

Report on USDA FSIS Guidance and Outreach to Small Meat Processors

Written by Rebecca Thistlethwaite, Extension Specialist and Director of the Niche Meat Processor Assistance Network, Oregon State University, Corvallis, OR 97331

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Executive Summary:

To be developed in final draft

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Background:

As part of the 2018 US Farm Bill, the following study was authorized-

SEC. 12107. REPORT ON FSIS GUIDANCE AND OUTREACH TO SMALL MEAT PROCESSORS.

(a) IN GENERAL.—The Secretary shall offer to enter into a contract with a land-grant college or university or a non-land-grant college of agriculture (as those terms are defined in section 1404 of the National Agricultural Research, Extension, and Teaching Policy Act of 1977 (7 U.S.C. 3101)) to review the effectiveness of existing Food Safety and Inspection Service guidance materials and other tools used by small and very small establishments, as defined by regulations issued by the Food Safety and Inspection Service, operating under Federal inspection, as in effect on the date of enactment of this Act, including—

1. The effectiveness of the outreach conducted by the Food Safety and Inspection Service to small and very small establishments;
2. The effectiveness of the guidance materials and other tools used by the Food Safety and Inspection Service to assist small and very small establishments; and
3. The responsiveness of Food Safety and Inspection Service personnel to inquiries and issues from small and very small establishments.

The Niche Meat Processor Assistance Network (NMPAN), a project housed within the College of Agricultural Sciences, Department of Crop and Soil Sciences at Oregon State University, is an Extension-based community of practice focused on the long-term viability of small and mid-sized processors who are essential to the local and regional meat and poultry sectors. They provide education, technical assistance and original research for the niche meat sector across the country.

NMPAN was awarded a cooperative agreement with USDA Food Safety Inspection Service (referred to as FSIS in the rest of the report) on August 1, 2019, to carry out the study as authorized in the 2018 Farm Bill described above. Subcontractor, the National Sustainable Agriculture Coalition based out of Washington, D.C., provided research support, organized stakeholder meetings, and developed the Humane Handling Case Study at the conclusion of the report.

Methodology:

Data collected for this study is primarily from 2016 to the present. The bulk of the data is from the beginning of the Trump administration and appointment of USDA Secretary Sonny Perdue in early 2017. The Principal Investigator decided that looking at the current administration of USDA-FSIS made the most sense for the purposes of this study since there has been significant change over the last few years.

Both primary and secondary data was collected for this report. Primary data sources included interviews, phone calls, meetings, and materials directly generated by USDA FSIS staff. It also includes in-depth interviews, survey data, focus groups, and roundtable meetings with small meat processors and other meat supply chain stakeholders. Secondary data sources included internet research, NGO reports, newspaper articles, relevant academic reports, and the NMPAN listserv archive from the past four years. A full list of references can be found in the Appendix B.

All feedback and data from individuals is anonymized to protect the identity of the person. There was an attempt to highlight the most common responses from processors and pull out the key themes, rather than discuss extreme or outlying opinions (for example, “let’s just get rid of federal inspection”). While it is true that meat processors rarely gave positive reports of USDA FSIS oversight and activities, there were certainly many processors who had little to no criticisms of the agency. The Principal Investigator made every attempt to capture constructive criticism and realistic ideas to mutually work together and solve problems. None of the forums, surveys, etc. were oriented to just be a sharing of grievances. Rather, questions were oriented around solutions.

The Principal Investigator made every effort to gather all known relevant information to paint an accurate and objective picture of the way that the USDA Food Safety Inspection Service is regulating and serving the needs of small and very small inspected meat establishments. Not every single inspected facility was surveyed for this report, that was outside of both the timeline and the budget of this study. The study also did not look at inspected egg establishments nor catfish, which are two other foods that FSIS regulates. There was a stronger emphasis placed on surveying animal slaughter facilities, cut and wrap, and meat processing establishments; and less emphasis on facilities that mostly manufacture processed foods more but may use some USDA inspected meat ingredients, such as a pizza manufacturer that puts cooked sausage on their frozen pizzas or similar such facilities. This is in line with what the Farm Bill language outlined as “small meat processors”.

The steps used in this research project included:

Step 1: Gather and analyze what NMPAN and USDA FSIS know already about these issues, including existing recommendations from different stakeholders. FSIS will provide information and analysis to Oregon State University, as described below.

- Understand all of the USDA FSIS outreach methods and practices of the last few years.
- FSIS will explain the process FSIS uses to develop guidance, including how FSIS received and evaluates comments, and make guidance available to the public. FSIS show Oregon State University how it posts guidance on its web site and where all guidance is posted.
- FSIS will explain how FSIS answers questions from small businesses through askFSIS (a web-based questions and answer service) and will share available demographic data and trends concerning askFSIS questions from small and very small establishments.
- FSIS will share information and details concerning publicly posted askFSIS questions and answers (Qs and As), the process FSIS uses to develop these Qs and As, and the responses FSIS has received from users concerning these Qs and As.
- FSIS has conducted numerous webinars, meetings and roundtables to provide guidance. FSIS will share a history of these activities and transcripts and other available information concerning webinars with Oregon State.
- The Office of Field Operations currently has the lead in providing direct outreach to small inspected establishments. OFO will identify the correct person to meet with OSU and provide information about FSIS's current direct outreach efforts.
- Review FSIS's own survey data (most recent and past) at national & regional levels. Although this information, is not yet published, FSIS will share the data and will share FSIS's preliminary analysis concerning this data.
- Review related academic literature and public reports
- Review NMPAN internal archives (documents, discussion notes) from our small processor working groups and regional meetings. Also NMPAN listserve archives.
- Analyze all of these to create a draft evaluation of FSIS effectiveness in the three areas named above, with recommendations.

Step 2: Test/verify the draft with key stakeholders:

- Have the following audiences review our draft, using a combination of phone/in-person interviews and email/online surveys:
 - NMPAN network members and board;

- AAMP staff and board;
- Focus groups at processor conventions or regional stakeholder meetings;
- NACMPI members;
- Other relevant stakeholders as needed.

NMPAN staff will aim to test (and adjust, change, expand as needed) our draft evaluation with a variety of processors that vary across geography, type of operation, and size. NMPAN will ask them not only about FSIS effectiveness across those three areas but also their own recommendations for future improvements (topics, delivery methods, staff training, timeliness, etc).

This draft serves as this step.

Step 3: Analyze stakeholder input and revise draft findings accordingly. Prepare these deliverables:

- Report for USDA-FSIS
- Public-facing report if requested

Below are the draft findings and recommendations, broken out by the three topic areas outlined in the Farm Bill SEC. 12107. There is some overlap and redundancy, which is to be expected. Outreach, guidance materials, and responsiveness to inquiries and issues sometimes have similar challenges and similar solutions. The report also includes a special Humane Handling Case Study, which is the most common reason why small and very small slaughterhouses receive an inspection violation/enforcement action from USDA FSIS and where there is great opportunity for improvement and “leveling the playing field”. It was also the top concern brought up in small plant roundtables over the last four years as well as in survey and focus group data. The Humane Handling Case Study was researched and written by project partner and subcontractor, the National Sustainable Agriculture Coalition.

Findings and Recommendations:

Outreach- The effectiveness of the outreach conducted by the Food Safety and Inspection Service to small and very small establishments.

Background: The definition of outreach is the activity of providing services to any population that might not otherwise have access to those services. In addition to delivering services, outreach has an educational role, raising the awareness of existing services. It includes identification of under-served populations and service referral. In the case of FSIS, they focus their outreach efforts on small and very small establishments, as well as new and beginning establishments. FSIS employs a variety of methods to conduct outreach, including direct outreach from the in-plant inspection staff, circuit staff, and their 10 District offices. In 2018,

FSIS also began a renewed emphasis on outreach by the EIAO staff, who work across circuits and regions. EIAOs now are supposed to dedicate 25% of their time to the provision of outreach. In addition, FSIS uses their website tools, as well as a Small Plant Help Desk phone number and Ask FSIS web portal to improve accessibility to information and help provide answers for those who have questions. Likewise, FSIS is hosting more constituent meetings and roundtables both in Washington D.C. and around the country so that they can talk with more stakeholders directly and meet them where they are.

There is some overlap between outreach and information tools, as many of them are being used for similar purposes of providing clarity, answering questions, and disseminating key information to stakeholders. Therefore, findings and recommendations may be similar.

What the Agency Affirms it is Doing:

- Developed and delivered their first small plant survey to all small and very small inspected establishments in 2018. The purpose of the voluntary survey was to (1) provide FSIS with feedback to inform communication, outreach, and technical support and (2) assess current outreach efforts related to food safety, humane handling, and food defense. The voluntary survey was completed by 1,371 plants for a return rate of 34%. Although the information generated by the survey is not available to the public, FSIS is using the data to make internal changes.
- Enhanced coordination of small plant technical assistance by combining the Small Plant Help Desk (SPHD) with Ask FSIS in 2019, in response to the Small Plant Survey. These two entities are all housed within the Office of Policy and Program Development (OPPD) now. In the last year, these entities have received over 12,532 inquiries, the vast majority from small and very small establishments.
- Around four OPPD staff answer all domestic questions, but sometimes questions are sent further up to issuance staff or OPPD administrators. Most questions are answered promptly within 24 hours. They have created standard operating procedures for answering questions so they are answered in a timely and consistent fashion.
- Ask FSIS publishes an archive of thousands of previously submitted questions and answers. They do not publish every single Q & A, but those that generally don't contain any sensitive business information. The searchable database can be utilized by establishments to gain clarity and circumvent the need for them to submit a new question.
- OPPD is creating a customer service dashboard and an **annual** customer service plan, as part of Secretary Perdue's enhanced emphasis on customer service.
- FSIS publishes and emails a weekly Constituent Update that goes to all inspected establishments and others who sign up for it. The Update goes to around people and is also archived on the website.
- Top FSIS leadership have attended eight small plant stakeholder meetings organized by NMPAN and NSAC since 2016. In addition, they have organized another meetings in various states. These meetings have provided a space to listen to feedback from small plants, answer questions, and provide updates on key policy changes, guidance documents, labeling backlog, testing requirements, etc.

- EIAO staff are reaching out to establishments to offer them non-regulatory outreach visits to answer questions, review plans, and provide advice prior to audits. The top topics that EIAO staff have been contacted about for outreach in the last year includes: HACCP, processing, sanitation, dual jurisdiction plants (FDA & FSIS), new establishments seeking grant of inspection, labeling, religious exemptions, and pathogen modeling for cooling or heating deviations.

What Small Processors are Saying:

- Ask FSIS is a useful tool, as both an archive of questions already submitted and a place to ask new questions. However, the answers provided are considered “agency interpretation” but not a definitive final answer. This can cause confusion for both inspection personnel and plant operators.
- The majority of small plants receive information directly from FSIS inspection program personnel (81%). A smaller number sought information from other sources including FSIS e-mail communications (44%) and through askFSIS (42%). Remaining categories of information outlets were approximately equal in response and usage (FSIS Small Plant Survey 2018).
- The majority of small plants stated that they receive information from various outlets but most commonly (in order of use): FSIS inspection program personnel, word of mouth (e.g., other establishment owners or personnel), and media outlets (e.g. Meatingplace), and not from webinars, compliance guides, or the FSIS website (FSIS Small Plant Survey 2018).
- In various sections of the Small Plant survey, respondents routinely commented that the FSIS website is difficult to navigate, is not user friendly, and query results of a targeted search using key words did not return relevant information. As such, respondents stated that utilization of Google and other search engines provided quicker, more targeted results to inquiries (FSIS Small Plant Survey 2018). It is important to note that major revisions have been made to the website since the survey was administered in 2018.
- Attendees of several of the small plant roundtables have been pleased with the opportunity to speak directly with top FSIS officials. They appreciate their efforts to travel and get to different parts of the country. Participants in these meetings have remarked that they believe communication lines have been opened and overall responsiveness has been improved. (Roundtable Notes)
- Some of the roundtables that FSIS has organized have been poorly attended with little notice/outreach to small processors nearby the meeting locations. Some of the meetings have included large plants that don’t fall into the definition of small or very small. Additionally, FSIS has led the agenda at these meetings and allowed for less processor-led discussions. They have been more of a “talking-at” type meeting rather than a “listening-to” format. (Comments from attendees of the FSIS roundtables)
- Small plants are still generally unaware of the EIAO outreach program, how to contact them, and how outreach differs from enforcement. Small plants continue to be wary of requesting EIAO services.

Recommendations and Potential Solutions:

- Ask FSIS/SPHD staff, IPP, and plant operators can convene a conference call to clarify Ask FSIS answers and aim to get a more definitive response. The burden to convene this conference call should not be on the plant operator and should be the responsibility of the IPP. It should also be communicated that this is always an option.
- It is somewhat unclear what the different roles and uses are of the Small Plant Help Desk and Ask FSIS. Is there a need for two entities, even though they utilize the same staff? It may be more clear to establishments to have one entity in which they can submit questions electronically or place a phone call, more of a “one-stop-shop”.
- There seems to be little knowledge of FSIS outreach resources, such as webinars, compliance guides, website resources, etc. Perhaps when new plants are applying for a grant of inspection, they can be made aware of all the resources. And currently inspected plants could receive an update in each Constituent Update of current/new resources, upcoming events, newly published guidance documents, etc. Likewise, IPP could download relevant compliance guides and highlight key points that they think plant operators should be aware of or may prove to be helpful.
- The FSIS website is still complex and hard to navigate. It is sometimes easier to use an internet search to find things on it rather than the search engine built into it. A plain language review and outside website design assistance could prove useful. It also has very limited resources on it in Spanish, and they are mostly geared towards consumer audiences. There is an increasing number of plant operators and plant personnel that speak and read Spanish.
- If FSIS is going to organize small plant roundtable meetings, they need to do a better job of inviting small and very small plants and gearing the agenda around their needs. They also need to give more space in the agenda for small plants to bring up their questions and discussion items. Small plants could even submit their proposed agenda items ahead of time so that FSIS can build the agenda around their needs. FSIS leadership should go on a plant tour or visit a small/very small plant when at these regional roundtables so they can better witness and understand the physical and operational constraints that small/very small plants face.
- FSIS should advertise the EIAO outreach program more thoroughly and make it clear to constituents that it is not an assessment/enforcement tool but rather information seeking and technical assistance oriented. EIAO staff could attend and set up a booth at more state and regional meat processor association conventions and get the word out to plant operators more extensively.
- EIAOs should develop a Sharepoint folder to disseminate tools, tips, best practices that they have learned in doing small plant outreach over the last couple years. More communication between staff and across districts could improve their results.
- More opportunities for FSIS staff, especially EIAOs, to attend relevant meat processor conventions, conferences, and gatherings. They could set up booths in trade shows and disseminate more information and outreach directly to processors. This could also build rapport and trust with face-to-face contact.

Information Tools- The effectiveness of the guidance materials and other tools used by the Food Safety and Inspection Service to assist small and very small establishments.

Background: Guidance documents are non-regulatory in nature, but seek to provide the current understanding of best practices to comply with FSIS regulations and maintain a safe meat supply. They are especially geared towards small and very small inspected establishments. The agency updated the guidance document template in 2014. As soon as a new guidance revision is published, they are disseminated via the FSIS Constituent Update, in monthly stakeholder meetings, and IPP often pass them along to establishments as applicable.

One guidance document that received quite a bit of attention and pushback from small plants was the 2017 revised Appendix A & B, which are guidelines for validating HACCP plans for further processed meats, such as jerky, sausage, bacon, ground meats, etc. The revised guidance document was posted on the Federal Register and open to public comment. FSIS received 52 public comments, with the vast majority in favor of utilizing the 1999 version and with many claiming that the new version was both inoperable and not science-based. In plant personnel also heard a lot of negative pushback from plant owners/operators when they shared the guidance with them. FSIS responded by allowing processors to continue to use the 1999 version or the 2017 version, and deciding to take some more time to look at the science. Most guidance documents do not receive this level of public comment nor pushback. However, the willingness of the agency to “go back to the drawing board” as it were on this guidance, indicates an openness to listening and not wanting to overburden plants.

Other information tools that FSIS employs includes their website, offering webinars, publishing newsletters, reports and documents, and answering questions via their Small Plant Help Desk and their online Ask FSIS portal.

What the Agency Affirms it is Doing:

- Made guidelines/guidance documents shorter and easier to read. They also include a plain language review to make sure the narrative is understandable and does not include too much jargon.
- Updating guidance documents more frequently and with stakeholder inclusion. They seek public comment on all new guidance documents or major revisions.
- Updated website to be more user friendly and accessible, with picture tiles for key topic areas, enhanced search engine, a new retail section, and other improvements. Significant website revisions were made in 2019.
- Streamlined operations at Small Plant Help Desk and AskFSIS by combining them in the same office with the same staff. This has resulted in more consistency of response and a faster response time.

What Small Processors are Saying:

- Poultry exemptions guidance document is woefully out of date. Has not been updated since 2006, despite the agency saying they are working on it at several roundtable meetings over the last few years.

- What happened to the generic HACCP plans online? They are no longer available. There are very few tools to help processors develop a HACCP plan that will be FSIS compliant. They have to reach out to trade associations or pay consultants instead of getting advice and information from FSIS. That should not be the case.
- If FSIS requires validation studies in HACCP plans, why do they not have a searchable database of all the peer-reviewed, publically-available validation studies? Why do small processors have to do all the research themselves? Plus, many peer-reviewed articles are not available to the public and are behind a paywall.

Recommendations and Potential Solutions:

- More visual aids, infographics, flow charts/decision trees
- Spanish publications and resources
- Model HACCP plans
- Create a searchable archive of all peer-reviewed validation studies for different meat products. Also include an archive of appropriate support documents for Robust Systematic Humane Handling Plans.
- How-to guides: how to get a grant of inspection, how to get your HACCP plan approved, how to pass a FSA, how to write a robust humane handling plan, how to determine animal consciousness/stunning effectiveness, etc.
- More communication with state inspection programs. Provide them all of the same outreach and information tools. Make sure those tools are getting to the state inspected “at least equal to” plants.

Responsiveness and Inclusion- The responsiveness of Food Safety and Inspection Service personnel to inquiries and issues from small and very small establishments.

Background: How does FSIS respond to inquiries, issues, petitions, phone calls, meeting recommendations, etc. Also labeling. Also enforcement actions- regulatory control, withholding, and suspensions.

What the Agency Affirms it is Doing:

- FSIS has a system for responding to petitions, but there is no required timeline. They have to post to the Federal Register, receive comments, review all the submitted comments, evaluate them, respond to them, and then eventually make a ruling on the petition. Some petitions take less than a year, while others take up to four years for resolution.
- FSIS Labeling Division has been expanding the options of which labels can be approved generically. This has reduced the backlog in the last couple years, with approval shrinking from what often would take 30-45 days down to 12-14 days.
- FSIS renewed their dedication to outreach by expanding the EIAO outreach program to be 25% of their time. This will improve communication and overall responsiveness to small plant needs.

- FSIS leadership is meeting with small plant stakeholders around the country to hear directly from them. They are also making their phone numbers and emails available to a wider audience and inviting small plants to contact them directly should they encounter problems and need clarity on an issue.

What Small Processors are Saying:

- Seems like the labeling backlog has subsided. Generic labeling generator in LSAS is also very helpful.
- Some district managers have been very helpful and committed to addressing small plant concerns, while others have not. Small plants do not want to have to go to district managers every time there is an issue with the IPP or circuit staff, but they often feel it is their only recourse.
- Lack of congruence in information presented: In the 149 conversations on the NMPAN listserv (that is comprised of 1,400 individuals, the majority of who are small or very small meat processors) that related to FSIS concerns and questions, the vast majority were centered around these topic areas: 1) Regulatory Information, 2) Technical information, 3) Inspector Issues/FSIS personnel, 4) Food Safety questions. Many of the conversations could have been solved by submitting questions to Ask FSIS or calling the Small Plant Help Desk. But people chose not to utilize those resources for some reason. Quite a few of the issues boiled down to having been given conflicting information from their IPP and things they found in the CFR, the FSIS website, or guidance documents/directives.
- Inconsistent inspection and regulatory discretion is too variable. Large plants are afforded more leeway than small and very small plants. Large plants also receive less scrutiny during slaughter due to much lower inspector/animal ratio than small plants.
- High turnover, poorly trained inspectors, and inconsistent training across districts.
- Not being able to ask for advice, particularly when applying for a grant of inspection, getting your HACCP plans approved, or developing a Robust Systematic Humane Handling Plan.
- Lack of opportunities to provide a voice and sit at the table in the development of new policy, directives, guidance documents, and programming. Other than submitting public comment on Federal Register items, which takes an inordinate amount of time for small operators who are also busy running their businesses or attending a regional roundtable meeting at their own expense, there are few opportunities to influence FSIS.
- NACMPI (National Advisory Committee on Meat & Poultry Inspection) has not met in four years and has usually only featured 1-2 small plant operators or industry stakeholders out of a dozen or so seats. The purpose of this federal advisory committee is to provide advice to the Secretary concerning State and Federal programs with respect to meat, poultry, and processed egg products inspection; food safety; and other matters that fall within the scope of the FMIA, PPIA and the Egg Products Inspection Act (EPIA). If small plants make up 90% of FSIS inspected establishments, shouldn't they make up 90% of the seats on this committee?
- Pathogen testing, requirements, and research. Performance standards are made with little small plant input. They are non-regulatory but are being used in a regulatory

manner because when plants are not consistently meeting standards, FSAs are often ordered for them. Another issue is that the pathogen liability falls completely on the plants, even though many of the pathogens are coming in on the animals. There is no upstream responsibility. This can be very hard on small plants, particularly if a recall is ordered.

- Salmonella Performance Standards in poultry are non-regulatory, yet being used to justify requiring a Food Safety Assessment (FSA).
- Humane handling regulations and violations (see case study below). Small and very small plants receive a disproportionate number of HH violations.
- There is much confusion regarding non-amenable species. Who inspects what species, how much does it cost for voluntary inspection, and why does voluntary inspection rates vary by plant and by state? For example, bison slaughter inspection can vary from \$15 to \$150 per head, which adds significant costs for the processor. For many small plants, processing non-amenable species is key to their business.
- Lack of enforcement of label claims, such as grassfed, humanely-raised, or natural. This puts farmers and processors at a competitive disadvantage that are actually complying with those claims or taking the time to verify them. FSIS should verify claims, not put the onus on processors.

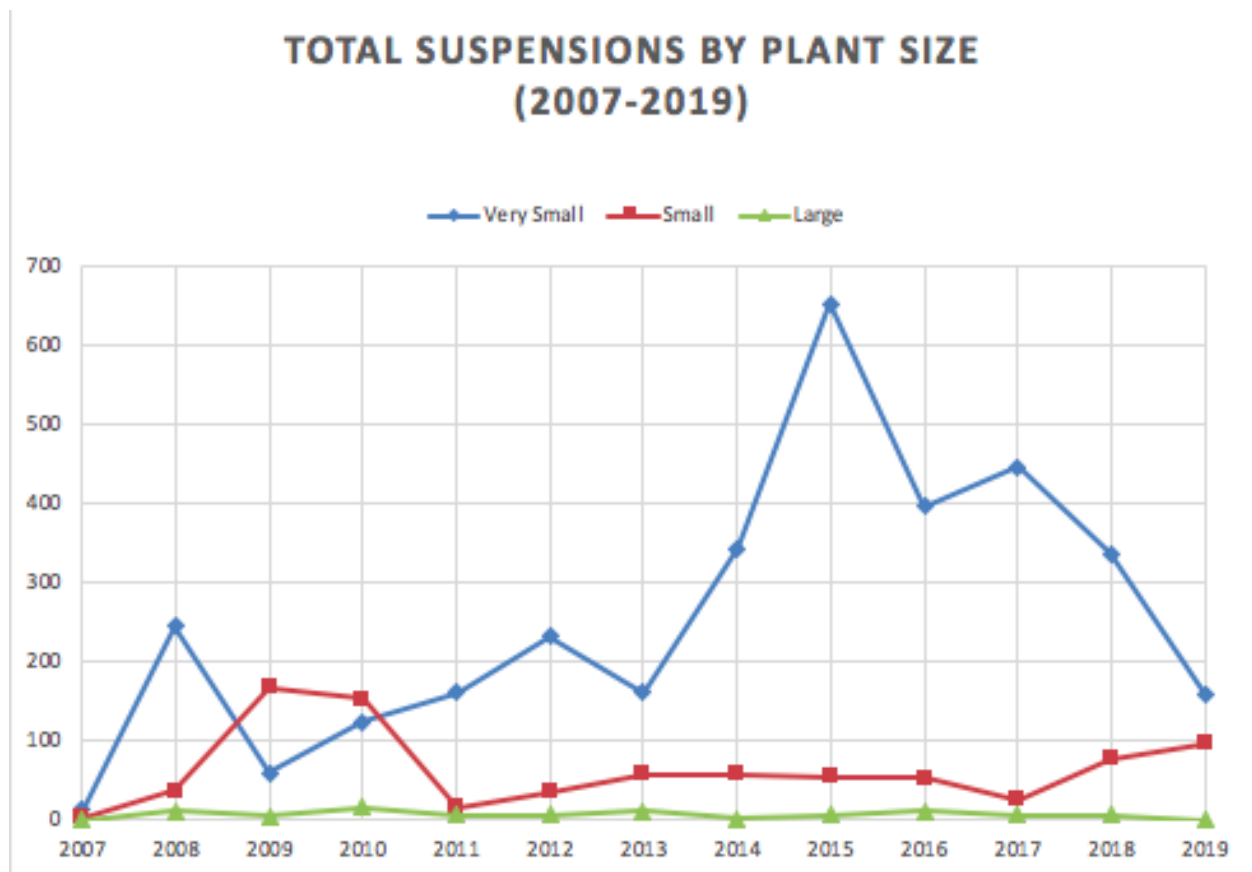
Recommendations and Potential Solutions:

- If a mis-stun is not egregious and simply human error (and if the plant has a Robust Plan in effect), allow the plant to be able to finish up animals slotted for the day and address any problems after inspection hours.
- More standardized and ongoing education/training for all inspection personnel. Include training in plants of all sizes and all species.
- Little research being done on how small and very small poultry plants can meet the salmonella performance standards. FSIS could allocate funds towards research in this arena and convene research teams, as they have done with other studies (such as modernization of poultry and swine inspection systems).
- Allocate funds and staff to create an FSIS Ombudsman office to help resolve and adjudicate small plant issues and concerns, such as inspector retaliation, humane handling violations, product recalls, overtime charges, etc. Provide a binding means for expert interpretation of the regulations.
- More accountability and oversight for rogue inspectors that are communicating inaccuracies or making up their own policies and interpretations of policies. FSIS OFO should study inspection decisions and enforcement actions across circuits and districts to correlate and calibrate inconsistencies and flag potential biases or staff problems. Take seriously the most notable personnel problems.
- Partner with USDA AMS to verify label claims. Remove all label claims that cannot be verified, such as “healthy” and “natural”.
- Create a monthly conference call specifically for small and very small plants to talk with FSIS leadership, hear about the latest policies and guidance documents that may affect them, and other Q & A as needed. Provide a system for plants to submit questions or

agenda ideas beforehand. Market and promote this conference call to all small and very small inspected establishments.

Humane Handling Case Study

USDA-inspected small and very small slaughter establishments in the United States suffer from a disproportionately higher rate of humane handling violations, from warnings through complete suspensions, than larger plants. In analyzing data from 2007 through the end of 2019 from the Animal Welfare Institute (see document [here](#)) who obtained their data from USDA FSIS Quarterly Enforcement Reports, 98.2% of all humane handling suspensions were received by small and very small plants. In 2019 alone, not a single large plant received a humane handling suspension- 100% of the suspensions were incurred by small/very small plants. One year in particular, 2015, saw a near doubling of violations over previous years, for some unknown reason.



The other concern this data points out is the number of days in suspension. Large plants are more likely to be suspended for one day or less, meaning they are back up and running under inspection swiftly. The graph below shows the range and median number of days by plant size over time. Small and very small plants are more likely to be suspended for longer than large plants, with 3 days being the median for a very small plant while 1 day is the median for large plants. Over this time period of 2007 to 2019, the longest a very small plant was shut down was 292 days, while only 9 days for a large plant. That could be a significant financial hit for a small

slaughter plant and if they are a co-packer for multiple farmers, that affects many more businesses too. While this data does not provide any backstory, such as how quickly the plant management responded to the violation or implemented corrective actions. We don't know how many previous violations the facilities have had, which could impact how quickly their corrective action plan is accepted. We don't know if the small and very small plants have a Robust Humane Handling Plan in place, proper head restraints, backup stunning device, etc. All of this is unknown. However, this data is concerning and calls for a deeper investigation by USDA FSIS staff to understand if their regulations or inspection staff have any implicit bias against small and very small plants. Or if much more outreach is needed to those plants than is currently afforded. This data below should be a call to action. All enforcement action data should be tracked over time, by district, by circuit, and by plant size to see if their systems or staff have any deficiencies or bias.

Plant size	Median	Mean	Range
Very Small	3	6	292
Small	2	4	119
Large	1	1	9

FSIS Current Suspension Protocols

FSIS has some steps in place to ensure small plants are able to avoid suspensions. The law is vague on when a suspension is necessary in the event of a humane handling violation.¹ Therefore, FSIS used their broad authority to create protocols through Directives, Notices, and Guidance that attempt to instruct FSIS inspectors and plant operators about when suspension is avoidable in the event of a humane handling violation.

FSIS's current protocols for addressing humane handling violations allows for some discretion and assurances that a plant can avoid suspension in the event of a humane handling violation if certain steps are taken by the plant. However, as noted by the data above, small and very small plants are still suspended at disproportionate rates, indicating that these steps are not clear or flexible enough for small and very small plants.

FSIS Directive 6900.2 instructs inspectors and plant operators when a humane handling violation warrants an immediate suspension. The document states that if a violation of the humane handling requirements causes injury to an animal of an "egregious nature" then an immediate suspension is warranted.² FSIS defines "egregious nature" to include actions that severely injure animals, including "stunning of animals and then allowing them to regain

¹ See 21 U.S.C. § 603(b). FSIS's authority under the Humane Methods of Livestock Slaughter Act (HMSA) allows, but does not require, inspectors to suspend the slaughtering line when they observe a violation of the Act. The law states "[t]he Secretary . . . may cause inspection to be temporarily suspended" if there is a violation of the HMSA.

² 9 C.F.R. § 500.3 (b); FSIS Directive 6900.2 - Humane Handling and Slaughter of Livestock, <https://www.fsis.usda.gov/wps/wcm/connect/2375f4d5-0e24-4213-902d-d94ee4ed9394/6900.2.pdf?MOD=AJPERES>.

consciousness; [and] multiple attempts, especially in the absence of immediate corrective measures, to stun an animal versus a single blow or shot that renders an animal immediately unconscious.”³

However, inspectors are instructed by FSIS not to suspend a plant for an egregious humane handling violation if the plant meets all of the following:

1. no recent humane handling violations;
2. consistently meets humane handling requirements;
3. has a written animal handling program that is a robust systematic approach;
4. the plant has proven to inspection personnel that all aspects of the plan ensure it is a robust systematic approach.⁴

If a plant meets all four of these factors, inspection personnel are told to issue a Notice of Intended Enforcement (NOIE) instead of a Notice of Suspension (NOS).⁵

Inspection personnel should also consider the following when deciding whether or not a plant should continue operating after an egregious humane handling violation:

1. Whether the establishment is operating under an animal handling program that provides for how the establishment will respond if an unforeseeable event of this type occurs;
2. Whether there is any basis for concern that the planned response in the establishment’s animal handling program will not effectively address the problem;
3. Whether the establishment has consistently and effectively implemented their animal handling program over time.”⁶

FSIS states that a robust systematic approach includes:

³ FSIS Directive 6900.2 - Humane Handling and Slaughter of Livestock, <https://www.fsis.usda.gov/wps/wcm/connect/2375f4d5-0e24-4213-902d-d94ee4ed9394/6900.2.pdf?MOD=AJPERES>

⁴ FSIS Directive 6900.2 - Humane Handling and Slaughter of Livestock, <https://www.fsis.usda.gov/wps/wcm/connect/2375f4d5-0e24-4213-902d-d94ee4ed9394/6900.2.pdf?MOD=AJPERES>; <https://www.fsis.usda.gov/wps/wcm/connect/da6cb63d-5818-4999-84f1-72e6dabb9501/Comp-Guide-Systematic-Approach-Humane-Handling-Livestock.pdf?MOD=AJPERES>

⁵ <https://www.fsis.usda.gov/wps/wcm/connect/37c6b39e-fd62-47a3-94e6-8baee9fcade2/13-06-FSIS-Final-Response.pdf?MOD=AJPERES>; <https://www.fsis.usda.gov/wps/wcm/connect/da6cb63d-5818-4999-84f1-72e6dabb9501/Comp-Guide-Systematic-Approach-Humane-Handling-Livestock.pdf?MOD=AJPERES>. A NOIE means an establishment will not be suspended, and instead, must provide adequate written corrective and preventative measures to ensure that livestock will be handled humanely. 9 C.F.R. 500.5; A notice of suspension, by contrast, results in the interruption of the assignment of inspectors to all or part of an establishment, and inspectors will not provide an establishment under suspension with marks of inspection, which is required for establishments to sell their product. 9 C.F.R. 500.1(c).

⁶ FSIS Directive 6900.2 - Humane Handling and Slaughter of Livestock, <https://www.fsis.usda.gov/wps/wcm/connect/2375f4d5-0e24-4213-902d-d94ee4ed9394/6900.2.pdf?MOD=AJPERES>

- a written humane handling program that includes the four factors of the Systematic Approach to Humane Handling and Slaughter (“systematic approach”)⁷
- the procedures the plant will implement to comply with humane handling regulations
- records that demonstrate the written program is being implemented
- records that demonstrate the program will prevent all identified potential non-compliances
- steps the plant will take to implement the written program
- that the written program is reviewed by inspection personnel.⁸

FSIS Directive 6900.2 also includes three pages on what inspection personnel review to determine whether or not the written program is a robust systematic approach.⁹ FSIS Public Health Veterinarians (PHVs) review the written plan and records to determine whether or not a systematic approach is robust on a monthly basis.¹⁰

Resources to Assist With Compliance

FSIS also developed a Compliance Guide for a Systematic Approach to the Humane Handling of Livestock in 2013 (“Compliance Guide”). The Compliance Guide includes the questions plants are asked by FSIS to determine if they have a systematic approach, and the three additional steps required to have a robust approach: 1) written procedures; 2) written records; and 3) review by FSIS.¹¹ The Compliance Guide includes the steps plants should take to ensure they have a robust systematic plan, a sample assessment tool, sample written plan language, and sample procedures and records.

FSIS also committed to additional assistance for small and very small plants. FSIS’s FY 17-21 Strategic Plan states they will “develop and implement an education and outreach campaign, targeting small and very small establishments, to ensure more consistent application of humane handling best practices and compliance with humane handling requirements.”¹² In the FY 17-21 Strategic Plan FSIS also stated that District Veterinary Medical Specialists will promote humane handling best practices by delivering educational material and guidance to establishments when conducting their routine humane handling verification visits, focusing on

⁷See 69 Fed. Reg. 54625 (describing the four factors: assessment, design, evaluation and response).

⁸FSIS Directive 6900.2 - Humane Handling and Slaughter of Livestock, <https://www.fsis.usda.gov/wps/wcm/connect/2375f4d5-0e24-4213-902d-d94ee4ed9394/6900.2.pdf?MOD=AJPERES>.

⁹FSIS Directive 6900.2 - Humane Handling and Slaughter of Livestock, <https://www.fsis.usda.gov/wps/wcm/connect/2375f4d5-0e24-4213-902d-d94ee4ed9394/6900.2.pdf?MOD=AJPERES>.

¹⁰ <https://www.fsis.usda.gov/wps/wcm/connect/e417b33c-d450-4970-accf-f80ffdc04e28/04-17.pdf?MOD=AJPERES>

¹¹ <https://www.fsis.usda.gov/wps/wcm/connect/da6cb63d-5818-4999-84f1-72e6dabb9501/Comp-Guide-Systematic-Approach-Humane-Handling-Livestock.pdf?MOD=AJPERES>

¹² <https://www.fsis.usda.gov/wps/wcm/connect/37c6b39e-fd62-47a3-94e6-8baee9fcade2/13-06-FSIS-Final-Response.pdf?MOD=AJPERES>

the most recent information and recommendations on effective animal restraint and stunning.¹³

Overall, FSIS has committed to ensuring plants are able to comply with the humane handling requirements and avoid suspension if an incident occurs. Therefore, small plants that have historically and consistently complied with the requirements and implemented a robust systematic approach should be able to avoid suspension.¹⁴ If implemented widely by both plants and inspectors, these protocols can reduce small and very small plant suspensions.

Impact on Small and Very Small Plants

There are currently some gaps that prevent small and very plants from avoiding suspensions in the event of a humane handling violation. Small and very small plant operators indicated two main gaps: 1) the lack of assistance, guidelines, and outreach to ensure small and very plants have and maintain a robust systematic approach; and 2) the lack of inspector consistency to ensure all plants are able to avoid suspension if they have an approved robust systematic plan, no recent violations, and consistently meet humane handling requirements.¹⁵

Historically, fewer small and very small plants implemented the systematic approach.¹⁶ Recent data indicates almost 100% of large plants have maintained a systematic approach, while small and very small plants had lower rates of adoption.¹⁷ Data also shows 56% of very small plants and 81% of small plants had a systematic approach that same year.¹⁸ In 2017, only approximately half of all plants were considered to have a robust systematic approach.¹⁹ The

¹³ <https://www.fsis.usda.gov/wps/wcm/connect/37c6b39e-fd62-47a3-94e6-8baee9fcade2/13-06-FSIS-Final-Response.pdf?MOD=AJPERES>

¹⁴ FSIS's Systematic Approach has become the dominant practice in slaughterhouses. FSIS stated that 35 percent of slaughterhouses had Systematic Approaches in 2013, but that number had risen to 75 percent by the end of 2016. <https://www.fsis.usda.gov/wps/wcm/connect/37c6b39e-fd62-47a3-94e6-8baee9fcade2/13-06-FSIS-Final-Response.pdf?MOD=AJPERES> (last accessed January 23, 2020).

¹⁵ See FSIS Directive 6900.2 - Humane Handling and Slaughter of Livestock, <https://www.fsis.usda.gov/wps/wcm/connect/2375f4d5-0e24-4213-902d-d94ee4ed9394/6900.2.pdf?MOD=AJPERES>.

¹⁶ <https://www.obpa.usda.gov/23fsis2016notes.pdf>.

¹⁷ In 2014, FSIS stated that "64% (486 of 755) of livestock slaughter plants have implemented a systematic approach to Humane Handling and Slaughter. Fifty-nine out of 59 large plants have adopted a systematic approach to humane handling." One hundred and sixteen out of 144 small plants have developed a systematic approach to humane handling (81%) and 311 out of 552 (56%) very small plants have adopted a systematic approach." <https://www.obpa.usda.gov/23fsis2016notes.pdf>.

¹⁸ In 2014, FSIS stated that "One hundred and sixteen out of 144 small plants have developed a systematic approach to humane handling (81%) and 311 out of 552 (56%) very small plants have adopted a systematic approach." <https://www.obpa.usda.gov/23fsis2016notes.pdf>.

¹⁹ In 2017, FSIS reported that "[a]pproximately 62 percent of all livestock establishments who received a monthly task had a written program and approximately 82 percent of those have a robust systematic approach. Fifty-one percent of all the livestock establishments assessed monthly for a robust systematic approach had one."

data affirms a lack of widespread adoption of the robust systematic approach, particularly among small and very small plants.

Small and very small plant operators say one reason there is a lack of adoption and FSIS approval of the robust systematic approach is the lack of clarity among both plant operators and FSIS inspection personnel. Plant operators are not always given clear instructions around what should be included and maintained for a systematic approach to be deemed “robust,” and sometimes this changes from month to month. Small and very small plant operators stated the Compliance Guide mock outline lacks sufficient detail to ensure their written plan will be approved. Some small and very small plant owners requested additional outreach and assistance to help develop a robust systematic approach. Overall, there is a lack of resources to ensure all plant owners clearly understand what a robust systematic approach must include.

Even for small and very small plants that have adopted a robust systematic approach, the prevention of a NOS is far from certain . There is no assurance for plants with an approved robust systematic approach that the plant will not be suspended in the event of a humane handling violation, because not all inspectors are aware of or applying these instructions uniformly.²⁰

While the current protocols provide some flexibility to ensure suspension can be avoided if certain conditions are met, it does not address the duration of a suspension when there is a failure to meet all of the conditions. There is no maximum number of days for suspensions, and extended idle periods can cause a disproportionate impact on smaller facilities that operate on thinner margins.

Recommendations

Overall, FSIS’s protocols should ensure small and very small plants are not disproportionately impacted by humane handling violation shutdowns. The following recommendations should be undertaken to assist small and very plant operators to comply with humane handling

²⁰ See FSIS Directive 6900.2 - Humane Handling and Slaughter of Livestock, 22-23 (2011), <https://www.fsis.usda.gov/wps/wcm/connect/2375f4d5-0e24-4213-902d-d94ee4ed9394/6900.2.pdf?MOD=AJPERES> (; FSIS Compliance Guidelines for a Systematic Approach to the Humane Handling of Livestock, FSIS, USDA, 8-9 (2013), <https://www.fsis.usda.gov/wps/wcm/connect/da6cb63d-5818-4999-84f1-72e6dabb9501/Comp-Guide-Systematic-Approach-Humane-Handling-Livestock.pdf?MOD=AJPERES> (“In establishments maintaining a robust systematic approach to humane handling and slaughter, and when the conditions (a. through d.) provided above exist, FSIS instructs inspection program personnel to take the following action. In the case of humane handling or slaughter noncompliance with egregious inhumane treatment – the inspector in charge recommends issuance of a Notice of Intended Enforcement rather than a Notice of Suspension”).

requirements and improve inspector consistency around humane handling requirements and enforcement:

1. FSIS should expand guides, online tools, trainings, outreach, education, and technical assistance to assure small and very small plants are able to adopt and maintain a robust systematic approach.

USDA should provide additional examples of robust systematic approach written plans beyond the one short outline in the Compliance Guide.²¹ FSIS should include in its Compliance Guide examples of successful robust systematic approach plans written by small, multi-species plants operators.

FSIS should also include in the Compliance Guide any specific exceptions for small and very small plants and multi-species plants and additional details that may facilitate compliance.

2. FSIS should assess whether or not the robust systematic approach is applicable to small, very small, and multispecies plants, and if there are areas where it should be revised or where additions should be made to assure it is applicable to all plants.

FSIS should collect data to determine the number of plants with an approved robust systematic approach throughout an entire year based on plant size (large, small, very small). If this data determines that small and very small plants have approved robust systematic approach and written plans at lower rates compared to large plants, FSIS should create a working group of small and very small plant operators to gather feedback on the robust systematic approach. FSIS should use that feedback to create guidance that ensures the robust systematic approach is practical for all plant sizes.

3. FSIS should ensure both inspection personnel and plant operations have a clear understanding of when a suspension will not occur for an establishment with a robust systematic approach.

FSIS states that there is no requirement that a plant implement a robust systematic approach, yet it is a main consideration in an inspector's decision to forego a suspension of a plant in the event of a humane handling violation.²²

FSIS should create a clear decision making guide specific to small and very small plants compliance with the humane handling requirements that includes information on when

²¹ <https://www.fsis.usda.gov/wps/wcm/connect/da6cb63d-5818-4999-84f1-72e6dabb9501/Comp-Guide-Systematic-Approach-Humane-Handling-Livestock.pdf?MOD=AJPERES>

²²FSIS Directive 6900.2 - Humane Handling and Slaughter of Livestock, <https://www.fsis.usda.gov/wps/wcm/connect/2375f4d5-0e24-4213-902d-d94ee4ed9394/6900.2.pdf?MOD=AJPERES>.

suspensions are not warranted. The decision making guide should be available to both inspectors and plant operators and added to the Compliance Guide and FSIS Directive 6900.2.

The decision making guide should clearly define what inspectors should consider when determining whether or not a plant has “no recent” humane handling violations.²³ For example, the decision making guide could state that no violations in the last six months is sufficient for meeting this requirement.

The decision making guide should also define how they consider whether or not a plant has “consistently” met humane handling requirements.²⁴ For example, the decision making guide should state that inspectors should issue an NOIE, rather than a Notice of Suspension, when a mis-stun with an immediate corrective action occurs at a plant as part of their robust systematic plan. This is one example of a plant with a consistent approach to the humane handling requirements.

FSIS should consider amending the rule that allows inspectors to suspend inspection without notice. If FSIS makes it clear in Notices, Directives, inspector training, and Guidance that the protocols must be followed, and plants are still suspended that follow the protocols, it may be necessary to remove this from FSIS regulations. I.²⁵ The rule could be amended to add an exception that prohibits immediate suspension if the current protocols for plants with a robust systematic approach is followed. FSIS could also draft a new proposed rule to clarify the protocols if the above suggestions are not sufficient to ensure inspector uniformity.

4. FSIS’s current protocols should include a timeline for suspension based on certain factors.

If inspection is suspended, FSIS has broad authority to decide when to reopen the plant²⁶ Unfortunately for small and very small plants, this has resulted in a several days or weeks shutdown.²⁷

FSIS should establish protocols for shutdowns that might occur at plants that have historically met the above mentioned protocols, with a robust systematic approach. The new protocols could follow a similar approach that includes requiring plants to implement a robust systematic

²³ See FSIS Directive 6900.2 - Humane Handling and Slaughter of Livestock, <https://www.fsis.usda.gov/wps/wcm/connect/2375f4d5-0e24-4213-902d-d94ee4ed9394/6900.2.pdf?MOD=AJPERES>; <https://www.fsis.usda.gov/wps/wcm/connect/da6cb63d-5818-4999-84f1-72e6dabb9501/Comp-Guide-Systematic-Approach-Humane-Handling-Livestock.pdf?MOD=AJPERES>

²⁴ See FSIS Directive 6900.2 - Humane Handling and Slaughter of Livestock, <https://www.fsis.usda.gov/wps/wcm/connect/2375f4d5-0e24-4213-902d-d94ee4ed9394/6900.2.pdf?MOD=AJPERES>; <https://www.fsis.usda.gov/wps/wcm/connect/da6cb63d-5818-4999-84f1-72e6dabb9501/Comp-Guide-Systematic-Approach-Humane-Handling-Livestock.pdf?MOD=AJPERES>

²⁵ 9 C.F.R. § 500.3.

²⁶ 21 U.S.C. § 603(b); FSIS rules state that “stunning procedures shall not be resumed until the inspector receives satisfactory assurances from the establishment operator that there will not be a recurrence.” 9 C.F.R. § 313.50.

²⁷ See supra pgs.

approach, and an assurance that a PHV will be available within two or three days to assist the plant with reopening. If corrective action is taken immediately, a plant with a robust systematic approach should be able to reopen within two or three days. FSIS should ensure that plant operators are at least aware of a general time frame for when the plant can resume operation if they have a robust systematic approach and immediate corrective actions.

Humane Handling Case Study Conclusion

Human error, the unpredictable nature of livestock, and the fast-paced environment of plants are all factors that may impact a plant's ability to comply with humane handling requirements. Congress provided discretion to inspectors to ensure they can consider these factors when they decide whether or not to suspend a plant in violation of humane handling requirements. FSIS's protocols are also not required to shut down plants. If these protocols are clear, size appropriate, and consistently applied by both inspectors and small plant operators, suspension should be avoidable.

Conclusions & Next Steps

To be developed after Step 2 feedback & survey process

Glossary

Appendix A & B-

CFR- Code of Federal Regulations

Constituent Update-

EIAO- Enforcement Investigations and Analysis Officer

Federal Register-

FSA- Food Safety Assessment

FSIS- Food Safety Inspection System

Guidance/Guideline Document-

HACCP Plan- Hazard Analysis & Critical Control Points Plan

Humane Handling-

IPP- In plant personnel

NACMPI-

NOIE- Notice of Intended Enforcement Action. NOIE is issued to a plant for noncompliances that do not pose an imminent threat to public health but may warrant withholding the marks of inspection or suspending the assignment of inspectors if not corrected.

Non-amenable species-

NOS- Notice of Suspension

NR- Noncompliance Record

OPPD- Office of Policy and Program Development

PHIS- Public Health Information System

PHV- Public Health Veterinarian

SPHD- Small Plant Help Desk

References