The Food Safety and Inspection Service's Lack of Statutory Authority to Suspend Inspection for Failure to Comply with HACCP Regulations

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I. INTRODUCTION

On July 25, 1996, the United States Department of Agriculture's Food Safety and Inspection Service (FSIS)[1] published a massive set of regulations designed to take meat and poultry inspection into the next century. Commonly referred to as the "Mega-Reg," these rules were intended to move inspection away from the organoleptic examination of animals, products, and facilities that had been the procedure since the 1906 Meat Inspection Act[2] to an inspection system focused on the current public health risk—microbial

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1. FSIS is the agency within the Department of Agriculture authorized to implement and to enforce the inspection acts. Even though the statutes themselves refer to the Secretary of Agriculture, for ease, this article will only refer to FSIS. 9 C.F.R. § 300.2; *see also* FOOD SAFETY AND INSPECTION SERVICES (FSIS), *About FSIS, at* http://www.fsis.usda.gov/About_FSIS/index.asp (last visited Apr. 8, 2005).

2. 21 U.S.C. § 601 (2004).

contamination—*Listeria monocytogenes*,[3] *Salmonella*,[4] and *E. coli* O157:H7.[5]

In conjunction with the change in inspection regulations, a change has been made in enforcement. If an inspected establishment did not modify its procedures to comply with the new rules, or was unable or unwilling to comply with the new regulatory requirements, FSIS would take administrative action to "suspend" inspectors at the establishment and if the establishment still could not comply, FSIS would move, in an administrative proceeding, to withdraw inspection. Since the Federal Meat Inspection Act (FMIA) and the Poultry Products Inspection Act (PPIA)[6] require inspection for the processing of meat and poultry products, suspension or withdrawal of inspection has the practical effect of closing a plant.

Since the implementation of the Mega-Reg, the agency has had mixed success with its new enforcement procedures. Although most establishments have chosen to work with FSIS to modify their procedures to allay any concerns the agency had, on a few occasions, no compromise was reached. In these cases, the establishment filed suit in federal district court challenging the agency's authority to remove inspectors for failure to comply with the Mega-Reg. In the three cases where the agency's authority was challenged, the establishment was successful and inspection was restored.[7]

The agency's lack of success has raised a question of whether FSIS indeed has the enforcement authority it claims or whether the agency merely failed to articulate the basis sufficiently in these cases. Based on a review of the enabling statutes and past cases, it would appear FSIS does have authority to suspend inspection but only in certain well-defined circumstances. The inspection acts simply are not sufficient to provide an enforcement basis for any and all non-compliances with the Mega-Reg. Indeed, FSIS can suspend inspection *only* if there are insanitary conditions at the facility, and

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3. CENTER FOR FOOD SAFETY AND APPLIED NUTRITION (CFSAN), *Foodborne Pathogenic Microorganisms and Natural Toxins Handbook, available at* http://vm.cfsan.fda.gov/~mow/chap6.html.

4. DIVISION OF BACTERIAL & MYCOTIC DISEASE, CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC), *Disease Information: Salmonellosis, at* http://www.cdc.gov/ncidod/dbmd/diseaseinfo/salmonellosis_g.htm (last visited Sept. 18, 2005).

5. DIVISION OF BACTERIAL AND MYCOTIC DISEASES, CDC, *Disease Information: Escherichia coli O157:H7, at* http://www.cdc.gov/ncidod/dbmd/diseaseinfo/escherichiacoli_g.htm (last visited Sept. 18, 2005).

6. 21 U.S.C. § 451 (1999).

7. *See infra* Section V.

those conditions have caused or could reasonably cause adulteration of any product. Without such showing, the government simply cannot suspend inspection.

II. STATUTORY FRAMEWORK

A. The Statutory Language

In cases of statutory authority, it is best to begin with the plain language of the authorizing legislation.[8] The only section which speaks of suspension that could be relevant to this inquiry is Section 8 of FMIA.[9] This section provides, in relevant part, "where the sanitary conditions of any such establishment are such that the meat or meat food products are rendered adulterated, [FSIS] shall refuse to allow said meat or meat food products to be labeled, marked, stamped, or tagged as 'inspected and passed.'"[10] Under the plain language of this provision, FSIS must have a basis to conclude that the insanitary conditions result in the products being "*rendered adulterated*" to impose suspension.[11]

FMIA also contains a section specifying what constitutes adulteration. In the context of the Mega-Reg, FSIS has relied on the adulteration provision dealing with insanitary conditions, which provides that a food may be adulterated "[i]f it has been prepared,

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8. *See generally* Chevron USA, Inc. v. Natural Resources Defense Council, Inc., 467 U.S. 837 (1984).

9. 21 U.S.C. § 608 (1999). The inspection acts also permit FSIS to refuse or withdraw inspection if:

- The establishment refused to destroy a condemned carcass, 21 U.S.C. § 604 (2004) (meat);
- The establishment refused to destroy condemned meat or meat food product, 21 U.S.C. § 606 (2004) (meat);
- The establishment (or a responsibly connected individual) had been convicted of certain crimes, 21 U.S.C. §§ 467 (1999) (poultry), 671 (2004) (meat); and
- A livestock slaughter facility is operating in violation of the Humane Slaughter Act, 7 U.S.C. §§ 1901-1906 (1999).

10. Section 8 of FMIA, 21 U.S.C. § 608 (1999).

11. The actual language of FMIA does not technically provide for suspension of inspection or the removal of federal inspectors. It only authorizes the refusal to mark products "inspected and passed." The inspector must remain in the facility. It is PPIA which speaks of "refusing inspection." 21 U.S.C. § 456(b) (2004). However, for the purposes of this article, we will treat the refusal to mark products the same as a suspension where the inspector actually leaves the facility.

packed, or held under insanitary conditions whereby it may have become contaminated with filth or whereby it may have been rendered injurious to health."[12] It would seem that the plain language authorizes FSIS to refuse to mark products or, in effect, suspend inspection if the cleanliness of the facility is so far below standards that the product may be implicated. There was no indication that a failure to comply with a Hazard Analysis Critical Control Point (HACCP)[13] regulation would be contemplated by the language, nor was it contemplated by the legislative history.

B. Legislative History

The first mandatory federal meat inspection act is almost 100 years old. Since the first enactment, one major, permanent change occurred in 1967. Amendments in 1986 would have resulted in substantial changes had the provisions not expired in 1992. For poultry, the inspection act developed separately, becoming a mandatory inspection program in 1957,[14] with its one major revision occurring in 1968, which made PPIA more consistent with the changes to FMIA the previous year.[15]

1. 1906 Meat Inspection Act

The first mandatory federal meat inspection program had its genesis in fiction, specifically, *The Jungle* by Upton Sinclair.[16] The book was written as an exposé of working conditions in the cities; only twelve pages of the book actually described the filth and animal disease at slaughterhouses. However, the description of the insanitary conditions and practices were enough to cause a public outcry for change. The net result was the creation of a mandatory federal meat inspection program as part of the Agricultural Appropriations Act of 1906.[17] The purpose of the program was the "restoration of public confidence, not only in our own country but in

12. Section 8 of FMIA, 21 U.S.C. § 601(m)(4). The identical language appears in Section 4(g)(4) PPIA, 21 U.S.C. § 453(g)(4) (1999).

13. 9 C.F.R. § 417.1 (2004).

14. 21 U.S.C. § 601 (2004).

15. *Id.*; Wholesome Meat Act, Pub. L. No. 90-201, 81 Stat. 584 (1967).

16. UPTON SINCLAIR, THE JUNGLE (Penguin Books 1985).

17. Agricultural Appropriations Act, Pub. L. 382, 34 Stat. 669 (1906) ch. 3913; REP. 4935, 59th Cong. 1st Sess. (1906).

other countries, in the purity and wholesomeness of American meat and meat products."[18]

The essence of the 1906 program has been virtually unchanged. All slaughtering and processing of meat for interstate or foreign commerce must be conducted under inspection by federal government officials. Indeed, no product may enter commerce unless it has been so inspected. Products found to be wholesome will be labeled "inspected and passed," while products found unwholesome shall be condemned and destroyed under the supervision of the inspector.[19]

The main focus of the 1906 Act was (and remains) the product itself and the condition of the facility. In order for a product to enter commerce, it cannot be "unsound, unhealthful, unwholesome, or otherwise unfit."[20] As to facilities, there was no provision in the 1906 Act for the government to refuse to provide inspection at any establishment. In order that sanitation be addressed, the Act simply prohibited products to be marked "inspected and passed" if produced under insanitary conditions. According to the accompanying congressional report, this provision "provides for a strict sanitary inspection of all establishments, under the provisions of this law and under rules and regulations to be prescribed by the Secretary of Agriculture."[21] Interestingly, the original act did not contain any provision defining "adulteration," nor was that term used in the act.[22]

2. 1906-1967

In 1907, Congress codified the 1906 appropriations language into the Meat Inspection Act.[23] For the next sixty years, there were no changes in terms of how meat was inspected under the law. Yet, there were two developments in other acts which would have implications for meat inspection.

The first development involved the Federal Food, Drug, and Cosmetic Act (FDCA).[24] A predecessor statute, the Pure Food and

18. REP. 4935, 59th Cong. 1st Sess. (1906) at 7.
19. 21 U.S.C. § 607 (1999).
20. 21 U.S.C. § 602 (2004).
21. *Id.*
22. *Id.*
23. Meat Inspection Act, Pub. L. No. 59-242, § 34 Stat. 1262 (1907).
24. Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301-397 (2004).

Drugs Act, was adopted in 1906 along with the Meat Inspection Act. However, the earlier statute did not address insanitary conditions with regard to food production or distribution. To remedy that deficiency, a definition of "adulteration" was introduced. A product may be adulterated, and hence illegal, "if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health."[25] According to the legislative history of this provision, the purpose of such a definition was to "require the observance of a reasonably decent standard of *cleanliness* in handling food products."[26] This provision would generate numerous cases on what constitutes "insanitary conditions." These cases would become relevant to meat and poultry inspection when, in 1967 and 1968, Congress adopted the identical definitions for the inspection acts.[27]

The second development was the adoption of a mandatory inspection program for poultry in 1957.[28] Until that time, poultry was primarily a local operation with consumers selecting live birds which would be custom-slaughtered at the retail location. Any company desiring federal inspection could request such service, but it was a voluntary program run by a different division of the United States Department of Agriculture (USDA).[29] However, as poultry operations became less local, Congress enacted PPIA in 1957.[30] Although modeled after the Meat Inspection Act, the provisions have never been completely consistent. For example, while mandatory post-mortem inspection of carcasses is required by both the meat and poultry inspection acts, inspection of further poultry processing is not mandated by the statute.[31] In the context of the agency's authority with regard to sanitary conditions, PPIA provided authority to "refuse to render inspection at any establishment whose premises, facilities, or equipment, or the operation thereof, fail to"

25. 21 U.S.C. § 342(a)(4) (1999).

26. S. 2800, 73rd Cong. (1934) (emphasis added).

27. In adopting this language for the Meat Inspect Act, Congress intended that "essentially the same criteria be applied in determining wholesomeness . . . ." S. REP. NO. 90-799, *reprinted in* 1967 U.S.C.C.A.N. 2188, 2203.

28. Poultry Products Inspection Act, Pub. L. No. 85-172, 71 Stat. 441 (1957).

29. The Agricultural Marketing Act of 1946, 7 U.S.C. § 1622(h) (2004).

30. Poultry Products Inspection Act, Pub. L. No. 85-172, 71 Stat. 441 (1957).

31. 21 U.S.C. § 455(b) (2004).

comply with the sanitary practices required by regulations of the Secretary.[32]

3. 1967-1968

In 1967, Congress amended the Meat Inspection Act. The previous act only addressed products moving in interstate or foreign commerce. Meat produced and sold solely within a state was not covered by the mandatory federal program. To ensure national uniformity, Congress enacted the Wholesome Meat Act[33] mandating that meat in intrastate commerce must be produced under a state inspection program at least equal to the federal program or the facility must be inspected by the federal government. The Wholesome Meat Act, when combined with the Meat Inspection Act, became FMIA.[34]

In addition to addressing intrastate issues, Congress made other revisions. First, it expressly specified certain instances when FSIS could suspend or withdraw inspection.[35] Second, it added a definitional section which included definitions of adulteration, including the provision related to insanitary conditions. Interestingly, Congress did not amend the provision dealing with refusal to mark products when produced under insanitary conditions; it maintained the existing version which was inconsistent with the poultry act.

In 1968, Congress adopted the Wholesome Poultry Act,[36] which made the same changes regarding the authority to suspend or withdraw inspection and the definition of adulteration. Congress

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32. Section 6 of the 1957 Act (currently codified at 21 U.S.C. § 456).

33. Wholesome Meat Act, Pub. L. No. 90-201, 81 Stat. 584 (1967).

34. Wholesome Meat Act, Pub. L. No. 90-201, 81 Stat. 584 (1967).

35. 21 U.S.C. § 608 (1999). The inspection acts also permit FSIS to refuse or withdraw inspection if:

- The establishment refused to destroy a condemned carcass, 21 U.S.C. § 604 (2004) (meat);
- The establishment refused to destroy condemned meat or meat food product, 21 U.S.C. § 606 (2004) (meat);
- The establishment (or a responsibly connected individual) had been convicted of certain crimes, 21 U.S.C. §§ 467 (1999) (poultry), 671 (2004) (meat); and
- A livestock slaughter facility is operating in violation of the Humane Slaughter Act, 7 U.S.C. §§ 1901-1906 (1999).

36. Wholesome Poultry Products Act, Pub. L. No. 90-492, 82 Stat. 791 (1968).

again left untouched the provision dealing with refusal to provide inspection for insanitary conditions.

4. 1986 Processed Products Inspection Improvement Act

In 1986, Congress amended FMIA to provide the government with more discretion in allocating resources for inspection of processed products.[37] FMIA permitted FSIS to move away from less than daily inspection of processing operations.[38] Given the controversy surrounding this change, the act would expire in six years absent Congressional re-authorization, which it did on November 11, 1992.

As part of the package to permit less continuous inspection, a new enforcement authority was added to Section 401 of FMIA. Under this section, FSIS could suspend and/or withdraw inspection for the repeated failure of an establishment to comply with agency regulations if such non-compliance posed a direct and substantial threat to public health.[39] However, in order to exercise this authority, FSIS had to follow very precise procedural requirements. In the conference report accompanying the legislation, Congress made clear that the power to suspend inspection was an "extraordinary power" and could only be exercised in extreme cases and then only with full due process protections.[40] For reasons unknown, though likely due to the procedural requirements, FSIS never once sought to exercise this authority.

C. Recap of the Statutory Precedents

Several observations can be made regarding the statutory provisions and legislative history summarized above. First, the plain language does not easily support an expansion of the authority regarding insanitary conditions as it relates to processing issues, such as HACCP. The initial inspection act was designed to address the sanitary condition of the facilities as reported in *The Jungle*, which focused on the cleanliness of the facility (or lack thereof). Second, the limited discussion of what constitutes "insanitary conditions"

37. Future Trading Act of 1986, Pub. L. No. 99-641, 100 Stat. 3556 (1986).

38. PPIA already permitted such discretion, and hence was not part of the 1986 Amendments. 21 U.S.C. § 455(b).

39. Future Trading Act of 1986, Pub. L. No. 99-641, 100 Stat. 3556 (1986).

40. H. CONF. REP. 99-995 at 37 (1986), *reprinted in* 1986 U.S.C.C.A.N. 6066, 6083.

would seem to imply that Congress intended the term be interpreted according to its common meaning of "cleanliness." Third, and most importantly, Congress was careful to restrict the authority to suspend operations to those precise situations specified in the statutes.[41]

No matter how a court wishes to interpret the statutory authority, it is undeniable that for FSIS to suspend inspections, insanitary conditions must be demonstrated at the facility. This, in turn, raises the issue of what constitutes "insanitary conditions."

III. INSANITARY CONDITIONS

In adopting the provisions dealing with sanitation, Congress did not define what constitutes "insanitary conditions." However, in practice, the government focused on the physical conditions of the facility, at least initially. For example, in an old FSIS Directive just recently revoked, FSIS defined sanitation by the performance standard of: "*look clean, feel clean and smell clean.*"[42]

Not surprisingly, in all but one of the cases brought under the insanitary conditions provision where the government was successful, there was evidence of "visual" insanitary conditions at the facility.[43]

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41. *See supra* Sections II.A. & B.

42. FSIS Directive 11,000.1, § 4.2.1.2 (Jan. 25, 2000) (emphasis in original).

43. *See* United States v. Park, 421 U.S. 658, 671 (1975) (noting visual evidence of rodent activity); United States v. Wiesenfeld Warehouse Co., 376 U.S. 86 (1964) (reflecting food in warehouse visually accessible to rodents, birds and insects); United States v. King's Trading, Inc., 724 F.2d 631 (8th Cir. 1983) (showing visual evidence of rodent activity); United States v. H.B. Gregory, 502 F.2d 700, 704-05 (7th Cir. 1974) (showing visual evidence of rodent activity); United States v. Cassaro, Inc., 443 F.2d 153 (1st Cir. 1971) (demonstrating visual evidence of insect infestation); United States v. Hammond Milling Co., 413 F.2d 608 (5th Cir. 1969) (finding visual evidence of rodent activity); International Exterminator, 294 F.2d 270 (5th Cir. 1961) (placing poisonous liquid in close proximity to foods); Berger v. United States, 200 F.2d 818, 821 (8th Cir. 1952) (reflecting visual evidence of rodent and bird activity, and insect infestation); Triangle Candy Co. v. United States, 144 F.2d 195 (9th Cir. 1944) (noting visual evidence of rodent activity and insect infestation); United States v. Gel Spices Co., Inc., 601 F. Supp. 1205 (E.D.N.Y. 1984) (showing visual evidence of rodent activity and insect infestation); G. A. Portello & Co. v. Butz, 345 F. Supp. 1204 (D.C. 1972) (reflecting visual evidence of physical contamination of meat containers); United States v. 1200 Cans, 339 F. Supp. 131 (N.D. Ga. 1972) (finding various visual insanitary conditions, including failure to wash and sanitize eggs prior to breaking); United States v. 44 Cases, Etc., 101 F. Supp 658 (E.D. Ill. 1951) (showing visual evidence of insect infestation and physical contamination); United States v. Roma Macaroni Factory, 75 F. Supp. 663 (N.D. Cal. 1947) (noting visual evidence of rodent activity); United

The seminal case where the government failed to establish physical contamination and, therefore, lost was *United States v. General Foods Corp.*[44] In that case, the Food and Drug Administration (FDA) sought to establish insanitary conditions through the use of laboratory analysis of mold.[45] The court rejected the FDA position noting that the laboratory analysis of the mold on equipment was not determinative, in part, because there was no visual evidence of build up or "slime" on the equipment.[46] Moreover, the court noted that the mold could not be eliminated through normal good manufacturing practices.[47]

Based upon the loss in *General Foods*, FDA adopted a policy that it would not initiate any insanitary conditions cases based solely on bacteriological analysis.[48] Although FDA reserved the right to bring actions based upon pathogens, in the years that followed, FDA always included some evidence of visual contamination even when the case was primarily brought due to pathogenic contamination.[49]

In only one case has the government been successful in the absence of any visual contamination—*United States v. Nova Scotia Foods Products Corp.*[50] However, that case did not involve a regulatory action against a product, rather it was brought by FDA to compel a smoked fish processor comply with the FDA's regulation regarding time-temperature-salinity (T-T-S) requirements for processing of smoked fish.[51]

States v. Lazere, 56 F. Supp. 730 (N.D. Iowa 1944) (demonstrating visual evidence of rodent activity and insect infestation).

44. 446 F. Supp. 740, 744 (N.D.N.Y.), *aff'd* 591 F.2d 1332 (2d Cir. 1978).

45. *Id.*

46. *Id.* at 752.

47. *Id.* at 754.

48. RICHARD A. MERRILL AND PETER BARTON HUTT, FOOD AND DRUG LAW 27 (The Foundation Press, Inc. 1980).

49. Continental Seafood, Inc. v. Schweiker, 674 F.2d 38 (D.C. Cir. 1982) (showing visual evidence of insanitary conditions supporting finding of *Salmonella* in shrimp); United States v. Blue Ribbon Smoked Fish, Inc. et al., 179 F. Supp. 30 (E.D.N.Y. 2001) (reflecting visual evidence of insanitary conditions supporting a finding of *Listeria monocytogenes* in fish); United States v. Union Cheese, 902 F. Supp 778, 786 (N.D. Ohio 1995) (demonstrating visual evidence of insanitary conditions supporting a finding of *Listeria monocytogenes* in cheese); United States v. 1200 Cans, 339 F. Supp. 131 (N.D. Ga. 1972) (finding visual evidence of insanitary conditions supporting finding of *Salmonella* in eggs).

50. 568 F.2d 240 (2d Cir. 1977).

51. *Id.* at 242-43.

Unlike the inspection acts, which grant FSIS the authority to establish not only sanitary requirements but processing requirements as well, FDCA does not grant FDA such authority.[52] Hence, to justify these types of regulations, FDA had to rely on the adulteration provisions. In the case of the T-T-S regulation, FDA used the adulteration provision dealing with insanitary conditions.[53] In *Nova Scotia*, the district court granted the FDA's request for an injunction,[54] and the processor appealed.[55]

For the purposes of the appeal, it was agreed by both parties that there were no physical "insanitary conditions" in the plant.[56] Hence, the straightforward legal issue was whether FDA could establish precise processing requirements under the statutory provision dealing with insanitary conditions. The Second Circuit held that FDA did have this authority.[57] Although the court ruled in the FDA's favor, the opinion evidences the court's recognition that it was stretching the language to support its conclusion that FDA needs such authority. For example, the court admitted "that on a first reading the language of the subsection appears to cover only 'insanitary conditions,' 'whereby it [the food] may have been rendered injurious to health' . . . and a plausible argument can be made that the references are to insanitary conditions in the plant itself . . . ."[58]

To justify its expansion beyond the plain language, the court relied on a series of FDA cases which held that FDCA should be read broadly to protect the public health.[59] The court also relied on the absence of any Congressional intent to limit FDA's authority, stating that "in the absence of compelling evidence that such was Congress' intention, [the court is] unwilling to prohibit administrative action

52. 21 U.S.C. §§ 301-397 (2004).
53. 21 U.S.C. § 342(a)(4).
54. 417 F. Supp. 1364 (E.D.N.Y. 1976).
55. *Id.*
56. *Nova Scotia*, 568 F.2d at 243.
57. *Id.* at 247.
58. *Id.* at 245 (emphasis in original). It should be noted that this decision was rendered before *Chevron*, 467 U.S. 837. It is questionable whether under the *Chevron* analysis the court could have ignored the plain language of the statute.
59. *Id.* at 246 (and cases cited therein).

imperative for the achievement of an agency's ultimate purposes."[60] Indeed, it found no evidence of Congressional intent on this issue.[61]

Beyond its statutory construction, the court marshaled other practical arguments to support its novel interpretation.[62] First, it commented that "no lawyer at the knowledgeable Food and Drug bar ever raised the question . . . or even hinted at" the lack of statutory authority. Second, the court noted that Department of Agriculture had such authority under the authority to establish sanitary conditions.[63] Under FMIA, similar standards have been established under Section 608 (sanitary conditions).[64] Third, a contrary holding would have implications far beyond the present case, since it would invalidate other similar FDA regulations.

In short, the court in *Nova Scotia* wrote a result-oriented opinion to justify its decision that FDA should have the authority to establish processing requirements for public safety and enjoin processors who refused to follow such regulations. As an interesting endnote, however, the court did invalidate the T-T-S rule on procedural grounds.[65]

IV. THE MEGA-REG

For over thirty years, there had been calls to take inspection into the modern age. When first enacted in 1906, the focus was placed upon animal diseases and insanitary conditions. The changes to FMIA in 1967[66] and the adoption of PPIA[67] still retained the focus on organoleptic examinations.

60. *Id.* (quoting In re Permian Basin Area Rate Cases, 390 U.S. 747, 780 (1968)).

61. *Nova Scotia*, 568 F.2d 240, 248. Consistent with the notion that the court recognized it was proceeding beyond the plain language, it commented that "We believe . . . that it would be in the public interest for Congress to consider" expressly addressing the issue of processing standards.

62. *Id.*

63. It is this reference that FSIS has relied upon to interpret Section 8 of FMIA—a statement that was, at most dicta. *Id.*

64. *Id.*

65. *Nova Scotia*, 568 F.2d at 248.

66. 21 U.S.C. § 601 (2004).

67. 21 U.S.C. § 451 (1999).

A. HACCP in General

In 1983, FSIS asked the National Academy of Sciences (NAS)[68] to evaluate the inspection system and recommend changes to enhance public health protection. In 1985, NAS issued a report, "Meat and Poultry Inspection: The Scientific Basis of the Nation's Program."[69] The report identified microbial contamination as the number one public health issue[70]—an issue with which the 1906 inspection system could not cope. To address pathogens, NAS recommended that FSIS require all establishments to adopt and to implement HACCP systems.[71] This recommendation was reiterated in two subsequent NAS studies: "Poultry Inspection: The Basis for a Risk Assessment Approach"[72] and "Cattle Inspection: Committee on Evaluation of USDA Streamlined Inspection System for Cattle (SIS-C)."[73]

NAS was not alone in calling for change; the Government Accounting Office (GAO) issued several reports, culminating in a 1994 report entitled "Food Safety: Risk-Based Inspections and Microbial Monitoring Needed for Meat and Poultry,"[74] which recommended the adoption of HACCP systems at meat and poultry establishments. Industry also called for adoption of HACCP systems as did the government's premier advisory body, the National Advisory Committee on Microbiological Criteria for Foods (NACMCF).[75] Indeed, NACMCF was the primary organization in refining and disseminating HACCP.

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68. *See* NATIONAL ACADEMY OF SCIENCES, *About NAS, at* http://www.nasonline.org/site/PageServer?pagename-=ABOUT_main_page (last visited Sept. 18, 2005).

69. *See* NATIONAL ACADEMY OF SCIENCES, *Meat and Poultry Inspection: The Scientific Basis of the Nation's Program* (1985).

70. *Id.*

71. *Id.*

72. *See* NATIONAL ACADEMY OF SCIENCES, *Poultry Inspection: The Basis for a Risk Assessment Approach* (1987).

73. *See* NATIONAL ACADEMY OF SCIENCES, *Cattle Inspection: Committee on Evaluation of USDA Streamlined Inspection System for Cattle* (1990).

74. *See* GENERAL ACCOUNTING OFFICE, *Food Safety: Risk Based Inspections and Microbial Monitoring Needed for Meat and Poultry* (1994).

75. *Id.*

Initially developed to provide safe food for the space program by Pillsbury,[76] HACCP is a food safety approach which seeks to prevent problems in processing rather than reacting to problems in the finished product.[77] An establishment identifies potential sources of food safety hazards with regard to each of its processes and products.[78] It then assesses whether those hazards pose a true risk in its operations—in other words, whether a hazard is reasonably likely to occur in absence of control.[79] The establishment also identifies the steps that can prevent, eliminate, or reduce the hazard to acceptable levels.[80] Having identified the risk and the step to eliminate the risk, the establishment completes the analysis by identifying those critical controls which can be employed in the process and then monitors those controls.[81] For example, raw meat may contain pathogens. It is reasonably likely that these pathogens would remain in ready-to-eat (RTE) products unless eliminated by a step in the process. Hence, in converting raw meat to RTE, the establishment must include a step to eliminate this hazard. This hazard elimination by cooking the meat at a particular time and temperature is sufficient to destroy the pathogens. To ensure safety, the establishment must only monitor the time and temperature of cooking to ensure the product has received a sufficient lethality. All of the analysis and the monitoring is documented so that with a review of the records, the processor can ensure the safety of the food so there would be no need to test every product for a pathogen.

B. FSIS's Initial Reluctance to Adopt HACCP Regulations

Notwithstanding the near universal support for HACCP by scientists and industry, FSIS did not move rapidly towards adoption. This reluctance was likely due to the fundamental change in

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76. *See* Delilah Dill Schuller, Comment, *Pathogen Reduction Through "HACCP" Systems: Is Overhaul of the Meat Inspection System All It's Cut Out To Be?*, 8 S.J. AGRIC. L. REV. 77, 85 (1998).

77. *See* FEDERAL DRUG ADMINISTRATION, *HACCP: A State of the Art Approach to Food Safety* (Oct. 2001).

78. *See* FEDERAL DRUG ADMINISTRATION & UNITED STATES DEP'T OF AGRICULTURE, NATIONAL ADVISORY COMMITTEE ON MICROBIOLOGICAL CRITERIA FOR FOODS, *HACCP & Application Guidelines*, Aug. 14, 1997, *available at* http://www.cfsan.fda.gov/~comm/nacmcfp .html [hereinafter NACMCF Report].

79. *See id.*

80. *See id.*

81. *See id.*

approach, which would be required to transition from an active organoleptic inspection system to a HACCP system where FSIS inspectors basically review records and monitor activities.

The unique feature of the inspection acts is that they mandate the continuous presence of a government inspector in the plant.[82] This inspector, in theory, must make an affirmative decision regarding each and every product as to whether or not it is adulterated. If he or she has any questions or concerns, such concerns must be addressed or the product will be retained or the equipment and facilities rejected for use.[83] As a result of this authority, FSIS adopted approval requirements for all aspects of a plant's operations including that the facility and equipment must be approved prior to use, that the maximum line speeds for slaughter operations must follow regulations, and that the product processing and labeling must be approved prior to use.[84] This system was known as "command and control," which is an appropriate name because virtually all aspects of a plant's operations were dictated by FSIS.[85]

HACCP does not work that way. It is a plant's responsibility to design its system based upon its unique facility and processes to monitor its operations and document compliance with its program, and to ensure no unsafe product enters commerce.[86] Placing the responsibility on the plant leaves the FSIS inspector with little to do. NACMCF published a report to address the issue of a regulator's responsibilities in a HACCP environment. That report, "The Role of Regulatory Agencies and Industry in HACCP,"[87] recommended that FSIS serve as a third-party monitor or auditor.[88] The agency could review the program and the records, conduct some limited verification tasks, but if the plant was following a valid program, the agency would be "hands off."[89]

The role of FSIS in HACCP effectively shifted its function from an active role to a more passive one. Not surprisingly, many of the in-plant inspectors opposed the change, as did many others in the

82. *See supra* Section II.
83. *Id.*
84. *Id.*
85. *Id.*
86. 9 C.F.R. § 417.2 (2004).
87. NACMCF, *The Role of Regulatory Agencies and Industry in HACCP* (1993).
88. *Id.*
89. *Id.*

agency. Moreover, many consumer activists were not enthusiastic with what was perceived as handing over the food safety to industry while "tying the hands" of the in-plant inspector.

C. Proposed Mega-Reg

It took a tragedy, the *E. coli* O157:H7 outbreak in the Pacific Northwest United States, to energize the government into action. In late 1992 through early 1993, dozens of people became ill and several died (primarily small children) due to the contamination of the ground beef used by a quick service restaurant. The incoming Clinton Administration recognized the need for action and responded to consumer concerns by focusing upon the one procedure which could address microbial contamination—HACCP.[90]

In 1995, USDA issued a proposed regulation which would mandate that all establishments develop and implement HACCP plans.[91] However, the following proposed regulations addressed more than just mandatory HACCP:

- To address consumer activist concerns, it required establishments producing fresh products to test those products for *Salmonella* and measure their effectiveness against a national standard.[92] The regulation called for the establishment to take additional actions if it failed the standard. The question of whether FSIS would take regulatory action in the event of a failure was not addressed.
- To continue with its "command and control" style, it proposed mandating that all establishments have at least one antimicrobial treatment at slaughter[93] and specified cooling requirements for red meat.[94]

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90. *See* Kerri E. Machado, Comment, *Unfit for Human Consumption: Why American Beef Is Making Us Sick*, 13 ALB. L. J. SCI. & TECH. 801 (2003).

91. Pathogen Reduction; Hazardous Analysis Critical Control Points (HACCP), 60 Fed. Reg. 6774 (Feb. 3, 1995).

92. Proposed 9 C.F.R. § 310.25 (2004) (meat); proposed 9 C.F.R. § 381.79 (2004) (poultry).

93. Proposed 9 C.F.R. § 310.25 (2004) (meat); proposed 9 C.F.R. § 381.69 (2004) (poultry).

94. Proposed 9 C.F.R. § 318.25 (2001); proposed 9 C.F.R. § 381.66 (2001) (poultry). Poultry already had such requirements.

- To ensure that establishments were accountable, FSIS asserted the authority to suspend inspection at a facility which failed to adopt a HACCP plan or if the agency determined the plan was "invalid." The suspension would take effect immediately and would remain until the establishment submitted an acceptable, modified HACCP plan. If the invalidity involved an adulterated product, the establishment would submit a testing plan to verify the effectiveness of the modification.[95]

The proposal also would require all establishments to have a sanitation standard operating procedure (SSOP).[96] Interestingly, the proposal did not call for suspending inspection for SSOP non-compliance. The inspector would merely apply a "U.S. Rejected" tag to any equipment or room if there was an SSOP failure, and the tag would remain until there was a reinspection by the inspector, and the conditions were found acceptable.[97] The name Mega-Reg was coined as to describe the breadth of the regulation.

Given the magnitude of the changes, especially in terms of how USDA would inspect meat and poultry establishments in the future, FSIS held a variety of public meetings, both on the rule in general and on particular aspects, such as testing. At one of the general meetings, the entire "knowledgeable" FSIS bar challenged the statutory authority of FSIS to suspend inspection for any reason other than the finding of insanitary conditions at the facility. Ironically, FSIS did not call for suspension for insanitary conditions in the proposal rather the rejection of equipment or retention of product.

D. Final Mega Reg

On July 25, 1996, FSIS published the final Mega-Reg.[98] In some regards, it was similar to the proposal in terms of mandating HACCP and SSOPs. Yet, in regards to testing, it was substantially changed. Moreover, the "command and control" components dealing with anti-microbial treatments and cooling requirements for red meat were dropped entirely.

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95. Proposed 9 C.F.R. § 326.7 (1996) (meat).
96. 9 C.F.R. § 416.12 (2001).
97. Proposed 9 C.F.R. § 308.3 (2000) (meat).
98. 9 C.F.R. pt. 416 (2001).

The four principal components of the final rule consisted of the following:

- All establishments must develop and maintain written SSOPs, designed to prevent direct product contamination.[99] In the preamble to the final regulation, USDA noted that SSOPs "are important tools for meeting existing statutory sanitation responsibilities . . . ."[100] FSIS did specify that SSOPs are a condition for receiving inspection,[101] but at the time the final rule was published, did not mention suspension of inspection for SSOP non-compliance.[102]
- All establishments must adopt and implement a HACCP plan.[103] The regulations did specify what would constitute an "inadequate HACCP system,"[104] but suspension was not expressly mentioned in the regulation, but was in the preamble.[105]
- Establishments that slaughter or produce raw products must test to ascertain process control.[106] Although FSIS retained the testing requirement, the organism changed from *Salmonella* to generic *E. coli*.[107] Moreover, in the preamble, FSIS clearly linked repeated failure to comply with this performance criterion as a basis for suspension.[108]
- FSIS will test for *Salmonella*, but now the testing will be conducted by FSIS, and the results compared against a national average.[109] The establishment's failure to meet the national

99. 9 C.F.R. pt. 416.11 (2001). In the final rule, FSIS combined the separate HACCP and SSOP rules dealing with meat and poultry individually.
100. FSIS HACCP Final Rule, 61 Fed. Reg. 38,806, 38,834 (July 25, 1996).
101. 9 C.F.R. § 304.3 (2001) (Meat); 9 C.F.R. § 381.22 (2001) (poultry).
102. In the preamble, FSIS noted that HACCP and SSOPs were different. HACCP focuses upon the effectiveness of processes, 61 Fed. Reg. 38,818 (July 25, 1996), whereas SSOPs focus upon meeting statutory sanitation responsibilities. 61 Fed. Reg. 38,834.
103. According to FSIS, HACCP is not the same as SSOPs, "In a sense, the [SSOP is] a prerequisite for HACCP." 61 Fed. Reg. 38,834.
104. 9 C.F.R. § 417.6 (2004).
105. 61 Fed. Reg. 38,806, 38,823 (July 25, 1996).
106. 9 C.F.R. § 310.25 (2004) (meat); 9 C.F.R. § 381.94 (2004) (poultry).
107. 9 C.F.R. § 310.25 (2004) (meat); 9 C.F.R. § 381.94 (2004) (poultry).
108. 61 Fed. Reg. 38,844 (July 25, 1996).
109. 9 C.F.R. § 310.25 (2004) (meat); 9 C.F.R. § 381.94 (2004) (poultry).

standard on three consecutive tests "will cause FSIS to suspend inspection services."[110]

In a 1999 ruling, FSIS added the last component of the new inspection system—the general sanitation performance standard.[111] These regulations basically streamlined the agency's existing sanitation regulations. Importantly, not all of the general sanitation regulations address direct product contamination or adulteration. For example, some general regulations addressed the required lighting at the facility.[112] The agency indicated it would take suspendsion action in the event there were violations of these standards.[113]

Although four of the five major components of the agency's inspection modernization mentioned suspension of inspection either in the text of the regulation or in the preamble, the final rules as adopted did not contain any procedural regulations on how FSIS would impose suspension. According to the preamble, "FSIS has decided not to finalize the proposed Rules of Practice at this time."[114]

In one regard, the agency was fortunate that it did not finalize the proposed Rules of Practice on July 25, 1999. Just three days earlier, a federal court had found FSIS had violated the Administrative Procedure Act (APA)[115] by failing to provide an establishment with prior notice before suspending inspection.[116] This case, *In re Velasam Veal Connection*[117] was the first of three FSIS losses in the agency's attempt to suspend inspection.

The Rules of Practice were not finalized until November 29, 1999.[118] At that time, FSIS was in the middle of the second of the three cases, *Supreme Beef Processors, Inc. v. USDA*.[119] Although two of the three cases began prior to the Rules of Practice, it is helpful to

110. 9 C.F.R. § 310.25(b)(3)(iii).
111. 9 C.F.R. §§ 416.2-416.8; 61 Fed. Reg. 56,400 (Nov. 1, 1996).
112. 9 C.F.R. § 416.2(c).
113. 61 Fed. Reg. 56,399, 56,400-56,401.
114. 61 Fed. Reg. 38,806, 38,823 (July 25, 1996).
115. 5 U.S.C. § 558(c) (2001).
116. 55 Agric. Dec. 300; 1996 WL 367077; 1996 WL 367076.
117. *Id.*
118. 9 C.F.R. pt. 500 (1999).
119. 113 F. Supp. 2d 1048 (N.D. Tex. 2000) *aff'd* 275 F.3d 432 (5th Cir. 2001).

discuss FSIS enforcement and the Rules of Practice before analyzing the trilogy of cases.

E. FSIS Rules of Practice for Enforcement of the Mega-Reg and Other Regulations

In its Rules of Practice, FSIS specifies what type of regulatory actions it will take, when each action is appropriate, and what procedures govern each action. In essence, there are three basic types of actions:

- "Regulatory Control Actions," where the in-plant inspector unilaterally takes some immediate action based upon a non-compliance with a regulatory requirement;[120]
- "Suspension," where the agency removes its inspectors from a part of the establishment or the entire establishment, in effect stopping operations. Suspension can be imposed with or without prior notice depending on the allegations;[121] and
- "Withdrawal," where the agency removes its inspectors permanently or for some set period of time.[122]

1. Regulatory Control Actions

In the vast majority of cases, an enforcement action begins with the in-plant inspector.[123] The in-plant inspector has significant authority to deal with individual instances of non-compliance. In regulatory parlance, the inspector can initiate "regulatory control action."[124] He or she can retain (i.e., "tag") a product to prevent shipment or further processing.[125] Until the inspector removes the tag, the product cannot move until it is brought into compliance.[126] The inspector can also reject equipment or the facility, prohibiting its use until it is brought into compliance. In many situations,

120. 9 C.F.R. § 500.1(a)(2004).
121. 9 C.F.R. § 500.1(c) (2004); 64 Fed. Reg. 66,541, 66,543 (Nov. 29, 1999).
122. 9 C.F.R. § 500.1(b) (2004).
123. 64 Fed. Reg. 66,541, 66,543 (Nov. 29, 1999).
124. 9 C.F.R. § 500.1(a) (2004).
125. 64 Fed. Reg. 66,541, at 66,542-66,543.
126. 64 Fed. Reg. 66,541.

production is stopped until the equipment or facility is made acceptable to the inspector.[127]

In terms of procedures, the inspector will act when he or she determines such action is necessary. Long-existing regulations provide for an appeal of any such decision through the inspector's chain of command: the immediate superior, the front-line supervisor, the District Office, and Field Operations Staff at headquarters to the FSIS Administrator.[128]

In addition to these regulatory control actions, most enforcement actions involve the issuance of a non-compliance record (NR).[129] A NR is to be written whenever the inspector determines that the establishment has failed to comply with a regulatory requirement, including HACCP.[130] If HACCP is a system that relies primarily on records, then the primary record for regulatory enforcement is the NR.[131] Not only does the NR document an individual instance of non-compliance, but these documents are also used by the agency to support a suspension. The NR form is designed to facilitate a quick review of non-compliances so that repetitive failures can be easily determined and combined to show that the system is inadequate in operation.[132] On every NR form the following statement is found, in bold: "**This document serves as written notification that your failure to comply with regulatory requirements could result in additional regulatory or administrative action.**" The "additional" action is suspension and withdrawal.[133]

2. Suspension

A suspension is the temporary removal of inspectors from the establishment.[134] It may be imposed with prior notice or, in certain circumstances, imposed without prior notice.[135] In either case, the

127. *Id.*
128. 9 C.F.R § 306.5 (2004) (meat); 9 C.F.R. § 381.35 (2004) (poultry).
129. 64 Fed. Reg. 66,541, 66,543 (Nov. 29, 1999).
130. 64 Fed. Reg. at 66,543.
131. *Id.*
132. *Id.*
133. 9 C.F.R. § 500.3 (2004); 9 C.F.R. § 500.4 (2004).
134. 9 C.F.R § 500.1(c) (2004).
135. 9 C.F.R. § 500.3 (2004); 9 C.F.R. § 500.4 (2004).

agency's district managers are delegated the authority to suspend inspection, with appeal rights to FSIS headquarters.[136]

Based on the *Velasam*[137] case, the Rules of Practice incorporate the requirements of APA[138] that prior notice and an opportunity to demonstrate or achieve compliance be provided unless there has been willful non-compliance or the non-compliance endangered the public health.[139] Pursuant to the regulations, prior notice will be given, unless: (a) the establishment has produced or shipped adulterated or misbranded products; (b) the establishment does not have a HACCP plan or a SSOP; (c) the sanitary conditions at the establishment would render products adulterated; and (d) the establishment violated the terms of a regulatory control action.[140]

Even when prior notice is given, the agency has specified a variety of situations where FSIS could suspend inspection if the establishment has not "demonstrated or achieved compliance," suspension of inspection could occur when (a) the HACCP system is inadequate due to multiple or recurring non-compliances;[141] (b) the SSOP has not been properly implemented or maintained based on multiple or recurring non-compliances; (c) the establishment is not maintaining sanitary conditions under the general sanitation performance standard;[142] (d) the establishment is not conducting the required generic *E. coli* testing; and (e) the establishment has failed to meet the *Salmonella* performance standard. These situations represent the agency's interpretation of its statutory authority to suspend and have little, if any, support by the statute.

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136. 9 C.F.R. § 500.5 (2004).

137. 55 Agric. Dec. 300; 1996 WL 367077; 1996 WL 367076.

138. 5 U.S.C. § 558(c) (2001).

139. *Id.*

140. 9 C.F.R. § 500.3. The regulation provides three other bases not relevant here—establishment personnel have harassed or intimidated an FSIS employee, the establishment has refused to destroy a condemned carcass or product, and in the case of livestock, the establishment has violated the Humane Slaughter Act.

141. 9 C.F.R. § 417.6 (2004) (identifying those instances when the agency will deem a HACCP plan to be inadequate—the plan does not meet the regulatory requirements, the establishment is not implementing the plan, with emphasis upon corrective actions and recordkeeping, and the adulterated product is produced or shipped).

142. 9 C.F.R. §§ 416.2-416.8 (1999).

3. Withdrawal

Withdrawal is a more permanent suspension.[143] It involves the removal of inspectors for a definite time or indefinitely.[144] The 1967 and 1968 amendments to the Inspection Acts[145] authorized FSIS to withdraw inspection from any establishment if the establishment or a responsibly connected individual was convicted of more than one misdemeanor involving transactions in food or any felony.[146] FSIS has exercised this authority quite frequently and consequently, the procedural rules have been well established.

FSIS follows the statutory requirement that an opportunity for a hearing be provided prior to withdrawal.[147] Under the general USDA Rules of Practice, [148] the agency would file a complaint with an administrative law judge (ALJ) who would hold a formal hearing. If the ALJ found for the agency, there would be an appeal directly to the USDA Judicial Officer with federal court review.[149]

Virtually all of the withdrawal cases prior to the Mega-Reg involved the agency's statutory authority to withdraw inspection if the establishment or a connected individual was convicted of any felony or more than one misdemeanor involving transactions in food. In these cases, the agency continued to provide inspection throughout the proceedings. The other cases involved situations where employees of the establishment had harassed or assaulted inspection personnel. Obviously, with these cases, inspection was suspended pending the litigation in order to protect FSIS employees. In all of the litigated withdrawal cases, the company was successful in only one instance, and such case was based upon procedure, not substantive grounds.[150]

In the new Rules of Practice, FSIS has greatly expanded the situations where it will seek withdrawal of inspection. In essence, the agency has asserted the right to seek withdrawal in the same

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143. 9 C.F.R § 500.6 (2004).
144. *Id.*
145. 21 U.S.C. § 601 (2004).
146. 21 U.S.C § 467 (2001); 21 U.S.C. § 678 (2001) (meat).
147. 5 U.S.C. § 558(c)(1), (2) (2001).
148. 7 C.F.R. pt. I, subpart H.
149. FMIA authorizes the district court to review. 21 U.S.C. § 678 (2001); PPIA authorizes the court of appeals. 21 U.S.C. § 467 (2001).
150. Cherin v. Lyng, 874 F.2d 501 (8th Cir. 1989) (holding FSIS failed to obtain the individual's concurrence in a settlement agreement).

situations where it has asserted the authority to suspend inspection. The agency has authority to withdraw in the following situations:

- Non-compliance with the Mega-Reg (HACCP, SSOPs, generic *E. coli* testing, the *Salmonella* performance standard, and the general sanitation performance standard); and
- Shipment of adulterated product.[151]

F. Enforcement Actions Under the Mega-Reg Generally

Since the Mega-Reg became effective, there have been literally hundreds of enforcement actions taken by FSIS.[152] The most common is a Notice of Intended Enforcement (NOIE).[153] The NOIE, consistent with the court's ruling in *Velasam*, provides an establishment with notice and an opportunity to demonstrate or achieve compliance with Mega-Reg requirements.[154] In most occasions, the establishment will take action to allay any concerns the agency might have and continue operations. In some cases, due to an inadequate response or repeated positive laboratory findings, an actual suspension may result, requiring additional actions on the part of the establishment to respond to agency concerns.[155]

If the thesis of this article is correct–that FSIS lacks the statutory authority to suspend inspection for most violations of the Mega-Reg–there have been hundreds of enforcement actions threatening and/or imposing suspension; the question becomes why has there been virtually no lawsuits? The answer may rest in several practical issues which make litigation a less attractive course of action. First, the NOIE has minimized the number of times actual suspension will be imposed—an establishment may demonstrate or achieve compliance by responding to issues raises in the NOIE without losing

151. 9 C.F.R. § 500.6 (2004). The regulation also includes harassment and assault, refusal to destroy condemned product, non-compliance with the Humane Slaughter Act, and refusal to conduct generic *E. coli* testing.

152. FSIS publishes a quarterly report of all enforcement actions taken. *See* FSIS, *available at* http://www.fsis.usda.gov/regulations_&_policies/quarterly_enforcement_reports/index.asp.

153. Allison Beers, *Industry Praises New Field Instructions*, FOOD CHEM. NEWS, Feb. 5, 2001 at 24.

154. *See* FSIS, *USDA Food Safety & Inspection Services Quarterly Regulatory and Enforcement Report, Oct. 2001 through Dec. 2001*, Mar. 2001, *available at* http://www.fsis.usda.gov/OA/haccp/enfrep00-4a.htm.

155. *Id.*

production time or going to litigation.. Second, many of the companies who have been involved in enforcement actions have a brand name which they wish to protect—a challenge to FSIS when the agency is alleging non-compliance with food safety regulations could damage a company's brand name. Third, the establishment may recognize it is placing itself at a competitive disadvantage by resorting to litigation. Fourth, even if a company is successful in litigation, it must not be forgotten that FSIS will continue inspecting the establishment when the case is over. The agency retains sufficient authority to increase the intensity of inspection and increase product testing for adulterants which will make operating under inspection more difficult. There have been three occasions when these practical considerations were not sufficient to dissuade the establishment from suing FSIS. In each of these cases, the establishment won.

V. THE TRILOGY OF LITIGATED SUSPENSION CASES

The number of cases filed in response to suspension actions is very limited. Indeed, the cases brought by establishments since the federal inspection system was created are few and far between. The practical factors must be weighed whenever litigation is considered and generally mitigate against the litigation option.

In the trilogy of cases, the need to challenge the suspension overcame the practical restrictions. In all of these cases, inspection had already been withdrawn (or would have been withdrawn the next day). Additionally, none of these firms had a recognizable brand name. Furthermore, the establishments believed either there was no violation or compliance was impossible. Finally, they recognized their business would be destroyed by a suspension so that future agency actions following the lawsuit would be moot if no lawsuit was initiated.

A. Velasam and Procedural Due Process

Strictly speaking, *In re Velasam Veal Connection*[156] was not a Mega-Reg case. The final Mega-Reg was not published until three days after the decision. However, it was perceived by many that the

156. 55 Agric. Dec. 300; 1996 WL 367077; 1996 WL 367076.

agency was testing its suspension authority in a case the agency thought itwould win.[157]

In early 1996, Velasam had entered a consent agreement with FSIS concerning the alleged harassment of FSIS officials.[158] The alleged harassment was linked to a 1995 recall of Velasam products based upon laboratory tests showing the presence of sulfites in the products. Sulfites cannot be added to meat directly since the substance masks spoilage, but can be added if the sulfites are a component of an ingredient. If added, the presence of sulfites need not be declared on the label if present at a level of ten parts per million (ppm) or less in the finished product.[159]

In May 1996, the agency conducted a laboratory test of one of Velasam's seasoning blends. The agency discovered the seasoning contained extremely low levels of sulfites fourteen parts per million (ppm). Without providing any notice or even the basis for its action, FSIS filed a complaint with the ALJ and summarily suspended inspection at Velasam on June 13, 1996.[160]

Velasam asserted that neither FMIA nor the previous consent agreement authorized the summary suspension and moved that the lawsuit be dismissed.[161] Under USDA Rules of Practice, an ALJ can grant any motion, except a motion to dismiss.[162] Accordingly, the ALJ did not grant the motion. This decision was appealed to the judicial officer who ruled that no motion to dismiss would be granted until the hearing was conducted. Alleging final agency action and irreparable harm, Velasam filed suit in the District Court for the Northern District of California asserting both that FSIS was required to provide notice and an opportunity to demonstrate or achieve compliance as required by APA and that FSIS lacked the statutory authority to suspend inspection.[163]

In its decision, the court chose to rule on the procedural issue thereby avoiding a ruling on the statutory authority. The court found that Section 558(c) of APA requires notice and opportunity

157. Litigation Notes from Dennis Johnson regarding *Velasam* (on file with author) [hereinafter Litigation Notes].

158. 55 Agric. Dec. 300, 1996 WL 367077 (U.S.D.A.); 1996 WL 367076 (U.S.D.A.).

159. FSIS Labeling Policy Memorandum 094B, Dec. 17, 1986, *available at* http://www.fsis.usda.gov/OPPDE/larc/Policies/PolicyMemos.pdf.

160. 55 Agric. Dec. 300, 1996 WL 367077 (U.S.D.A.); 1996 WL 367076 (U.S.D.A.).

161. *Id.*

162. 7 C.F.R. § 1.144 (2001).

163. *See* Litigation Notes, *supra* note 157.

prior to any suspension of a license absent public health concern or a willful violation.[164] Since this opportunity was not granted to Velasam, the court ordered FSIS to restore inspection during the pendency of the administrative proceeding. Interestingly, in discussing whether there was a willful violation, the district court noted: "Even presuming there is substantial evidence that Velasam added sulfites . . . the Court finds that at least a serious question is raised as to whether or not the [FSIS sulfite] policy is clear enough . . . ."[165] In light of the decision and the court's questioning as to whether any violation occurred, FSIS and Velasam settled the matter without hearing.[166]

As noted above, the *Velasam* caused consternation within FSIS. The agency officials were hoping to obtain a court decision supporting their interpretation that the agency can impose a suspension without any prior notice. The agency had included such a provision in this Mega-Reg proposal. Although the Rules of Practice were removed before the final rule published,[167] the *Velasam* decision was immediately incorporated into agency practice and ultimately incorporated in the rules regarding prior notice. Not only was notice required, but also there could be no suspension if the establishment could demonstrate or achieve compliance. Hence, the NOIE was born, which benefits both industry and FSIS. It provides establishments with due process, and by so doing, it helped minimize the number of actual suspensions which could have resulted in more frequent litigation challenging the suspension authority.

B. Supreme Beef and the Requirement of Adulteration

FSIS promised to issue its Rules of Practice following the promulgation of the final Mega-Reg, but FSIS did not do so for

164. *See id.*

165. *See id.*

166. As of this writing, Velasam is still in business, but lost most of its customers forever. Velasam did file a *Bivens* action against several FSIS officials in there personal capacity and won a judgment which is currently on appeal. *Id.*

167. Since the final rule was sent to the Federal Register on July 18, 1996, it could not have been modified based on the *Velasam* opinion, but it would be fair to say the Rules of Practice may not have been modified to provide notice had *Velasam* been decided differently. The text of the prior notice section of the regulations (9 C.F.R. § 500.4) dealing with "opportunity to demonstrate or achieve compliance" are taken verbatim from Section 558(c) of APA.

several years. Meanwhile, FSIS initiated enforcement actions, but did so consistently with *Velasam*—the agency provides notice and an opportunity to demonstrate or achieve compliance. However, it was simply a matter of time before a lawsuit was filed challenging the agency's authority to suspend for non-compliance with the Mega-Reg. When the first suit was filed, it did not challenge FSIS's asserted authority to suspend for HACCP or SSOP non-compliance, but rather the suspension for failure to meet the *Salmonella* performance standard.

The *Salmonella* performance standards were based on a national average incident rate. However, for ground beef, the national rate was an average of two distinct geographic rates. The northern plants[168] accounted for seventy percent of the samples but only thirty percent of the total positives. Conversely, the southern plants had seventy percent of the positives, while only comprising thirty percent of the samples.[169]

Under the Mega-Reg, if an establishment failed the performance standard on three consecutive tests, it was subject to suspendsion.[170] Given the ground beef standard's bias against southern establishments, it was not surprising that the first triple failure occurred in the south—specifically Texas.[171]

In October 1999, when Supreme Beef Processors, Inc., a beef grinder in Texas, failed its third set, FSIS issued an NOIE requiring the company to take action to ensure compliance with the standard.[172] As a result, Supreme took a variety of actions, and FSIS started a fourth set of samples. When it became clear that Supreme would fail the fourth set, FSIS notified Supreme that the agency was suspending inspection the next day. In response, Supreme filed for and received a temporary restraining order (TRO) requiring FSIS to continue inspection at the facility.[173] The primary argument used by Supreme was that FSIS lacked the statutory authority to suspend

168. *See* FSIS, *Nationwide Federal Plant Raw Ground Beef Microbiological Survey, Aug. 1993—Mar. 1994, available at* http://www.fsis.usda.gov/OPHS/baseline/rwgrbeef.pdf.
169. *Id.*
170. 9 C.F.R. § 310.25(b)(3) (2004). A third consecutive failure "constitutes failure to maintain sanitary conditions and failure to maintain an adequate HACCP plan."
171. Indeed, the second three set failure also occurred in Texas, but no litigation arose since the company passed FSIS verification (fourth) series. Supreme Beef Processors, Inc. v. USDA, 113 F. Supp. 2d 1048 (N.D. Tex. 2000).
172. *Id.*
173. *Id.* at 1051.

inspection based on the results of the *Salmonella* performance standard testing.

Although the performance standard regulation indicates that three consecutive failures constitutes non-compliance with sanitation and HACCP requirements,[174] FSIS only defended its action on the basis of the statutory provision dealing with insanitary conditions, Section 8 of FMIA. There was no challenge or defense made on the basis of the HACCP regulations. Hence, the agency's action could be justified, if at all, on whether there were insanitary conditions at the facility.[175] In this regard, the proceedings before the district court did not go well for the agency. At the hearing following the TRO, the Administrator of FSIS conceded during cross-examination that the agency sought suspension simply because of the *Salmonella* failures. Indeed, the Administrator basically admitted that there were no insanitary conditions at Supreme.[176]

The district court continued the TRO to allow both sides to brief the matter. During that time, FSIS initiated an intensified testing program at Supreme—not a testing program for *Salmonella*, but for the adulterant *E. coli* O157:H7. During the testing a product tested positive for the adulterant, and a recall took place.[177] Notwithstanding this positive test result, the court granted a preliminary

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174. *Id.*

175. The agency did try to assert that Supreme had not exhausted its administrative remedies. After the suit was filed, FSIS finally issued its Rules of Practice. 64 Fed. Reg. 66,541, 66,543 (Nov. 29, 1999). The agency tried to argue that under the rules, Supreme had to complete an administrative hearing before an ALJ. This defense was rejected by the District Court.

176. Q. Is it correct to say Mr. Billy that the Notice of Suspension that Supreme received about failure to maintain sanitary conditions is based solely on the alleged failure of ground beef to meet the *Salmonella* performance standards?

A. It's based on the successive failure of three *Salmonella* sample sets.

Q. It is not based on inspectors making a judgment and determination that the plant was in an insanitary condition?

A. There have not been significant problems with the sanitation practices in the plant.

Q. Is that a yes?

A. Yes, it would be a yes. Yes.

R. 1237-1238 on appeal to the Fifth Circuit No. 00-11008, *Supreme Beef Processors, Inc. v. USDA*, 275 F.3d 432 (5th Cir. 2001).

177. Recall Notification Report 062-99, Food Safety and Inspection Services, Dec. 26, 1999, *available at* http://www.fsis.usda.gov/0A/recalls/rnrfiles/rnr062-99.htm. Interestingly, the company was apprised of the positive on Christmas day.

injunction, holding that FSIS lacked the statutory authority to suspend inspection on the basis of the *Salmonella* failure.[178]

FSIS appealed, relying heavily on the *Nova Scotia*[179] case. According to FSIS, the term "sanitation" can cover all food safety controls at the establishment, and the *Salmonella* standard serves as a proxy to assess the effectiveness of those controls.[180] The Fifth Circuit rejected FSIS's argument. Without rejecting *Nova Scotia*, the court found that the *Salmonella* performance standard did not fit within the statutory provisions dealing with sanitation.[181] First, the *salmonella* performance standard "regulates the procurement of raw materials," not conditions *at* the establishment, which is required by the term "rendered" in the sanitary conditions provision.[182] Cross-contamination would not be sufficient.[183] Second, the mere presence of *Salmonella* does not render the product adulterated since *Salmonella* itself is neither an adulterant in raw ground beef, nor is it an indicator of adulterating pathogens.[184] Hence, the court concluded that the sanitary conditions provisions could not justify suspension.[185]

The court was careful to distinguish *Nova Scotia*. The Fifth Circuit referred to comments made by the Second Circuit indicating

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178. 113 F. Supp. 2d at 1055.

179. 568 F.2d 240.

180. For virtually the entire time the case was pending, FSIS was conducting daily testing of Supreme's product for *E. coli* O157:H7. Agency testing of fresh product puts a strain on a business for if the business ships, and there is a positive, the product must be recalled, which is not conducive to good customer relations. If the company holds the product for the five to seven days it takes to receive confirmed results from the agency, much of the fresh product's shelf life is gone. In addition, in the case of Supreme, it lost several government contracts due to the FSIS allegations. This all combined to force Supreme into bankruptcy. Ironically, once Supreme was in bankruptcy, FSIS moved to dismiss the appeal since it was moot in that the company may be out of business and hence not need inspection. The Fifth Circuit found that the case was not moot. *Supreme Beef Processors*, 275 F.3d 432, 438. Moreover, it allowed the National Meat Association to intervene so that even if Supreme did not resume its business, the case could be heard on appeal. *Id.*

181. *Id.* at 443.

182. *Id.* at 441.

183. *Id.* at 442.

184. *Supreme Beef Processor*, 275 F.2d at 442-43. Indeed, the court commented that FSIS may not actually want such a result, for if *Salmonella* is an indicator of an adulterant, it would mean that a raw product with *Salmonella* would be adulterated, eliminating many raw products currently being sold. *Id.*

185. *Id.*

a plausible argument could be made that the statute could apply only to conditions, not processes.[186] Moreover, unlike *Nova Scotia*, where the government looked to operations in the plant, the government in *Supreme* was focusing upon conditions outside the facility (i.e., incoming raw materials), which was unprecedented.[187]

In short, FSIS lost the case as a result of its inability to demonstrate the statutory requirements of the insanitary conditions provisions—the conditions must relate to the plant and there must be product adulteration. The issue of whether sanitation could encompass processing was not decided.

C. Nebraska Beef

The last of the "suspension cases," *Nebraska Beef*,[188] is very unsatisfying for the legal scholar because it did not truly advance the issue. Nebraska Beef had received an NOIE in 2002 due in part to concerns with condensation and sanitary dressing practices at slaughter. Moreover, Nebraska Beef was implicated in a positive *E. coli* O157:H7 test in ground product.[189]

In January 2003, while the President of Nebraska Beef, company counsel, and the company's trade association representative were meeting with the USDA Undersecretary for Food Safety, the District Office suspended inspection at the facility. The establishment promptly filed a request for a TRO to reinstate inspectors.[190]

In the complaint, Nebraska Beef alleged that its products were safe, that FSIS lacked the statutory authority to suspend, and that suspension imposed irreparable injury on the company.[191] The district court issued the TRO with most of its discussion centering on the economic harm caused by suspension. Instead of fighting the issue, FSIS simply entered a consent agreement with Nebraska Beef, stating that the company will comply with all FSIS regulations.[192]

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186. *Id.* at 441.
187. *Id.* at 442 n.38.
188. Nebraska Beef. Ltd. v. USDA, 2003 U.S. Dist. LEXIS 25104 (D. Neb. 2003); Nebraska Beef, Ltd. v. USDA, 2004 U.S. Dist. LEXIS 4993 (D. Neb. 2003).
189. *Id.*
190. *Id.*
191. *Id.*
192. *Id.*

Although FSIS touted that the case supported its authority, neither the opinion nor the settlement agreement supported such a claim. It could be the case that FSIS was simply caught unaware. Following *Nebraska Beef*, the agency embarked on an internal program designed to ensure it had adequate documentation throughout any enforcement proceeding.

VI. FSIS LACKS THE AUTHORITY TO SUSPEND FOR MEGA-REG VIOLATIONS

Based upon the trilogy of cases, it is clear that FSIS simply lacks the authority to suspend inspection for HACCP non-compliance, as well as non-compliance with the *Salmonella* and general sanitation performance standards. Even with SSOP non-compliance, the agency must meet its burden of proof.

A. The Language of Statute Does Not Authorize Suspension

Once again, the starting point is the language of the statute.[193] The section which speaks of suspension provides, in relevant part, "where the sanitary conditions of any such establishment are such that the meat or meat food products are rendered adulterated, [FSIS] shall refuse to allow said meat or meat food products to be labeled, marked, stamped, or tagged as 'inspected and passed.'"[194] Under the plain language of this provision, FSIS must have a basis to conclude the products are "rendered adulterated" as a precondition to imposing suspension.[195]

In regards to the meaning of "rendered," all courts have held that the conditions must be intrinsic to the establishment.[196] Mere cross-contamination is not sufficient.[197] As for the meaning of "adulterated," the agency must demonstrate that the product would

193. *See generally Chevron*, 467 U.S. 837 (1984).

194. Section 8 of FMIA, 21 U.S.C. § 608 (2004).

195. The actual language of FMIA does not technically provide for suspension of inspection or the removal of federal inspectors. It only authorizes the refusal to mark products "inspected and passed." The inspector must remain in the facility. It is PPIA which speaks of "refusing inspection." 21 U.S.C. § 456(b) (2004). However, this is more of a technical difference since the mere presence of an inspector at the facility does not change the effect of a suspension.

196. *Supreme Beef Processors*, 275 F.3d 442 n.38.

197. *Id.* at 442.

be adulterated as that term is specified by FMIA or PPIA.[198] Hence, findings of pathogenic organisms on raw products which do not adulterate the product would be insufficient to justify the use of Section 8's suspension authority. More specifically, the presence of *Salmonella* on any raw product would not constitute adulteration and could not be used to justify suspension.

In the cases under Section 8, FSIS would need to establish adulteration under Section 1(m)(4) of FMIA.[199] This section provides that a product is adulterated "[i]f it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health." Under this section, actual contamination of product need not be shown.[200] However, the government must show that the food was processed under conditions whereby there is a reasonable possibility that the product was contaminated from the insanitary conditions.[201]

Accordingly, to meet its burden of proof, FSIS must establish that insanitary conditions existed at the establishment and there is a reasonable possibility that the food will become contaminated with filth or rendered injurious as the result of those insanitary conditions.[202] Addressing the latter factor first, in the absence of a nexus between the conditions and the product, no adulteration could occur. Non-compliance with the FSIS general sanitation performance standard alone, which unlike the SSOPs does not deal with

198. *Id.* at 438-39.

199. 21 U.S.C. § 601(m)(4) (2004).

200. United States v. H. B. Gregory, 502 F.2d 700, 704 (7th Cir. 1974); United States v. General Foods Corp., 446 F. Supp. 740, 752 (N.D.N.Y.), *aff'd* 591 F.2d 1332 (2d Cir. 1978). Many of the cases cited in this article interpret the identical language from FDCA, 21 U.S.C. § 342(a)(4). In adopting this language for the FMIA, Congress intended that "essentially the same criteria be applied in determining wholesomeness . . . ." S. REP. NO. 90-799, *reprinted in* 1967 U.S.C.C.A.N. 2188, 2203.

201. United States v. International Exterminator Corp., 294 F.2d 270, 271 (5th Cir. 1961); Berger v. United States, 200 F.2d 818, 821 (2d Cir. 1952); *General Foods Corp.*, 446 F. Supp. at 752.

202. 21 U.S.C. § 601(m)(4) (2004); *Gregory*, 502 F.2d at 704.

direct contamination, would not be grounds for suspension.[203] Hence, the critical issue is the meaning of "insanitary conditions."[204]

B. The Case Law Does Not Support Suspension Absent Visible Evidence of Insanitary Conditions at the Facility

Based upon the thorough review of the case law regarding insanitary conditions, in order for the government to be successful, it must introduce evidence of visible, insanitary conditions of the facility. There is one exception—*Nova Scotia*. In that case, the court expanded the definition of insanitary conditions to include processing as opposed to the physical condition of the facility.[205] However, the *Nova Scotia* case is so readily distinguishable that it does not support FSIS's asserted suspension authority.

As an initial matter, the court in *Nova Scotia* recognized it was expanding the definitions of insanitary conditions beyond the normal meaning.[206] However, the court was willing to read the statutory provision expansively for a number of reasons: (a) a public health statute should be read broadly, (b) Congress gave no indication to read the provision narrowly, (c) the "knowledgeable" bar had never challenged FDA's authority, (d) FSIS had established similar standards, and (e) invalidating this rule would invalidate other rules.[207] On each of these points above, FSIS's asserted authority to suspend for reasons other than insanitary plant conditions fails to meet the reasons used by the court in *Nova Scotia* to justify its expansive reading.

First, FMIA and PPIA are public health statutes and should be read broadly.[208] However, the issue before the court in *Nova Scotia* was not whether an agency can suspend inspection. In *Nova Scotia*, the issue was whether FDA could regulate the processing in the first

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203. 9 C.F.R. § 500.4 (2004). United States v. International Exterminator Corp., 294 F.2d 270, 271 (5th Cir. 1961); Berger v. United States, 200 F.2d 818, 821 (2d Cir. 1952); *General Foods Corp.*, 446 F. Supp. at 752.

204. 21 U.S.C. § 601(m)(4) (2004).

205. *Nova Scotia*, 568 F.2d at 245.

206. *Id.* The court admitted that "on a first reading the language of the subsection appears to cover only 'insanitary conditions,' '*whereby* it [the food] may have been rendered injurious to health' . . . And a plausible argument can be made that the references are to insanitary conditions in the plant itself . . . ." *Id.*

207. *Id.* at 246-48.

208. *Id.* at 246.

instance to protect the public health.[209] Here, the issue is not whether FSIS can adopt HACCP regulations since such authority is clearly granted in the inspection acts.[210] The issue was whether FSIS can suspend inspection for the failure to follow such regulations. Suspension simply is not necessary to achieve the public health goal. Indeed, FSIS has sufficient statutory authority to protect the public health by seeking an injunction "to prevent and restrain violations" of a public health requirement—the same injunctive authority sought by FDA in *Nova Scotia.*[211]

The second basis of the *Nova Scotia* decision is congressional intent. On the issue of suspension, Congress clearly did not intend to provide the agency with unfettered discretion when it came to suspension of inspection. Not only did Congress prescribe precisely when such authority could be exercised, but also it specified how it should be exercised. For example, in the case of withdrawal based upon convictions, the statute provides the due process requirements.[212] More importantly, in the 1986 Amendments (which expired in 1992), Congress called the power to suspend an "extraordinary authority" and should be exercised only in a federal district court proceeding with full due process protections for the establishment.[213] Third, in the public meetings on the Mega-Reg, every lawyer present testified that, with the exception of insanitary conditions at the plant resulting in adulterated product, FSIS lacked the authority to suspend for HACCP and *Salmonella* performance standard failures.[214]

In response to the last two justifications, FMIA does give FSIS the authority to promulgate processing standards, and the "knowledgeable bar" is in agreement with this authority. The only regulations which would be invalid here are those Sections of the Rules of Practice in 9 C.F.R. Part 500, which are not within FSIS's statutory authority. In sum, the reasons which led the court in *Nova*

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209. *Nova Scotia*, 568 F.2d at 242-43, 245.

210. Section 21 of FMIA provides the "all inspections and examinations . . . shall be made in such a manner as described in the rules and regulations prescribed by "FSIS." 21 U.S.C. § 621 (1999); *see also* Section 14(b) of PPIA, 21 U.S.C. § 463 (1999).

211. Section 21 of PPIA, 21 U.S.C. § 467(c); Section 404 of FMIA, 21 U.S.C. § 674.

212. Section 18 of PPIA, 21 U.S.C. § 467; Section 401 of FMIA, 21 U.S.C. § 671 (2004).

213. H.R. REP. 99-624 at 37 (1986), *reprinted* in 1986 U.S.C.C.A.N 6066, 6083.

214. H.R. REP. 99-624 at 37 (1986), *reprinted* in 1986 U.S.C.C.A.N 6066, 6083.

Scotia to abandon the plain language of the statute do not apply in the case of FSIS' authority to suspend inspection in cases other than "traditional" insanitary conditions.

C. FSIS's Previous Actions Have Demonstrated the Need For Judicial Involvement in Suspension Matters

Beyond these legal arguments, there is a policy argument to support the conclusion that FSIS lacks the authority asserted—the need to ensure suspension is imposed only when it is justified. It should be noted that under the Rules of Practice FSIS can suspend inspection without any external review outside the agency. It can even withdraw inspection based on the review of an ALJ.

Without the requirement of a disinterested third party review, which would occur if FSIS requested an injunction from a federal district court, there can be errors. Indeed, there have been errors. The one thread linking the three "suspension cases" is that the agency could not justify its actions to the court.

In *Velasam*,[215] the court noted that FSIS had no evidence that there had been a violation.[216] Yet, Velasam was closed for over a month. In *Supreme*, FSIS testified that there were no problems with sanitation at Supreme. Yet, Supreme would ultimately file for bankruptcy.[217] In *Nebraska Beef*,[218] though it will never be known, the speed with which FSIS settled and the initiation of a new internal procedure at the agency to handle enforcement cases creates an inference that the agency was ill-prepared to defend its actions calling into serious question whether the suspension should have been imposed in the first instance.

As an endnote to *Velasam* and *Nebraska Beef*, following the suspension, both companies filed a federal claims action against various FSIS personnel in their individual capacities. Velasam received an award in its case, and Nebraska Beef's case is still pending.[219]

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215. 55 Agric. Dec. 300; 1996 WL 367077; 1996 WL 367076.

216. *Id.*

217. Although Supreme won its case, it lost the war——FSIS began testing all product for *E. coli* O157:H7 on a daily basis, an unprecedented action which raises the appearance of vindictiveness. Ultimately, the delay in shipping posed by this intensified testing resulted in Supreme's bankruptcy.

218. Nebraska Beef. Ltd. v. USDA, 2003 U.S. Dist. LEXIS 25104 (D. Neb. 2003); Nebraska Beef, Ltd. v. USDA, 2004 U.S. Dist. LEXIS 4993 (D. Neb. 2003).

219. *Id.*

FSIS has chosen never to institute an injunction against an inspected establishment for the failure to follow the regulations. Indeed, when FSIS had the authority to suspend under the 1986 Amendments, but only through a district court proceeding, it never exercised the authority. It would seem that FSIS would rather act unilaterally as prosecutor, judge, jury, and executioner than make a case before a federal judge. Based upon the agency's track record, it is easy to understand why.

VII. CONCLUSION

It is a truism of administrative law that an agency cannot take action except as authorized by statute.[220] In the case of the inspection acts, Congress has provided FSIS with the authority to suspend only in discrete circumstances, none of which authorize suspension for an inadequate HACCP program or the failure to comply with a *Salmonella* performance standard or the general sanitation performance standards. To assert that FSIS has such authority is not only contrary to the plain language of the statute, Congressional intent, and case law, but is also simply ill-advised.

220. *See generally Chevron*, 467 U.S. 837 (1984).