

Food Safety News



FSIS and the era of enforcement

By Dr. Michael Fisher on November 21, 2022

Editor's note: This is part three of a four-part series.

Ten years after issuing the Pathogen Reduction; Hazard Analysis and Critical Control Point (PR/HACCP) Systems: Final Rule, The USDA's Food Safety and Inspection Service (FSIS) had not produced a single metric demonstrating progress in reducing pathogens or foodborne illness. Unwilling to acknowledge failure, FSIS rationalized the absence of progress, not as a failure of FSIS policy, but as the result of industry lobbyists. **Industry lobbied against FSIS initiatives in the past.** They must be doing it again.

FSIS turned to the only metric it truly controlled as a measure of success: enforcement actions (i.e., regulatory control action, withholding action, suspension). The FSIS logic was simple. Enforcement actions are as accurate a measure of food safety as traffic citations are an accurate measure of highway safety (sarcasm intended). When enforcement actions taken is

your only measure of success, you document as many enforcement actions as possible, and you do not allow your enforcement actions to be overturned. The FSIS bureaucracy is very effective at both.

Presumption of Innocence or Guilt

Presumption of innocence is a tenet of American jurisprudence. FSIS is tasked with conducting inspection to determine if regulatory compliance does/does not exist. The burden of proof rests with FSIS, not industry. The standard of proof is a preponderance of evidence. Evidence is the available body of facts indicating that the establishment failed to meet the applicable regulatory performance standard.

In theory, inspection program personnel (IPP) implement an enforcement action when a preponderance of evidence supports a determination that noncompliance is more probable than not. In theory, if the establishment disagrees, the establishment can offer a refutation of the IPP evidence. In theory, the immediate FSIS supervisor weighs the IPP evidence and the establishment refutation against the applicable regulatory performance standard, and decides the appeal based on a preponderance of evidence.

FSIS policy turns this tenet of American jurisprudence upside down. The PR/HACCP final rule states that “establishments will be afforded greater autonomy in decision-making affecting their own operations,” meaning that the responsibility for achieving compliance rests with the establishment and that FSIS will allow the establishment to determine the methods by which it achieves compliance. FSIS interprets this to mean that the establishment must prove that its choice of method achieves compliance, placing the burden of proof on industry. FSIS considers industry guilty until industry proves itself innocent.

The Rules of Practice [9 CFR 500.2(a)(3)] authorize IPP to take a regulatory control action when conditions “preclude FSIS from determining that product is not adulterated or misbranded,” meaning that, IPP may retain product while they gather additional information to determine if noncompliance exists. FSIS interprets this to mean that the inability of IPP to determine compliance supports a determination of noncompliance. For FSIS, the absence of evidence is evidence. It is FSIS policy that any determination of noncompliance is valid until proven false via the appeal process, and that by not appealing the noncompliance, the establishment validates the noncompliance. IPP can assert, in the absence of evidence, that noncompliance exists. The supervisor accepts the assertion as true because the establishment

cannot prove the assertion false. In effect, FSIS has “weaponized stupid” and eliminated the need for supervisory oversight.

The result is a history of noncompliance based on an absence of evidence, which FSIS may use to justify a Food Safety Assessment (FSA). The predictable outcome of an FSA is the identification of “concerns” suggesting an inadequate HACCP system [9 CFR 417.6], and a recommendation for further enforcement action. Like a determination of noncompliance, it is FSIS policy that any FSA recommendation is valid; therefore, FSIS performs zero quality control on the FSA. So, on the recommendation of IPP, the FSIS District Manager issues a Notice of Intended Enforcement (NOIE), informing the establishment that FSIS intends to implement a suspension. The FSIS decision to implement a suspension is administrative, not regulatory. If FSIS chooses to implement a suspension, an establishment cannot prevent it.

The establishment has two courses of action available: dispute the FSA findings and “petition the Government for a redress of grievances” or accept the FSA findings and correct the underlying “concerns.” Either way, FSIS can take and maintain the suspension until the petition or corrective action is complete.

Petition or Corrective Action

The First Amendment to the U.S. Constitution guarantees an establishment the right to petition government for redress of grievances. An establishment has a legal right to appeal an enforcement action without fear of punishment or reprisal. The First Amendment does not require government to respond. It is an FSIS tenet that “if it is not written down, it did not happen.” FSIS can and will ignore any petition not presented in written form.

The Fifth Amendment prohibits government from depriving a citizen of liberty or property without due process. Any FSIS enforcement action is a deprivation of liberty or property. Procedural due process requires government to provide an establishment with notice, an opportunity to be heard, and a decision made by a neutral decisionmaker. The federal court system, not FSIS, provides procedural due process. Standing between the establishment and procedural due process is the doctrine of exhaustion of administrative remedies, the requirement that the establishment first pursue the FSIS administrative remedy defined in FSIS Directive 13,000.3 before seeking judicial review.

Any appeal of alleged noncompliance must pass up the FSIS chain of command until granted. It is FSIS policy that by ending the appeal process, the establishment validates the noncompliance. Moving an appeal through the FSIS chain of command can take months. Most establishments give up long before that. Once the FSIS Administrator denies the appeal, the establishment can seek judicial review in federal District Court [5 USC 702]. Only then is the establishment provided notice, an opportunity to be heard, and a decision by a neutral decisionmaker. The federal district court charges substantial filing and administrative fees. Given the time obstacle created by the doctrine of exhaustion of administrative remedies and the monetary cost of judicial review, no appeal can survive if FSIS chooses to oppose it.

An establishment may request a formal proceeding before an Administrative Law Judge (ALJ) if FSIS implements a suspension not held in abeyance, refuses to grant inspection, or rescinds or refuses label approval. If an establishment requests a formal proceeding, FSIS requests that the USDA, Office of General Council (OGC) file an administrative complaint requesting that the Secretary withdraw the establishment's grant of inspection. OGC then notifies the establishment of the administrative complaint. Failure to respond within 20 days constitutes a waiver of hearing. The establishment's request for a formal proceeding is denied, and a Judge issues an order refusing or rescinding the grant of inspection. The establishment must choose between a consent decision and a hearing. A consent decision is a negotiation. If the establishment and FSIS cannot agree on a consent decision, a hearing is held. The consent decision/hearing process can take up to a year, maybe longer. If the ALJ rules in favor of FSIS, the establishment can appeal to the OGC Judicial Officer. If the Judicial Officer rules for FSIS, the establishment can seek judicial review in federal District Court. The FSIS requirement to provide procedural due process has been satisfied. In the meantime, the suspension remains in place.

If the establishment acknowledges the underlying noncompliance, due process does not apply. The establishment must demonstrate to the satisfaction of FSIS that it corrected the noncompliance. FSIS can require the establishment to implement corrective actions that exceed the applicable regulatory requirements. If the establishment objects, then the establishment can appeal per 9 CFR 500. In the meantime, the enforcement action remains in place.

Epilogue

The FSIS enforcement action procedures are administrative, not regulatory. Legal tenets such as presumption of innocence and standards of proof do not apply.

If the establishment petitions for a redress of grievances, FSIS can make the administrative process onerous and economically disenfranchise the establishment, unless the establishment submits to its will. The FSIS administrative state effectively functions as judge, jury, and executioner. This administrative power is equally functional as a resource management tool. The more establishments driven out of the system, the fewer establishments consuming inspection resources: a definite benefit to a federal agency struggling with insufficient manpower to conduct its required mission.

FSIS offers a free choice in which only one choice is offered (i.e., do it my way) because the alternative (i.e., bankruptcy) is highly undesirable. The FSIS bureaucracy does not obstruct the pathway to due process; however, it does put in place a detour of such magnitude that few establishments have sufficient political clout or pockets deep enough to navigate the detour. Those who choose to travel the detour (i.e., Supreme Beef Processors) risk finding themselves a **party to bankruptcy**. Such is the administrative power of FSIS.

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Marianne Eikleberry Foege

10 months ago

Thank you for your very informative articles. It is government bureaucracy at its worst. I am sure there are many fine people who are working in FSIS who just go home scratching their heads the longer they work there and the more knowledgeable they become of the system they are trapped in.

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John Munsell

10 months ago

First: I challenge Francisco & JQ Public to fully identify themselves.

The seriousness of FSIS overreach and unaccountability is NOT fully covered in Dr. Fisher's revelations. We desperately need a contemporary Upton Sinclair, whose book would not be focused on the meat industry but instead to reveal the corruption at FSIS, originating in DC and perpetrated by hatchet men at the District Offices. FSIS, like many bureaucracies, is unaccountable for its misbehavior, and has morphed into a 4th branch of gov not restricted by checks and balances to which the legitimate 3 branches of gov must adhere. The vast majority of inspectors are reputable, but must submit to whatever his/her supervisors require, under the mandate of the District Office of course.

After I went public in 2002, I received numerous unsolicited communications from plant owners across the country, all of whom related mostly identical tyranny from FSIS hierarchy overseeing their plants. But MUCH MORE IMPORTANT, I received numerous calls from FSIS inspectors and supervisors, all of whom validated the claims made by plant owners. Ever wonder why there is such bad morale within agency employees? Cognitive dissonance, a psychological conflict caused by being required to enforce unscientific & nonsensical policies and administrative enforcement actions, is a common malady amongst inspection personnel, whose careers would be destroyed if they spoke out for justice.

The judge's decision in the Supreme Beef debacle reveals how Dr. Fisher's statements are erudite. That decision taught our industry that while our legitimate and fully defensible appeals run the gauntlet of layers of agency officials and legal authorities, the lights are off in our plants. This guarantees the death of any plant whose owner attempts to use his/her constitutional right to challenge any despot in the FSIS bureaucracy. The term "appeal process" would better be named "bankruptcy".

I could go on forever with accurate historical accounts of FSIS intentional mistreatment of plants, but that would be better read in a modern-day version of "The Jungle". Hey Francisco and JQ Public, would you endorse such an expose?

John Munsell, Miles City, MT

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Francisco 

10 months ago

It is sad that someone that worked for FSIS have no clue about what the agency mission is. Regardless of how many college degrees he has. Undermining the work and effort that all the field Food inspectors, Consumer Safety Inspectors, Veterinarians, people at the district offices do. He worked during the era of "Command in Control" where the retaliation and intimidation was the normal. The due process was given to the establishments since 1997 after the Jack in the Box E.coli 0157:H7 outbreak (kids died). The responsibility was given to the establishments to develop and implement programs and procedures (HACCP's, SSOP's, GMP's, etc..). FSIS has the responsibility to verify that those programs are implemented in accordance with Title 9 Code of Federal Regulations. So yeah, Food Inspectors, Consumer Safety Inspectors, PHV's, SPHV's, VMO's, etc... are regulators because the set of regulations that are enforce every day. And no, the FSIS goal is not to shut down establishments, actually is the contrary. Is up to every establishment to stay in business by delivering safe products to the people. And also, is up to the establishment if wants to deviate from obey the federal regulations by not implementing their own programs.

I became more conscious when I read The Jungle, Upton Sinclair 1906.

The article does not contribute anything.

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Michael Fisher  Francisco

10 months ago

Francisco: I presented a clear argument based on verifiable sources for what I believe the FSIS mission is and is not. If you wish to present an argument I will be happy to debate you. If not, I support your right to your opinion that I "have no clue about what the agency mission is." Shining light on how FSIS fails to carry out the will of Congress is not undermining Food inspectors, Consumer Safety Inspectors, Veterinarians, and district office personnel. I want them there. I want them verifying compliance. No, due process has not been given to plants. The Courts, not FSIS, provide due process. I too read "The Jungle," but I choose to not base my consciousness of federal inspection in the 21st Century on a novel written over 100 years ago. I look forward to hearing your argument.

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J Q Public

10 months ago

Why is this being published by food safety news? Editor note or not, the tenor and tone of the series of articles doesn't lend anything besides the author doesn't like USDA and the way it regulates industry. The author seems to trot out lots of well worn and tired arguments, amidst vague appeals to constitutional law as if we haven't been regulating meat and other food producers for many years.

In his previously column the author posited that the federal government has no role in regulating meat and now he claims every agency action must be reviewed by a federal court otherwise the rights of food firms are being violated. He claims the government has no business regulating pathogens in meat for human consumption. This is really too much nonsense to read. Good grief.

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Michael Fisher  J Q Public

10 months ago

JQ: The series is published in FSN because I submitted it to FSN for consideration and they found it worth of publication. I neither like nor dislike the USDA. I am an advocate for federal inspection by FSIS; but, I do believe FSIS is in need of reform. If my arguments are well worn and tired, it is only because they have been made repeatedly and ignored repeatedly by people who think that, just because they have performed a task for many year, that they know what they are doing. Psychologists call that mindset 'the illusion of explanatory depth.' I did not say, nor do I claim that the federal government has no role in regulating meat. FSIS clearly has a role the regulation of meat and poultry products in Commerce. Nor do I say or claim that every agency action must be reviewed by a federal court. I do say that industry has a constitutional right to take their grievances before a federal judge, but are obstructed in doing so by the administrative power of FSIS. Yes, FSIS has no authority to regulate pathogens. FSIS has authority to prevent adulterated meat from entering Commerce. If that meat contains pathogens, then I expect FSIS to prevent it from entering commerce. You may feel that my writing is "too much nonsense to read," but your response suggests that you read it and thought about it. Thank you for that.

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John Munsell Michael Fisher
10 months ago

The discussion of FSIS abuse of enforcement actions could be well stated in Dr. Fisher's irrefragable statement above: "I do say that industry has a constitutional right to take their grievances before a federal judge, but are obstructed in doing so by the administrative power of FSIS". Touche! That's the bottom line. So, I would ask J Q Public and Francisco what their reaction is to that one sentence. Focus exclusively on that one sentence, and for the moment set aside everything else.

Here's a prime example for which I'd be remiss if I didn't refer to it. Scurrilous agency retaliatory actions taken by the FSIS Front Line Supervisor against Riley Meats and its owner Bart Riley in Butte Montana several years ago were well described in two front page revelations in Montana newspapers perhaps 4 years ago. Even Francisco and J Q Public could not argue against the well documented agency abuses against this small processing plant, agency actions which by the way are not unique to Montana alone. Agency actions were so heinous that all the members of the Montana Congressional Delegation [from both parties] jointly signed a letter sent to the USDA Office of Inspector General, requesting an investigation. So, what transpired? To this date, OIG has refused to even provide a reply letter to the Montana delegation even acknowledging agency receipt of the letter. So much for a well deserved investigation! For the same reason FSIS avoids a rolling recall which would implicate many plants and MANY inept FSIS recumbent supervisors, OIG adroitly avoids a rolling revelation of intentional agency misdeeds spanning our nation. Since OIG refuses to admit the truth, the Riley Meats scenario would be an excellent, and lengthy chapter in the new version of "The Jungle". Thanks to Dr. Fisher, an agency insider, for his courage in publicly exposing scandalous agency actions he witnessed when working at FSIS.

And I'm still waiting for Francisco and J Q Public to publicly reveal their full names.

Oh by the way, the actions and behavior of the FSIS Front Line Supervisor in Montana have become much more professional and transparent subsequent to the front line stories detailing his misbehavior. His improved behavior is the only tangible response we've yet seen as a result of the investigation request sent to OIG.

John Munsell

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