) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| (0/8) | 8.51 (4/47) | 5.88 (1/17) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 5.00 (3/4) | 50.00 (7/14) | 54.55 (6/11) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 5.29% | 5.64% | 9.4% | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |

Ex. A-17

| EstNbr | EstName | NR# | Date | Shift | Task | TaskName | Regs | Description | Status |
|--------|-------------------------|--------------------------|------------|-------|-----------|-------------------------------|-----------------------|--|--------|
| M791C | Clemens Food Group, LLC | QCF041 503551 3N-1 | 03/13/2019 | 1 | 06D0 2 | Other Inspection Requirements | 303.1(h), 310.1(a) | <p>On March 13, 2019 at approximately 1332 hours while performing his off-line inspection duties (b)(6) (b)(6) observed an Other Inspection Requirements noncompliance. While inspecting the 12 heads on the head rack at the establishments head inspection area (b)(6) noticed that a head had an un-incised mandibular lymph node. (b)(6) immediately notified (b)(6) of his findings and that he will document them in an NR. The immediate corrective action was to have the mandibular lymph node incised. After inspection of the newly incised lymph node, (b)(6) found the head free of pathological concerns. (b)(6) (b)(6) previous findings on Wednesday, March 13, 2019: At Approximately 0955 hours (b)(6) (b)(6) discovered two heads out of approximately 20, with un-incised lymph nodes. One head had neither lymph node incised. The other head, only one lymph node was un-incised. (b)(6) spoke with (b)(6) of the findings (b)(6) immediately had the lymph nodes incised and (b)(6) found them free from pathological concern. (b)(6) explained the importance of making sure all heads are 100% checked by establishment sorters. (b)(6) agreed and said he would talk to his team members. At Approximately 1310 hours (b)(6) had observed, out of 16 heads on the rack, one had an un-incised lymph node. (b)(6) showed (b)(6) the finding. (b)(6) immediately had the lymph node incised. (b)(6) (b)(6) found the head to be free from pathological concern. (b)(6) spoke with (b)(6) and explained how this was the second finding today regarding un-incised lymph nodes. (b)(6) understood the importance and said he would talk to the team members about the importance of incising all lymph nodes. This is in Noncompliance with the following regulation(s): 9 CFR 303.1(h) The Administrator may in specific</p> | CLOSED |

| EstNbr | EstName | NR# | Date | Shift | Task | TaskName | Regs | Description | Status |
|--------|-------------------------|--------------------------|------------|-------|-----------|-------------------------------|-----------------------|--|--------|
| M791C | Clemens Food Group, LLC | QCF391 503132 8N-1 | 03/28/2019 | 1 | 06D0 2 | Other Inspection Requirements | 303.1(h), 310.1(a) | <p>On Thursday, March 28, 2019 at approximately 1410 hours while performing a Routine Livestock Finished Standards Task, (b)(6) observed a Non-Compliance with the head presentation at the viscera station. She randomly chose fifteen heads to check the mandibular lymph nodes. While observing those heads, (b)(6) noticed that six of the heads had at least one missing lymph node, and one of the heads had no lymph nodes present on the head (a total of approximately twenty three percent of the lymph nodes not present for inspection). (b)(6) immediately used a regulatory control action and stopped the line and called for a supervisor at the viscera inspection station, and informed (b)(6) of her findings. He stated that he would inform the supervisor in-charge of the head inspection area and FSQA personnel of her findings. She then relinquished the regulatory control action and allowed for the production line to begin again. This is a Non-Compliance with 9 CFR 310.1(a) which states "Careful post-mortem examination and inspection shall be made of the carcasses and parts thereof of all livestock slaughtered at official establishments. Such inspection and examination shall be made at the time of slaughter unless, because of unusual circumstances, prior arrangements acceptable to the Administrator have been made in specific cases by the circuit supervisor for making such inspection and examination at a later time;" and 9 CFR 303.1(h) which states "The administrator may in specific classes of cases waive for limited periods any provisions of the regulations in this subchapter 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/or processing techniques may be tested to facilitate definite improvements: Provided, That such waivers of the provisions of such regulations are not in conflict</p> | CLOSED |

Table: Noncompliance Reports in Response to FOIA2020-128

| EstNbr | EstName | NR# | Date | Shift | Task | TaskName | Regs | Description | Status |
|--------|---------|-----|------|-------|------|----------|------|--|--------|
| | | | | | | | | <p>with the purposes or provisions of the Act.” (b)(6) was informed of the Non-Compliance verbally and now in writing with this Non-Compliance Record. A similar Non-Compliance Record was found NR# QCF0415035513N-1 Dated March 14, 2019, written for a similar root cause. The actions the establishment management has taken thus far have not prevented additional similar Non-Compliance Records. This document serves as notification that continued failure to meet regulatory requirement(s) could result in additional regulatory or administrative action.</p> | |

| EstNbr | EstName | NR# | Date | Shift | Task | TaskName | Regs | Description | Status |
|--------|-------------------------|------------------|------------|-------|-------|-------------------------------|--------------------|---|--------|
| M791C | Clemens Food Group, LLC | QCF5010063911N-1 | 06/11/2019 | 1 | 06D02 | Other Inspection Requirements | 303.1(h), 310.1(a) | <p>On 6/11/2019, I observed Other Inspection Requirements, Post-Mortem Staffing Standards and Waiver Exemption presentation noncompliance. At approximately 0855 hour, establishment personnel notified me that (b)(6) (b)(6) had retained a carcass and parts for veterinary disposition. I then proceeded to the harvest floor where (b)(6) (b)(6) informed me that she railed out a carcass and parts (MPD60544056), because the viscera was presented to her for disposition without lungs to examine. When I examined the carcass and parts for retained carcass MPD60544056, I found that there were no lungs available for me to examine with the rest of the carcass and parts. This finding illustrates noncompliance with 9 CFR 310.1 (a), because FSIS inspection personnel were prevented from making a careful post-mortem inspection of each carcass and its associated parts. Further, this finding illustrates noncompliance with 9 CFR 303.1 (h), because establishment personnel did not have the carcass and viscera identified from each hog, at the point of inspection, as required by 310.2 (a), per the establishment's line speed and inspection staffing standards waiver. At approximately 0950 hour, I notified Ramero Rosa that the above described finding would be documented on a noncompliance record. Retained carcass MPD60544056 and it available associated parts appeared to be without disease. However, because parts needed for careful post-mortem disposition were missing, a final disposition could not be determined. Therefore, establishment management elected to render as inedible retained carcass MPD60544056 with its available associated parts. In plant inspection personnel documented a similar noncompliance finding on noncompliance record QCF3915031328N/1, dated 3/28/2019. This noncompliance describes 23 percent of the mandibular lymph nodes</p> | CLOSED |

Table: Noncompliance Reports in Response to FOIA2020-128

| EstNbr | EstName | NR# | Date | Shift | Task | TaskName | Regs | Description | Status |
|--------|---------|-----|------|-------|------|----------|------|---|--------|
| | | | | | | | | <p>missing from heads presented to inspection personnel. To address this noncompliance finding establishment management stated that a supervisor or team lead would be offline to monitor lymph node presentation and provide coaching, when needed. However this action has not prevented a similar noncompliance from occurring. This document serves as notification that continued failure to meet regulatory requirements could lead to further regulatory or administrative action.</p> | |

| EstNbr | EstName | NR# | Date | Shift | Task | TaskName | Regs | Description | Status |
|--------|-------------------------|--------------------------|------------|-------|-----------|-------------------------------|-----------------------|--|--------|
| M791C | Clemens Food Group, LLC | QCF281 308502 ON-1 | 08/20/2019 | 1 | 06D0 2 | Other Inspection Requirements | 303.1(h), 310.1(a) | <p>On Tuesday August 20, 2019 at approximately 0835 hours while performing his on the line inspection duties, (b)(6) observed the following Other Inspection Requirements noncompliance: (b)(6) observed a head at the pan line inspection area with a lymph node un-incised. (b)(6) was able to make a tear into the lymph node to inspect it himself. About a minute later (b)(6) observed another head with an un-incised lymph node. (b)(6) placed a US Retain Tag #MPD 60544198 to tag the carcass for the SPHV. A few moments later another head was observed with un-incised lymph nodes (b)(6) placed US Retain Tag #MPD60544194 to tag the carcass for the SPHV. At this point (b)(6) calls for an establishment supervisor. When (b)(6) arrives, (b)(6) requests the presence of his SPHV. (b)(6) returned after a minute and said he informed (b)(6) of his request. At this time (b)(6) (b)(6) asks why the carcasses were retained. (b)(6) (b)(6) informed him they were retained for un-incised lymph nodes. During this discussion (b)(6) (b)(6) observed yet another head with an un-incised lymph node and was able to remove it and check it in front of (b)(6) At approximately 0845 hours (b)(6) arrived at the pan line (b)(6) was in the middle of informing him of the findings. At this time (b)(6) (b)(6) observed another head with un-incised lymph nodes. This head had neither left nor the right lymph node incised. (b)(6) took a regulatory control action and stopped the line (b)(6) (b)(6) showed (b)(6) the findings. (b)(6) (b)(6) then called for a supervisor. When (b)(6) arrived, (b)(6) informed him that they would be receiving a noncompliance under the Other Inspection Requirements. Under SPHV instruction (b)(6) placed US Retain Tag #MPD6054199 on the carcass to be railed out. The production line was</p> | CLOSED |

| EstNbr | EstName | NR# | Date | Shift | Task | TaskName | Regs | Description | Status |
|--------|---------|-----|------|-------|------|----------|------|---|--------|
| | | | | | | | | <p>then restarted. After (b)(6) left the area and before 0900 (b)(6) had observed two more heads with neither the left nor right lymph nodes being incised. (b)(6) took regulatory control each time and an establishment team member incised the lymph nodes so that (b)(6) (b)(6) could fulfill the 100% inspection requirement. (b)(6) findings from the retained hogs are as follows: "MPD 60544194, CFG Harvest Tattoo BB21, barrow, no head lymph nodes incised." "MPD 60544198, BB21, barrow, only the right mandibular/submandibular lymph node incised, left unincised." "MPD 60544199, B22, gilt, no head lymph node incised." This is in Noncompliance with the following regulation(s): 9 CFR 303.1(h) "The Administrator may in specific classes of cases waive for limited periods of any provisions of the regulations in this subchapter 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/or processing techniques may be tested to facilitate definitive improvements: Provided, That such waivers of the provisions of such regulations are not in conflict with the purposes or the provisions of the Act." 9 CFR 310.1(a) "A careful post-mortem examination and inspection shall be made of the carcasses and parts thereof of all livestock slaughtered at official establishments. Such inspection and examination shall be made at the time of slaughter unless, because of unusual circumstances, prior arrangements acceptable to the Administrator have been made in specific cases by the circuit supervisor for making such inspection and examination at a later time." (b)(6) (b)(6) was informed of the noncompliance both verbally and now in writing with this NR. A Review of the previous 90 day's NR's revealed NR #QCF5010063911N-1 dated 06/11/2019. This NR is being directly associated with NR</p> | |

Table: Noncompliance Reports in Response to FOIA2020-128

| EstNbr | EstName | NR# | Date | Shift | Task | TaskName | Regs | Description | Status |
|--------|---------|-----|------|-------|------|----------|------|---|--------|
| | | | | | | | | #QCF5010063911N-1. The actions the establishment management has taken thus far have not prevented additional similar noncompliance. This document serves as notification that continued failure to meet regulatory requirement(s) could result in additional regulatory or administrative action. | |

| Dist rict | EstNbr | EstName | MOINbr | Date | Task Code | TaskName | Status | MOI_Agenda |
|-----------|--------|---------------------------------|----------------|-----------|-----------|----------|-----------|---|
| 05 | M360 | Smithfield Packaged Meats Corp. | DAM1114035014E | 14MAR2018 | | | Finalized | <p>Attendees: (b)(6)</p> <p>(b)(6)</p> <p>(b)(6) Items to discuss: 1. SIP data? Any more positives? If plant wants to change the agreed upon program, they need to contact Dr. Isabel Arrington. Isabel.arrington@fsis.usda.gov. Plant gave new SIP Data day of meeting and they have two positives so far. The plant changed out the person doing the swabbing and made sure chlorine in wash cabinets is at a level towards the high end of the accepted range. 2. Still waiting on the written pre-requisite programs. I was only able to see a few of the many used here. Plant said with new HACCP plans from Smithfield some pre-requisite programs will go away. 3. Returned legs from San Diego. When will they arrive? Plant not sure. Still in San Diego 4. Parking issues. New hires not being told where they can not park and then they park in the exit driveway blocking cars. Can we get only 4 cones for the USDA parking and leave the rest of the spots without cones? Plant will tell the Security firm this info. 5. Casing line dumping fecal onto floor when could be made to dump into floor drain. Stomach ingesta catch pans? Maybe add hoses to direct discharge directly into floor drain? 6. Last week with potential needle from farm. Was it ever identified or what was done to determine it wasn't likely. Plant said it was not found and ran all product through metal detector. Maybe pig was DOA or DIP. 7. Temp gauge on second brisket saw. Temp around 170 when other saw is 180. Now gauge is hard to read due to condensation. Plant will get new temp gauge installed. 8. Slaughter floor: Carcass on floor cart awaiting to be hoisted back up is being sprayed by floor cleaners. This allows dirty floor material to be kicked up and land on product. Plant discussed this issue with the floor cleanup crew to prevent a reoccurrence. 9. Head station: Some lymph nodes not being cut and when incised (after line was stopped by USDA) there was abscess material inside. Maybe HIMP auditor needs sharper knives to help with the cutting of the LNs</p> |

| Dist rict | EstNbr | EstName | MOINbr | Date | Task Code | TaskName | Status | MOI_Agenda |
|-----------|--------|---------------------------------|----------------|-----------|-----------|----------|-----------|---|
| 05 | M360 | Smithfield Packaged Meats Corp. | DAM5514081915E | 15AUG2018 | | | Finalized | <p>Attendees: (b)(6)</p> <p>(b)(6)</p> <p>(b)(6) Items to discuss: 1. Parking for USDA: No changes to parking issue. (b)(6) will need to park inside next week as all the USDA spaces in the lot will be occupied by plant employees. Plant will try to find a fix to this issue. 2. Pork Cut. exit sign by the loin packing area not placed where it can be seen without opening the door. Management said they will get it taken care of. 3. SIP data. So far only one positive on a pre-chill carcass (Salmonella) 4. Updated supervisor and QA list for each area of the plant. (so we know who to contact for each area) 5. RTE sample taken on Friday was negative. Residue sample negative. The exploratory intact (Sirloin) tested positive for Salmonella sp. Plant given copies of results. 6. HIMP inspectors are spread thin, and this could affect their sorting ability.</p> <p>New NR's 3. DAM4507085815N/1 (8/15/18) At 0450 the 1st floor chopper room fresh sausage dept. was released for me to perform my pre-op inspection task. I found a piece of pork product from previous day's production on a stainless steel strainer (food contacted surface). I notified the QA who released the room after he finished conducting his pre-op checks. 6. 8/13/18 DAM3813084413N/1: At approx. 9am while conducting a records check I observed a Operational Record dated 8/06/2018 for the Offal Department was no properly filled out. The "Direct Observation" box was left blank, and was not signed, yet it was signed-off by a supervisor. I pointed out my findings to (b)(6) and informed him I would issue a NR</p> <p>DAM1911083813N/1: (8/13/2018) while performing PHIS task records review on Operational SSOP I observed the following. 2 records are not authenticated / are missing initials Record dated 08/08/2018 "Enhanced Pork Dept." 2nd shift, this record is not initialed. This record was double checked and signed off by a QA supervisor on 08/09/2018 Record dated 08/08/2018 "Pork Cut Dept." 1st shift, this record is not initialed. This record was double checked and signed off by a QA supervisor on 08/09/2018. 9CFR 416.16(a) Each official establishment shall maintain daily records sufficient to document the implementation and monitoring of the Sanitation SOP's and any corrective actions taken. The establishment employee(s) specified in the Sanitation SOP's as being responsible for the implementation and monitoring of the procedure(s) specified in the Sanitation SOP's shall authenticate these records with his or her initials and the date.</p> |