275 F.3d 432
United States Court of Appeals,
Fifth Circuit.

SUPREME BEEF PROCESSORS, INC., Plaintiff–Appellee,
v.
UNITED STATES DEPARTMENT OF AGRICULTURE, Defendant–Appellant.

No. 00–11008.
|
Dec. 6, 2001.

**Synopsis**

Meat processor that allegedly failed to implement adequate health hazards prevention plan sued United States Department of Agriculture (USDA), on theory that USDA had exceeded its authority under Federal Meat Inspection Act (FMIA) when it used *Salmonella* tests to evaluate compliance with performance standards. Parties cross-moved for summary judgment. The United States District Court for the Northern District of Texas, A. Joe Fish, J., 113 F.Supp.2d 1048, granted plaintiff's motion for summary judgment, and denied motion for reconsideration, 2000 WL 963483, and appeal was taken. The Court of Appeals, Patrick E. Higginbotham, Circuit Judge, held that: (1) government's appeal from judgment of district court finding that *Salmonella* performance standards of USDA exceeded the USDA's statutory authority, and enjoining enforcement of these standards against meat processor, was not rendered moot by processor's Chapter 7 case; (2) association of meat processors was entitled to intervene; (3) legislature's use of term "rendered," in federal statute providing that meat product is adulterated, and subject to regulation by the USDA, if it is "prepared, packed or held under insanitary conditions whereby it may have been rendered injurious to health," indicates that deleterious change in product must occur while it is being "prepared, packed or held"; and (4) USDA could not use *Salmonella* tests conducted on meat processing plant's final products to determine whether plant was insanitary.

Affirmed and remanded.

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Appeal from the United States District Court for the Northern District of Texas.

Before REAVLEY, HIGGINBOTHAM and PARKER, Circuit Judges.

**Opinion**

PATRICK E. HIGGINBOTHAM, Circuit Judge:

Certain meat inspection regulations promulgated by the Secretary of Agriculture, which deal with the levels of *Salmonella* in raw meat product, were challenged as beyond the statutory authority granted to the Secretary by the Federal Meat Inspection Act. The district court struck down the regulations. We hold that the regulations fall outside of the statutory grant of rulemaking authority and affirm.

I

The Federal Meat Inspection Act authorizes the Secretary of Agriculture to "prescribe the rules and regulations of sanitation" covering

> slaughtering, meat canning, salting, packing, rendering, or similar

> establishments in which cattle, sheep, swine, goats, horses, mules and other equines are slaughtered and the meat and meat food products thereof are prepared for commerce.... [1]

Further, the Secretary is commanded to,

> where the sanitary conditions of any such establishment are such that the meat or meat food products are rendered adulterated, ... refuse to allow said meat or meat food products to be labeled, marked, stamped, or tagged as "inspected and passed." [2]

In sum, the FMIA instructs the Secretary to ensure that no adulterated meat products pass USDA inspection, which they must in order to be legally sold to consumers. [3]

The FMIA contains several definitions of "adulterated," including 21 U.S.C. § 601(m)(4), which classifies a meat product as adulterated 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." [4] Thus, the FMIA gives the Secretary the power to create sanitation regulations and commands him to withhold meat approval where the meat is processed under insanitary conditions. The Secretary has delegated the authority under the FMIA to the Food Safety and Inspection Service.

In 1996, FSIS, after informal notice and comment rulemaking, adopted regulations ***435** requiring all meat and poultry establishments to adopt preventative controls to assure product safety. These are known as Pathogen Reduction, Hazard Analysis and Critical Control Point Systems or "HACCP." [5] HACCP requires, *inter alia,* that meat and poultry establishments institute a hazard control plan for reducing and controlling harmful bacteria on raw meat and poultry products. In order to enforce HACCP, FSIS performs tests for the presence of *Salmonella* in a plant's finished meat products.

The *Salmonella* performance standards set out a regime under which inspection services will be denied to an establishment if it fails to meet the standard on three consecutive series of tests. [6] The regulations declare that the third failure of the performance standard "constitutes failure to maintain sanitary conditions and failure to maintain an adequate HACCP plan ... for that product, and will cause FSIS to suspend inspection services." [7] The performance standard, or "passing mark," is determined based on FSIS's "calculation of the national prevalence of *Salmonella* on the indicated raw product." [8]

In June, 1998, plaintiff-appellee Supreme Beef Processors, Inc., a meat processor and grinder, implemented an HACCP pathogen control plan, and on November 2, 1998, FSIS began its evaluation of that plan by testing Supreme's finished product for *Salmonella*. After four weeks of testing, FSIS notified Supreme that it would likely fail the *Salmonella* tests. Pursuant to the final test results, which found 47 percent of the samples taken from Supreme contaminated with *Salmonella,* [9] FSIS issued a Noncompliance Report, advising Supreme that it had not met the performance standard. Included in the report was FSIS's warning to Supreme to take "immediate action to meet the performance standards." Supreme responded to FSIS's directive on March 5, 1999, summarizing the measures it had taken to meet the performance standard and requesting that the second round of testing be postponed until mid-April to afford the company sufficient time to evaluate its laboratory data. FSIS agreed to the request and began its second round of tests on April 12, 1999.

On June 2, 1999, FSIS again informed Supreme that it would likely fail the *Salmonella* tests and, on July 20, issued another Noncompliance Report—this time informing Supreme that 20.8 percent of its samples had tested positive for *Salmonella*. Supreme appealed the Noncompliance Report, citing differences between the results obtained by FSIS and Supreme's own tests conducted on "companion parallel samples." Those private tests, Supreme asserted, had produced only a 7.5 percent *Salmonella* infection level, satisfying the performance standard. FSIS denied the appeal; but based on Supreme's commitment to install 180 degree water source on all boning and trimming lines, granted the company's request to postpone the next round of *Salmonella* testing for 60 days. FSIS later withdrew the

  

extension, however, after learning that Supreme was merely considering installation of the water source.

The third set of tests began on August 27, 1999, and after only five weeks, FSIS advised Supreme that it would again fall short of the ground beef performance standard. ***436** On October 19, 1999, FSIS issued a Notice of Intended Enforcement Action, which notified Supreme of the agency's intention to suspend inspection activities. The Notice gave Supreme Beef until October 25, 1999 to demonstrate that its HACCP pathogen controls were adequate or to show that it had achieved regulatory compliance. Although Supreme Beef promised to achieve the 7.5 percent performance standard in 180 days, it failed to provide any specific information explaining how it would accomplish that goal, and FSIS decided to suspend inspection of Supreme's plant.

On the day FSIS planned to withdraw its inspectors, Supreme brought this suit against FSIS's parent agency, the USDA, alleging that in creating the *Salmonella* tests, FSIS had overstepped the authority given to it by the FMIA. Along with its complaint, Supreme moved to temporarily restrain the USDA from withdrawing its inspectors. The district court granted Supreme's motion and, after a subsequent hearing, also granted Supreme's motion for a preliminary injunction.

The National Meat Association filed a motion to intervene as a plaintiff in the district court. The district court denied the motion on the grounds that NMA was adequately represented by Supreme in this litigation. The district court allowed NMA and other industry groups, as well as various consumer advocacy groups, to file briefs.

On cross-motions for summary judgment, the district court granted summary judgment in favor of Supreme, finding that the *Salmonella* performance standard exceeded the USDA's statutory authority and entering a permanent injunction against enforcement of that standard against Supreme. The USDA now appeals.

## II

We first must address the USDA's suggestion of mootness. In September, 2000, during the pendency of this appeal, Supreme filed for Chapter 11 bankruptcy. The USDA moved to lift the stay on the appeal and filed a suggestion of mootness with this Court. Supreme argued that it intended to resume operations after reorganization and that the injunction against enforcement of the *Salmonella* performance standard was critical to that reorganization. A motions panel of this Court denied the motion to remand the case with instructions to dismiss as moot on January 2, 2000. On May 9, 2001, the Bankruptcy Court converted Supreme's case into a Chapter 7 liquidation.

**[1]** **[2]** The USDA has again raised the question of mootness. While we are not bound by the earlier determination of the motions panel, which in any event was made while Supreme was still in Chapter 11, rather than Chapter 7, proceedings,[10] Supreme asserts that it has substantial assets and could emerge solvent from the Chapter 7 liquidation proceeding. "In general a matter is moot for Article III purposes if the issues presented are no longer live or the parties lack a legally cognizable interest in the outcome."[11] The possibility that Supreme may continue to function as a meat processor even after ***437** its Chapter 7 proceeding satisfies Article III.[12]

The USDA argues that this case is moot because even if Supreme reopens "it is conceivable that it will not open at the same establishment where the violations of the *Salmonella* standard occurred and will not use the same suppliers." However, the district court's order is not specific to Supreme's place of business nor its suppliers. The Amended Final Judgment provides in part:

> 1. 9 C.F.R. 310.25(b) is hereby declared to be outside the statutory authority of the United States Secretary of Agriculture (the "Secretary") and the United States Department of Agriculture (the "USDA")....

This injunction issued because the district court determined that the USDA was without statutory authority to promulgate the *Salmonella* performance standards—it cannot be logically restricted to a particular facility.

**[3]** Furthermore, NMA, having submitted a brief as an *amicus curiae* supporter of Supreme, again moved to intervene as an appellee, arguing that were we to find that the case was moot with respect to Supreme, NMA's interests were no longer adequately represented

by Supreme and this inadequacy only arose during the pendency of the appeal.

**[4]** We granted NMA's motion to intervene. "A party is entitled to an intervention of right if (1) the motion to intervene is timely; (2) the potential intervener asserts an interest that is related to the property or transaction that forms the basis of the controversy in the case into which [it] seeks to intervene; (3) the disposition of that case may impair or impede the potential intervener's ability to protect [its] interest; and (4) the existing parties do not adequately represent the potential intervener's interest."[13] The district court denied NMA's motion to intervene because it found that NMA's interests were adequately represented by Supreme. In all other respects, NMA satisfies the requirements of intervention as of right under Rule 24(a),[14] and we address only adequacy of representation here.

**[5]** We recognize that while Supreme retains a legally cognizable interest in the outcome of this case, this is because of the possibility that Supreme will emerge from bankruptcy as an entity wishing to carry out meat processing operations. It is also possible, we understand, that Supreme will not so emerge from bankruptcy and be dissolved, perhaps during the pendency of any petition for panel rehearing, rehearing *en banc,* or writ of certiorari before the U.S. Supreme Court. NMA need only show that Supreme's representation ***438** "may be" inadequate,[15] and we find the possibility that the case could be mooted by decisions made in Supreme's Chapter 7 proceeding sufficient to satisfy this requirement of Rule 24(a). Were Supreme to cease to exist as a legal entity, or were the case to otherwise become moot with respect to Supreme, NMA would be put in the position of having to re-litigate identical issues on which Supreme was successful in the district court. The interest in avoiding piecemeal litigation is thus served by allowing NMA's intervention.[16]

Having concluded that this case is not moot, we now turn to the question of whether the *Salmonella* performance standard represents a valid exercise of rulemaking authority under the FMIA.

## III

**[6]** Our analysis in this case is governed by the approach first enunciated by the Supreme Court in *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*[17] The *Chevron* inquiry proceeds in two steps. First, the court should look to the plain language of the statute and determine whether the agency construction conflicts with the text.[18] Then, "[i]f the agency interpretation is not in conflict with the plain language of the statute, deference is due."[19] The district court held the *Salmonella* performance standard invalid as exceeding the statutory authority of the USDA under the first step of the *Chevron* inquiry.

### A

Following *Chevron*, we first repair to the text of the statute that the USDA relies upon for its authority to impose the *Salmonella* performance standard. The USDA directs us to 21 U.S.C. § 601(m)(4), which provides that a meat product is adulterated

> 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.

This statutory definition is broader than that provided in 21 U.S.C. § 601(m)(1), which provides that a meat product is adulterated

> if it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance, such article shall not be considered adulterated under this clause if the quantity of such substance in or on such article does not ordinarily render it injurious to health.

Thus if a meat product is "prepared, packed or held under insanitary conditions" such that it *may* be adulterated for purposes of § 601(m)(1), then it is, by definition, adulterated for purposes of § 601(m)(4). The USDA is

then commanded to refuse to stamp the meat products "inspected and passed." [20]

**[7]** The difficulty in this case arises, in part, because *Salmonella,* present in a substantial proportion of meat and poultry ***439** products, is not an adulterant *per se,* [21] meaning its presence does not require the USDA to refuse to stamp such meat "inspected and passed." [22] This is because normal cooking practices for meat and poultry destroy the *Salmonella* organism, [23] and therefore the presence of *Salmonella* in meat products does not render them "injurious to health" [24] for purposes of § 601(m)(1). *Salmonella*-infected beef is thus routinely labeled "inspected and passed" by USDA inspectors and is legal to sell to the consumer.

Supreme maintains that since *Salmonella*-infected meat is not adulterated under § 601(m)(1), the presence or absence of *Salmonella* in a plant cannot, by definition, be "insanitary conditions" such that the product "may have been rendered injurious to health," as required by § 601(m)(4). The USDA, however, argues that *Salmonella* 's status as a non-adulterant is not relevant to its power to regulate *Salmonella* levels in end product. This is because the USDA believes that *Salmonella* levels can be a proxy for the presence or absence of means of pathogen [25] controls that are required for sanitary conditions under § 601(m)(4). However, as we discuss, and as the USDA admits, the *Salmonella* performance standard, whether or not it acts as a proxy, regulates more than just the presence of pathogen controls.

The district court agreed with Supreme and reasoned that "[b]ecause the USDA's performance standards and *Salmonella* tests do not necessarily evaluate the *conditions* of a meat processor's establishment, they cannot serve as the basis for finding a plant's meat adulterated under § 601(m)(4)." [26] The district court therefore held that the examination of a plant's end product is distinct from "conditions" within the plant for purposes of § 601(m)(4) because *Salmonella* may have come in with the raw material.

We must decide two issues in order to determine whether the *Salmonella* performance standard is authorized rulemaking under the FMIA: a) whether the statute allows the USDA to regulate characteristics of raw materials that are "prepared, packed or held" at the plant, such as *Salmonella* infection; and b) whether § 601(m)(4)'s "insanitary conditions" such that product "may have been rendered injurious to health" includes the presence of *Salmonella*-infected beef in a plant or the increased likelihood of cross-contamination with *Salmonella* that results from grinding such infected beef. Since we are persuaded that the *Salmonella* performance standard improperly regulates the ***440** *Salmonella* levels of incoming meat and that *Salmonella* cross-contamination cannot be an insanitary condition such that product may be rendered "injurious to health," we conclude that the *Salmonella* performance standard falls outside of the ambit of § 601(m)(4).

## B

### 1

**[8]** In order for a product to be adulterated under § 601(m)(4), as the USDA relies on it here, [27] it must be "prepared, packed or held under insanitary conditions ... whereby it may have been *rendered* injurious to health." [28] The use of the word "rendered" in the statute indicates that a deleterious change in the product must occur while it is being "prepared, packed or held" owing to insanitary conditions. Thus, a characteristic of the raw materials that exists before the product is "prepared, packed or held" [29] in the grinder's establishment cannot be regulated by the USDA under § 601(m)(4). [30] The USDA's interpretation ignores the plain language of the statute, which includes the word "rendered." Were we to adopt this interpretation, we would be ignoring the Court's repeated admonition that, when interpreting a statute, we are to "give effect, if possible, to every clause and word of a statute." [31]

**[9]** The USDA claims, however, that the *Salmonella* performance standard serves as a proxy for the presence or absence of pathogen controls, such that a high level of *Salmonella* indicates § 601(m)(4) adulteration. [32] Supreme oversimplifies ***441** its argument by claiming, essentially, that the USDA can never use testing of final product for a non-adulterant, such as *Salmonella,* as a proxy for conditions within a plant.

  

We find a similar, but distinct, defect in the *Salmonella* performance standard. The USDA admits that the *Salmonella* performance standard provides evidence of: (1) whether or not the grinder has adequate pathogen controls; and (2) whether or not the grinder uses raw materials that are disproportionately infected with *Salmonella.* Supreme has, at all points in this litigation, argued that it failed the performance standard not because of any condition of its facility, but because it purchased beef "trimmings" that had higher levels of *Salmonella* than other cuts of meat. The USDA has not disputed this argument, and has merely argued that this explanation does not exonerate Supreme, because the *Salmonella* levels of incoming meat are fairly regulated under § 601(m)(4). [33] Our textual analysis of § 601(m)(4) shows that it cannot be used to regulate characteristics of the raw materials that exist before the meat product is "prepared, packed or held." Thus, the regulation fails, but not because it measures *Salmonella* levels and *Salmonella* is a non-adulterant. The performance standard is invalid because it regulates the procurement of raw materials.

2

Our determination here is not in tension with the Second Circuit's decision interpreting identical language under the Food, Drug, and Cosmetic Act in *United States v. Nova Scotia Food Products Corp.* [34] In *Nova Scotia* the defendant challenged an FDA regulation requiring the heating of smoked fish to combat the toxin formation of *Clostridium botulinum* spores, which cause botulism. The defendant argued that "the prohibition against 'insanitary conditions' embraces conditions only in the plant itself, but does not include conditions which merely inhibit the growth of organisms already in the food when it enters the plant in its raw state." [35] The court gave "insanitary conditions" a broad reading and upheld the regulation. [36] Nevertheless, it conceded that "a plausible argument can, indeed, be made that the references are to insanitary conditions in the plant itself, such as the presence of rodents or insects...." [37]

While this may appear to conflict with our determination that pre-existing characteristics of raw materials before they are "prepared, packed or held" are not within ***442** the regulatory reach of § 601(m)(4), the regulations at issue in *Nova Scotia* did not attempt to control the levels of *Clostridium botulinum* spores in incoming fish, as the performance standard does to *Salmonella* in incoming raw meat. Instead, the regulations in *Nova Scotia* required the use of certain heating and salination procedures to inhibit growth of the spores. [38]

*Nova Scotia* did not consider the argument before us today, which is that the statute does not authorize regulation of the levels of bacterial infection in incoming raw materials. The argument that *Nova Scotia* entertained was that "Congress did not mean to go so far as to require sterilization sufficient to kill bacteria that may be in the food itself rather than bacteria which accreted in the factory through the use of insanitary equipment." [39] The required sterilization under the regulations at issue in *Nova Scotia* obviously occurred within the plant and did not regulate the quality of incoming fish.

3

The USDA and its amicus supporters argue that there is no real distinction between contamination that arrives in raw materials and contamination that arises from other conditions of the plant. This is because *Salmonella* can be transferred from infected meat to non-infected meat through the grinding process. The *Salmonella* performance standard, however, does not purport to measure the differential between incoming and outgoing meat products in terms of the *Salmonella* infection rate. Rather, it measures final meat product for *Salmonella* infection. Thus, the performance standard, of itself, cannot serve as a proxy for cross-contamination because there is no determination of the incoming *Salmonella* baseline.

Moreover, the USDA has not asserted that there is any correlation between the *presence* of *Salmonella* and the *presence* of § 601(m)(1) adulterant pathogens. The rationale offered by the USDA for the *Salmonella* performance standard—that "intervention strategies aimed at reducing fecal contamination and other sources of *Salmonella* on raw product should be effective against other pathogens" [40] —does not imply that the presence of *Salmonella* indicates the presence of these other, presumably § 601(m)(1) adulterant, pathogens. [41] Cross-contamination of *Salmonella* alone cannot form the basis of a determination that a plant's products are ***443** §

601(m)(4) adulterated, because *Salmonella* itself does not render a product "injurious to health" for purposes of both §§ 601(m)(1) and 601(m)(4).

Not once does the USDA assert that *Salmonella* infection indicates infection with § 601(m)(1) adulterant pathogens.[42] Instead, the USDA argues that the *Salmonella* infection rate of meat product correlates with the use of pathogen control mechanisms and the quality of the incoming raw materials. The former is within the reach of § 601(m)(4), the latter is not.

IV

Because we find that the *Salmonella* performance standard conflicts with the plain language of 21 U.S.C. § 601(m)(4), we need not reach Supreme's numerous alternative arguments for invalidating the standard, which were not addressed by the district court.

V

We AFFIRM and REMAND with instructions that the final judgment of the district court be amended to include the National Meat Association.

**All Citations**

275 F.3d 432, 51 Fed.R.Serv.3d 1445

Footnotes

1 21 U.S.C. § 608.
2 *Id.*
3 The FMIA requires that adulterated meat products be stamped "inspected and condemned" and destroyed. 21 U.S.C. § 606.
4 *Id.* § 601(m)(4).
5 9 C.F.R. Pt. 417.
6 *Id.* § 310.25(b).
7 *Id.* § 310.25(b)(3)(iii).
8 *Id.* § 310.25(b)(2) tbl. 2 n.a.
9 The performance standard for raw ground beef is 7.5 percent. *Id.*
10 *AT&T Communications of the Southwest, Inc. v. City of Dallas,* 243 F.3d 928, 930 (5th Cir.2001) (stating that although a motions panel had denied a motion to vacate as moot, court could consider arguments on appeal and "overturn [the motions panel] where necessary." (quoting *Mattern v. Eastman Kodak, Co.,* 104 F.3d 702, 704 (5th Cir.1997))).
11 *Sierra Club v. Glickman,* 156 F.3d 606, 619 (5th Cir.1998).
12 Since we find that Article III is satisfied by Supreme's continuing legally cognizable interest in the outcome, we need not address its argument that this case falls into that category of disputes capable of repetition yet evading review.
13 *John Doe No. 1. v. Glickman,* 256 F.3d 371, 375 (5th Cir.2001).
14 Fed.R.Civ.P. 24(a). There can be no serious dispute that NMA's original motion to intervene was timely and that NMA has an interest in this lawsuit, given that it deals with the application of a performance standard that affects NMA's members. NMA has standing to pursue this appeal. "An association has standing to bring a suit on behalf of its members when: (1) its members would otherwise have standing to sue in their own right; (2) the interests it seeks to protect are germane to the organization's purpose; and (3) neither the claim asserted nor the relief requested requires the participation of individual members." *Central and South West Services, Inc. v. EPA,* 220 F.3d 683, 698 (5th Cir.2000).
15 *Sierra Club v. Espy,* 18 F.3d 1202, 1207 (5th Cir.1994).
16 *See, e.g., Goodman v. Heublein,* 682 F.2d 44, 47 (2d Cir.1982) (granting motion to intervene in part to avoid piecemeal litigation).
17 467 U.S. 837, 104 S.Ct. 2778, 81 L.Ed.2d 694 (1984).
18 *Nat'l R.R. Passenger Corp. v. Boston & Maine Corp.,* 503 U.S. 407, 417, 112 S.Ct. 1394, 118 L.Ed.2d 52 (1992).
19 *Id.*
20 21 U.S.C. § 608.

  

21 *See American Pub. Health Ass'n v. Butz,* 511 F.2d 331, 334 (D.C.Cir.1974) ("[T]he presence of salmonellae on meat does not constitute adulteration within this definition [of 'adulterated,' provided in 21 U.S.C. § 601(m) ]."). The USDA agrees in this case that *Salmonella* is not an adulterant *per se,* meaning it is not a § 601(m)(1) adulterant. Appellant's Brief at 11.

22 21 U.S.C. § 608.

23 *Butz,* 511 F.2d at 334 ("American housewives and cooks normally are not ignorant or stupid and their methods of preparing and cooking of food do not ordinarily result in salmonellosis.").

24 *Cf. Continental Seafoods, Inc. v. Schweiker,* 674 F.2d 38, 41 (D.C.Cir.1982) (stating that *Salmonella* is a *per se* adulterant in shrimp).

25 The USDA uses the term "pathogen" to refer to both § 601(m)(1) adulterants, such as pathogenic *E.coli,* and non-adulterants, such as *Salmonella.* Thus, under the proxy theory, *Salmonella* control correlates with adulterant-pathogen control.

26 *Supreme Beef Processors, Inc. v. USDA,* 113 F.Supp.2d 1048, 1052–53 (N.D.Tex.2000) (emphasis in original).

27 The USDA does not contend that failure of the *Salmonella* performance standard serves as a proxy for contamination with filth, the other prong dealt with by § 601(m)(4). Even if the USDA made such an assertion, § 601(m)(4) speaks of insanitary conditions such that a product "becomes" contaminated with filth, which has a similar textual meaning as "rendered."

28 21 U.S.C. § 601(m)(4) (emphasis added).

29 This case does not require us to define precisely when a product begins the process of being "prepared, packed or held." We recognize only that this process cannot begin until the raw materials are brought to the plant. Thus, the condition of the raw materials may not be regulated by § 601(m)(4).

30 However, measures that would alter such a characteristic, such as heating fish to destroy the bacteria that causes botulism, are within the scope of § 601(m)(4). *See* Part III.B.2.

31 *Duncan v. Walker,* 533 U.S. 167, 121 S.Ct. 2120, 2125, 150 L.Ed.2d 251 (2001) (quoting *United States v. Menasche,* 348 U.S. 528, 538–39, 75 S.Ct. 513, 99 L.Ed. 615 (1955)).

32 We note that the USDA's assertions on this point are suspect. It is clear that the motivation behind the *Salmonella* performance standard was the regulation of *Salmonella* itself, and the FSIS has admitted as much in the Final Rule, though this admission is absent from the USDA's briefs in this case. *See* Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems; Final Rule, 61 Fed.Reg. 38806, 38850 ("Because testing for *E. coli* cannot serve as a surrogate for the presence of *Salmonella,* FSIS's *specific public health objective of reducing nationwide* Salmonella *levels on raw meat and poultry products, including raw ground products,* requires a standard and testing regime that are directed at *that* pathogen." (emphasis added)). The difficulty with this, of course, is that the USDA has no statutory authority to regulate the levels of non-adulterant pathogens.

> While we do not question the agency's expertise, we also note that several equivocal statements about the effectiveness of *Salmonella* levels as a proxy for pathogen controls appear in the Final Rule. *See Id.* at 38835 ("And, interventions targeted at reducing *Salmonella may be beneficial* in reducing contamination by other enteric pathogens." (emphasis added)); *Id.* at 38846 ("[I]ntervention strategies aimed at reducing fecal contamination and other sources of *Salmonella* on raw product *should be* effective against other pathogens.").

33 The USDA repeatedly asserts that it has the power to regulate the *Salmonella* levels of incoming raw materials used in grinding establishments. *See, e.g.,* Appellant's Reply Brief at 12 ("To operate in a sanitary manner, a plant must match the level of its pathogen controls to the nature of the meat it purchases. The greater the risk of contamination in the incoming product, the greater the need for strategies to reduce microbial contamination."); 61 Fed.Reg. at 38846 ("Establishments producing raw ground product from raw meat or poultry supplied by other establishments cannot use technologies for reducing pathogens that are designed for use on the surfaces of whole carcasses at the time of slaughter. *Such establishments may require more control over incoming raw product, including contractual specifications to ensure that they begin their process with product that meets the standard ....* ") (emphasis added).

34 568 F.2d 240 (2d Cir.1977).

35 *Id.* at 245.

36 *Id.* at 246 ("When agency rulemaking serves the purposes of the statute, courts should refuse to adopt a narrow construction of the enabling legislation which would undercut the agency's authority to promulgate such rules.").

37 *Id.* at 245.

38 *Id.* at 243 (describing time-temperature-salinity regulations for hot-process smoked fish). This is consistent with the entirety of cases dealing with this statute, none of which concern "conditions" extrinsic to the place where the products are "prepared, packed or held." *See, e.g.*, *United States v. Gel Spice Co., Inc.*, 773 F.2d 427, 430 (2d Cir.1985) (rodent infestation in plant); *United States v. King's Trading, Inc.,* 724 F.2d 631, 632 (8th Cir.1983) (rodent infestation

  

in warehouse); *United States v. 1,638 Cases of Adulterated Alcoholic Beverages and Other Articles of Food,* 624 F.2d 900, 901–02 (9th Cir.1980) (flooding in storage area); *United States v. Certified Grocers Co-op.,* 546 F.2d 1308, 1310–11 (7th Cir.1976) (rodent infestation in warehouse). Even the USDA does not argue that § 601(m)(4) reaches "conditions" external to the establishment, but rather that control of pathogen levels in incoming raw materials are necessary to maintain sanitary conditions *inside* of the establishment. *See* Appellant's Brief at 38–39.

39 *Id.* at 246.

40 61 Fed.Reg. at 38846.

41 One might speculate that such a conclusion would create problems for the USDA, because a statement that *Salmonella* was a proxy for, for example, pathogenic *E. coli* could arguably require the determination that the presence of *Salmonella* rendered a product § 601(m)(1) adulterated. This would prevent *Salmonella*-infected meat from being sold in the United States to consumers.

42 The *amicus curiae* consumer groups in their brief appear not to recognize the distinction between a correlation between *Salmonella* and other enteric pathogens in raw materials and a correlation between reductions in *Salmonella* and reductions in other enteric pathogens when the same control methods are used. *See* Brief of Amicus Curiae Consumer Groups at 10–11.