UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE

In re: Fecal Contamination of Poultry and Meat	Docket No. __

PETITION FOR RULEMAKING

Submitted to:

FSIS Docket Clerk
Department of Agriculture
Food Safety and Inspection Service
Room 2534 South Building
1400 Independence Ave., SW
Washington, DC 20250-3700

Date:

March 14, 2013

Reply to:

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INTRODUCTION

The Federal Meat Inspection Act[1] and the Poultry Products Inspection Act[2] direct the Secretary of the Department of Agriculture ("USDA") to inspect all meat and poultry. Together the acts 1) allow meat or poultry that is unadulterated to be labeled as wholesome and fit for consumers to eat and 2) require adulterated meat or poultry to be condemned.[3] USDA's Food Safety and Inspection Service oversees the inspection of all meat and poultry products.

Inconsistent with its statutory mandate, USDA regularly passes at inspection meat and poultry that is contaminated with feces. Although USDA implements a "zero tolerance" policy for fecal contamination, this policy applies to visible fecal contamination only. The result is that fecally contaminated meat and poultry products pass inspection as long as the feces on them are not "visible" to the naked eye.[4]

This inspection policy conveys a misleading promise of "wholesomeness." Feces may contain round worms, hair worms, tape worms, and leftover bits of whatever the animal excreting the feces may have eaten, not to mention the usual fecal components of digestive juices and various chemicals that the animal was in the process of excreting. Americans deserve fair notice that food products deemed "wholesome" by USDA would be deemed disgusting by the average consumer and adulterated under any reasonable reading of federal law.

To prevent the ongoing violation of law and to stop the continued release of fecally contaminated meat and poultry from slaughterhouses and processing plants, the Physicians Committee for Responsible Medicine, pursuant to the Administrative Procedure Act[5] and USDA regulations,[6] petitions USDA to take the following actions:

1. Declare feces an adulterant and regulate feces as an adulterant.

2. Amend sections 317.2(l)(2), 381.125(b)(2)(i), and 381.125(b)(2)(ii) of Title 9 of the Code of Federal Regulations such that all meat and poultry product labels uniformly disclose the presence of feces.

3. Amend section 381.96 of Title 9 of the Code of Federal Regulations to remove the word "wholesome" from the official inspection legend for poultry such that the legend reads as follows: "Inspected by U.S. Department of Agriculture."

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[1] 21 U.S.C. §§ 601–695.
[2] 21 U.S.C. §§ 451–472.
[3] 21 U.S.C. §§ 451, 604.
[4] The regulations adhere to this standard even though other methods, such as laser-induced fluorescence imaging, can detect feces that the human eye cannot. *See* Cho B, Kim MS, Chao K, Lawrence K, Park B, Kim K. Detection of fecal residue on poultry carcasses by laser-induced fluorescence imaging. *J Food Sci.* 2009;74(3):E154-9.
[5] 5 U.S.C. § 553(e).
[6] 7 C.F.R. § 1.28; 9 C.F.R. §§ 392.1–392.9.

STATEMENT OF FACTS

I. Federal Statutes, Regulations, and Directives

A. Federal Meat Inspection Act

In 1906, Congress mandated USDA to conduct inspections of cows, pigs, goats, sheep, and horses used for food before and after slaughter and during the processing operation to prevent the distribution and sale of meat that was unwholesome, adulterated, unhealthful, and not properly marked, labeled, and packaged.[7] Under the act, USDA must ensure that only unadulterated carcasses are approved for further distribution to consumers. If meat is unadulterated, USDA must affix an inspection legend indicating that the meat has been inspected by USDA, passed the inspection, and is safe to eat.[8] The mandatory inspection legend for all unadulterated meat products reads, "Inspected and passed."[9]

The underlying principle of the Federal Meat Inspection Act is that adulterated meat is unfit for consumption and cannot be passed at inspection by USDA for sale to the public.[10] All adulterated carcasses must be marked as "inspected and condemned" and are prohibited from use as food.[11] Under the Federal Meat Inspection Act, meat 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;
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> . . .
>
> if it consists in whole or part of any filthy, putrid, or decomposed substance or is for any other reason unsound, unhealthful, unwholesome, or otherwise unfit for human food.[12]

The Federal Meat Inspection Act also prohibits the misbranding of meat. Meat is misbranded "if its labeling is false or misleading in any particular" or "if it fails to bear . . . the inspection legend and . . . such other information as the Secretary may require . . . to assure that it will not have false or misleading labeling."[13]

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[7] See 21 U.S.C. § 601.
[8] See 21 U.S.C. § 601(n)(12).
[9] 21 U.S.C. § 604.
[10] See 21 U.S.C. § 608.
[11] 21 U.S.C. § 604.
[12] 21 U.S.C. § 601(m)(1), (m)(3).
[13] 21 U.S.C. § 601(n)(1), (n)(12).

B. Poultry Products Inspection Act

As with the Federal Meat Inspection Act, Congress enacted the Poultry Products Inspection Act to protect the "health and welfare of consumers" by assuring that products containing the meat of chickens, turkeys, ducks, geese, and guineas "are wholesome, not adulterated, and properly marked, labeled, and packaged."[14] Like the Federal Meat Inspection Act, the Poultry Products Inspection Act requires inspections,[15] defines "adulterated" as shown above,[16] and prohibits misbranding.[17] Again, the basic principle underlying the Poultry Products Inspection Act is that adulterated poultry is unfit for consumers to eat. Although the Poultry Products Inspection Act also mandates application of an inspection legend to all unadulterated poultry indicating that it has passed at inspection, the act does not specify the language that must be included on the legend, leaving discretion of this matter to USDA.[18]

C. USDA Regulations and Food Safety and Inspection Service Directives

USDA permits several inspection legends for meat, including "Inspected and passed," "U.S. Inspected and Passed," or "U.S. Inspected and Passed by Department of Agriculture," all of which contain the required phrase, "inspected and passed."[19] For poultry, USDA authorizes only one inspection legend: "Inspected for wholesomeness by U.S. Department of Agriculture."[20] All poultry that has passed inspection must bear the "Inspected for wholesomeness" legend.[21] In addition to the official inspection legends, USDA requires a handling label on all raw meat and poultry products.[22] Under most circumstances, the mandatory label advises that the meat or poultry "product was prepared from inspected and passed meat or poultry."[23]

USDA has directed its Food Safety and Inspection Service to enforce a zero tolerance standard for visible fecal material. This standard is reflected in USDA regulations, which require that establishments prevent contamination of livestock carcasses and carcass parts by fecal material and promptly remove contamination if it occurs.[24] The regulations similarly require that establishments prevent poultry carcasses contaminated with visible fecal material from entering the "chilling tank,"[25] the large vat of water that serves as a common bath for all poultry carcasses after inspection. When inspectors observe feces at or after post-mortem livestock inspection or when poultry carcasses are about to enter the chilling tank, inspectors are supposed to condemn

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[14] 21 U.S.C. § 451.
[15] 21 U.S.C. § 455.
[16] 21 U.S.C. § 453(g)(1), (g)(3).
[17] 21 U.S.C. § 453(h).
[18] 21 U.S.C. §§ 453(m), 457(a).
[19] See 9 C.F.R. § 301.2.
[20] 9 C.F.R. §§ 381.1, 381.96.
[21] 9 C.F.R. § 381.123(a).
[22] 9 C.F.R. §§ 317.2(l); 381.125(b).
[23] 9 C.F.R. §§ 317.2(l)(2); 381.125(b)(2)(i).
[24] 9 C.F.R. § 310.18(a)
[25] 9 C.F.R. § 381.65(e).

the affected product unless the visible feces are removed by reprocessing.[26] Reprocessing such as trimming, vacuuming, or washing of a carcass may remove only the incidental visible contamination.[27]

In 1996, USDA began implementing its Pathogen Reduction and Hazard Analysis and Critical Control Point Systems ("HACCP").[28] HACCP is intended to identify hazards that may arise at "critical points" in the production process of meat and poultry and devise measures to minimize the risks associated with these hazards. Under HACCP, all meat and poultry plants must 1) develop and implement a system of preventive controls, 2) develop and implement written standard operating procedures for sanitation, and 3) conduct a microbial spot-check for generic E. coli.

HACCP's E. coli spot-checking system is meant to verify whether the plant's systems are working as intended to prevent fecal contamination.[29] The plant operates the generic E. coli testing program by testing carcasses on a per volume basis,[30] specifically 1 out of every 22,000 chicken carcasses, 1 out of every 300 cattle carcasses, and 1 out of every 1,000 pig carcasses.[31] The plant collects the samples, tests the samples, and records the results.[32] The data relating to the testing program are maintained by the plant.[33]

To evaluate whether a plant complies with generic E. coli testing program procedures, federal inspectors spot-check the recorded test results. Test results that do not meet the performance standard for generic E. coli indicate that an establishment may not be maintaining process controls sufficient to minimize fecal contamination. In such case, the inspector is to complete a non-compliance record and "take further action as appropriate to ensure that applicable provisions of the law are met."

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[26] See Livestock Carcasses and Poultry Carcasses Contaminated With Visible Fecal Material, 62 Fed. Reg. 63,254, 63,255 (Nov. 28, 1997). See also USDA, FSIS Directive 6420.2: Verification of Procedures for Controlling Fecal Material, Ingesta, and Milk in Slaughter Operations (Mar. 31, 2004), http://www.fsis.usda.gov/OPPDE/rdad/FSISDirectives/6420.2.pdf; USDA, FSIS PHIS Directive 6420.2: Verification of Procedures for Controlling Fecal Material, Ingesta, and Milk in Slaughter Operations (Apr. 11, 2011), http://www.fsis.usda.gov/OPPDE/rdad/FSISDirectives/PHIS_6420.2.pdf.

[27] 9 C.F.R. §§ 310.18, 381.91(b)(1).

[28] See Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems, 61 Fed. Reg. 38,806 (July 25, 1996) (to be codified at 9 C.F.R. pt. 417).

[29] Id. See also 9 C.F.R. §§ 310.25, 381.94.

[30] Information provided in this section can be found at 9 C.F.R. §§ 310.25(a), 381.94(a).

[31] Id.

[32] Id.

[33] Id.

ARGUMENT

USDA advises the public that its inspection system, with its "zero tolerance" policies and testing programs, guarantees a wholesome food supply. Yet it is clear that USDA's inspection system does not prevent contamination by feces. Thus, USDA must undertake stringent and proactive rules, policies, and enforcement measures to prevent the continued fecal contamination of meat and poultry. At the same time, USDA must vigilantly warn consumers, and no longer mislead them, about the risks inherent to consuming meat or poultry products that have passed inspection under the current system.

I. USDA Should Declare Feces, Whether Visible or Not, an Adulterant and Regulate Feces as an Adulterant

USDA has recognized that feces are the major source of contamination in livestock and poultry slaughterhouses[34] and that consumption of meat and poultry contaminated with feces is the primary vehicle for transmitting foodborne pathogens to humans.[35] Yet, the current policy regarding fecal contamination of meat and poultry addresses only feces that are "visible" to the naked eye or discovered in HACCP spot-checks, permits processes that contribute to the spread of fecal contamination, and authorizes plants to reprocess contaminated carcasses using methods that do not guarantee the elimination of feces.

Transport, handling, slaughter, and process methods under current large-scale food-animal production make it likely that many animals will be contaminated with feces and that "visible" feces will not be seen or removed completely. If neither the plant workers nor the inspectors see the feces, a carcass contaminated with feces will pass through the plant for sale to consumers.

A. Fecal Contamination of Poultry[36]

Poultry plants collectively slaughter more than 20 million birds every day, typically on high-speed automated production lines. At these poultry plants, chickens are stunned, killed, bled, and sent through scalding tanks, which help remove feathers but also act as reservoirs that transfer feces from one carcass to another. As USDA's Food Safety and Inspection Service has stated, "cross-contamination can also occur during scalding from microorganisms present on the external and internal surfaces of the carcass and in the scalding water."[37] After scalding, feathers and intestines are mechanically removed. Intestinal contents can spill onto machinery and contaminate the muscles and organs of the chicken and those processed afterward.

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[34] USDA, New Detector Spots Unseen Fecal Contamination on Meat (Mar. 17, 1998), http://www.ars.usda.gov/is/pr/1998/980317.htm.

[35] Livestock Carcasses and Poultry Carcasses Contaminated With Visible Fecal Material, 62 Fed. Reg. 63,254, 63,255 (Nov. 28, 1997).

[36] Information in this section regarding common processing procedures can be found at Food Safety & Inspection Service, USDA, Improvements for Poultry Slaughter Inspection Technical Report (May 16, 2008), http://www.fsis.usda.gov/oppde/nacmpi/feb2008/poultry_slaughter_tech_report.pdf.

[37] Id. at 7:320-21.

The eviscerated carcasses are then rinsed and checked for visible fecal matter. However, some slaughter lines process as many as 140 birds per minute, allowing inspectors minimal time to examine each carcass for visible feces. Because the same machine eviscerates thousands of birds an hour—without intervening decontamination—contamination by feces may easily spread to other birds. At this line speed and with the minimal number of federal poultry inspectors required, an inspector generally has mere seconds to thoroughly check each chicken's chest, cavity, interior, and flesh for nearly a dozen diseases, bruises, cancers, lesions, other defects, and feces.[38]

After the visual check for fecal matter, carcasses are typically chilled in ice water, effectively a communal bath in which feces spread from bird to bird, permeating the carcasses. After chilling, a chicken may be cut up, allowing for further fecal spread from carcass to implements. The remains are then packaged, carrying the contamination to consumers. A 2009 USDA study found that 87 percent of chicken carcasses tested positive for generic E. coli, a sign of fecal contamination, after chilling and just prior to packaging.[39]

Industry experts coined the term "fecal soup" to describe the content of both the scalding and chilling tanks. As explained in 2008 by Stan Painter, current Chair of the National Joint Council of Food Inspection Locals, the government meat inspectors' union, "you take a chicken that eats, sleeps, craps and everything in one little space, they enter the scald vat dirty, and it takes only a few minutes to become just brown fecal soup."[40] More recently, a federal inspector said,

> [I]f the fecal contamination is not touching the bird's skin, it is not considered fecal contamination. We often see birds going down the line with intestines still attached, which are full of fecal contamination. If there is no fecal contamination on the bird's skin, however, we can do nothing to stop that bird from going down that line. It is more than reasonable to assume that once the bird gets into the chill tank (a large vat of cold water), that contamination will enter the water and contaminate all of the other carcasses in the chiller. That's why it is sometimes called "fecal soup."[41]

Testing conducted in 2012 by an independent laboratory at the request of the Physicians Committee for Responsible Medicine confirms the need for a more comprehensive policy regarding fecal contamination.[42] According to the results, generic E. coli is present in nearly one

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[38] Food Safety News, Poultry Inspectors Protest Inspection Proposal at USDA (Apr. 3, 2012), http://www.foodsafetynews.com/2012/04/poultry-inspectors-protest-inspection-proposal-at-usda/#.UDZKWdWns7k.

[39] Altekruse SF, Berrang ME, Marks H, et al. Enumeration of Escherichia coli cells on chicken carcasses as a potential measure of microbial process control in a random selection of slaughter establishments in the United States. *Appl Environ Microbiol.* 2009;75(11):3522-3527.

[40] Stan Painter, Remarks at Plenary Session of the National Advisory Committee on Meat and Poultry Inspection (Feb. 6, 2008), http://www.fsis.usda.gov/OPPDE/NACMPI/Feb2008/Plenary_020608.pdf.

[41] Comment submitted by Amanda Hitt, Director of the Food Integrity Campaign, Government Accountability Project, to Food Safety & Inspection Service, USDA, at 13 (May 25, 2012), http://www.regulations.gov/contentStreamer?objectId=0900006481020a96&disposition=attachment&contentType=pdf.

[42] All information provided in this and the following paragraph can be found at Physicians Committee for Responsible Medicine, Fecal Contamination in Retail Chicken Products (2012),

out of every two supermarket chickens. As explained above, federal regulations require slaughter and processing plants that produce meat and poultry to test carcasses for generic E. coli as an indicator for fecal contamination.

The testing sampled 120 chicken products—whole chickens, breasts, drumsticks, thighs, or wings—purchased in ten cities in nine states from the following grocery store chains: Albertsons, Dominick's, Fry's, Giant, Harris Teeter, H-E-B, Jewel-Osco, Kroger, Pic 'n Save, Piggly Wiggly, Publix, Ralphs, Randalls, Safeway, and Winn-Dixie. Brands tested included Perdue, Pilgrim's, Sanderson Farms, Covington Farms, Eating Right, Foster Farms, Gerber's Poultry, Harris Teeter, Harvestland, H-E-B, Hill Country Fare, Murray's, Nature's Promise, Open Nature, Smart Chicken, Piggly Wiggly, Publix, Red Bird Farms, Roundy's, Safeway, Safeway O Organics, Springer Mountain Farms, Super G, Supervalu, and Wild Harvest Natural.

The products were purchased, and store packaging was left undisturbed. The packages were placed unopened in coolers with ice packs and immediately shipped overnight to EMSL Analytical Inc., a certified, independent analytical testing laboratory in Chicago, Illinois. Using detection methods standard for food testing,[43] EMSL tested for the presence of generic E. coli. in the products. Results revealed that 48 percent of all chicken samples tested positive for feces. Among skinless breasts, 49 percent of products were contaminated, compared with 28 percent of breasts with skin intact, indicating that skin removal did not reduce fecal contamination in the samples tested. Of the antibiotic-free chicken samples, 46 percent tested positive for fecal contamination, while 48 percent of conventional samples tested positive.

B. Fecal Contamination of Meat

As the New York Times reported in 2009, at "slaughterhouses, the potential for contamination is present every step of the way, according to workers and federal inspectors. The cattle often arrive with smears of feedlot feces, and the hide must be removed carefully to keep it off the meat."[44] Slaughter of cattle and pigs is executed by plant workers, not machines. At more than 300 cattle slaughtered per hour and more than 1,000 pigs slaughtered every hour, the spread of feces is unavoidable. Organs are torn and their contents spilled. Feces are smeared and splattered. Because feces may have already spread from one cow to another during transport, when cattle undergo the dehiding process, additional fecal contamination can result.

Because pigs' hides are not removed during the slaughter process, pig carcasses are put through a communal scalding tank, similar to the defeathering tank for chickens. Contaminated carcasses enter the same water as do the other pig carcasses, potentially infecting the uncontaminated ones. Scalding is followed by dehairing, in which "rotating drums equipped with scraper blocks . . .

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http://www.pcrm.org/health/reports/fecal-contamination-in-retail-chicken-products.

[43] See Lattuada CP, Dillard LH, Rose BE. Examination of Fresh, Refrigerated, and Frozen Prepared Meat, Poultry and Pasteurized Egg products. In: Dey BP, Lattuada CP. Examination of Microbiology Laboratory Guidebook. Vol. 1-2. 3rd ed. Washington, DC. 1998, http://www.fsis.usda.gov/OPHS/microlab/mlgchp3.pdf.

[44] Michael Moss, *The Burger That Shattered Her Life*, N.Y. TIMES, Oct. 3, 2009, http://www.nytimes.com/2009/10/04/health/04meat.html?_r=2&pagewanted=all.

rotate the carcasses to remove the hairs."[45] Recontamination of the carcasses occurs at dehairing.[46]

Until 1978, USDA required the condemnation of any carcass with visible fecal contamination. Thereafter, USDA allowed carcasses contaminated with visible feces to be "reprocessed," rather than condemned.[47] As long as feces are no longer visible after the corrective reprocessing action, the carcass may continue to be processed.

Current USDA policy allows livestock carcasses to be steam vacuumed (hot water is sprayed on a carcass and then vacuumed off), washed with an acid rinse, or trimmed to remove fecal contamination. Yet Steam vacuuming to remove fecal contamination from meat carcasses removes only "incidental visible contamination."[48] And although chemical rinses may wash off visible traces of feces, feces not visible to the naked eye may remain on the carcass.[49]

C. USDA Should Regulate Feces as an Adulterant

A policy that addresses only visible fecal contamination is sorely inadequate. Visible feces can be overlooked because of the speed involved in slaughtering and processing, and traces of feces too small or diluted to be seen by the naked eye can pass inspection. A more comprehensive policy that addresses all fecal contamination is necessary.

As set forth above, under the Federal Meat Inspection Act and the Poultry Products Inspection Act, meat or poultry is adulterated "if it bears or contains any poisonous or deleterious substance which may render it injurious to health" or "if it consists in whole or part of any filthy, putrid, or decomposed substance or is for any other reason unsound, unhealthful, unwholesome, or otherwise unfit for human food."

Meat and poultry products contaminated with feces clearly meet these criteria. Feces "may render [food] injurious to health," feces are a "filthy, putrid, or decomposed substance," and feces render products "unsound, unhealthful, unwholesome, or otherwise unfit for human food." Indeed, under no circumstances are feces considered wholesome. In a medical setting, feces and animal carcasses that may be contaminated with pathogenic bacteria are regulated as "medical waste" consistent with specific restrictions to minimize human exposure—mandatory incineration or disposal in a biohazard container.[50] Outside scientific institutions, the presence of feces can shut down the neighborhood swimming pool for days, whereas the presence in that

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[45] Food Safety & Inspection Service, USDA, Public Health Risk-Based Inspection System for Processing and Slaughter Technical Report, at 13:503-06. (Apr. 18, 2008), http://www.fsis.usda.gov/OPPDE/NACMPI/Feb2008/Processing_Slaughter_Tech_Rpt_041808.pdf.

[46] Id.

[47] 9 C.F.R. §§ 310.18, 381.91(b)(1).

[48] USDA, USDA Announces Approval of Trial Tests for Steam Process to Remove Contamination from Meat Carcasses (Mar. 24,1995), http://www.usda.gov/news/releases/1995/03/0262.

[49] See, e.g., USDA, Steaming Out the Salmonella Risk (Feb. 8, 2007) (quotations removed), http://www.ars.usda.gov/is/AR/archive/oct97/steam1097.htm.

[50] See, e.g., College of Biological Sciences, The Ohio State University, Guidelines for Research & Biomedical Waste Disposal (2002).

same pool of a stone, a feather, or a rusty nail—other substances unfit for consumption—will warrant only the mildest response.

In United States v. Pilgrim Market Corporation,[51] the government brought criminal charges against a slaughterhouse for distributing meat and poultry products that were adulterated because they were contaminated with rodent feces. The government asserted that the presence of rat feces caused the product to be adulterated because it consisted of a "filthy, putrid and decomposed substance" and "was unsound, unhealthful, unwholesome and otherwise unfit for human food."[52] Rodent feces are no more of a health hazard than livestock or poultry feces and there is no logical basis for treating one as an adulterant and the other not. Meat or poultry contaminated with feces falls within the definition of "adulterated" under both the Federal Meat Inspection Act and the Poultry Products Inspection Act and should be treated as such.

Both the Federal Meat Inspection Act and the Poultry Products Inspection Act authorize USDA to declare feces an adulterant and to regulate it as such.[53] For example, in 1994, USDA declared that ground beef contaminated with *E. coli* O157:H7 is adulterated under the Federal Meat Inspection Act.[54] In 2012, USDA announced, for raw beef, a "zero-tolerance policy for six additional strains of E. coli."[55] USDA also has declared salmonella and *L. monocytogenes* on ready-to-eat products adulterants.

By not declaring feces an adulterant and by failing to impose stringent regulations to prevent its spread, USDA is derelict in its duty to ensure a "wholesome" food supply. USDA's reliance on educating consumers about proper handling and cooking techniques further violates the Federal Meat Inspection Act and the Poultry Products Inspection Act by allowing adulterated products to pass at inspection and placing the burden of decontaminating adulterated products on consumers. This is no way to protect public health.

To provide mandatory, and meaningful, protection to consumers, USDA should declare feces an adulterant and regulate it as such.

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[51] 944 F.2d 14 (1st Cir. 1991).
[52] Id. at 17-18.
[53] 21 U.S.C. §§ 463(b), 621.
[54] USDA, USDA Targeting Six Additional Strains of E.coli in Raw Beef Trim Starting Monday (May 31, 2012), http://www.usda.gov/wps/portal/usda/usdamediafb?contentid=2012/05/0171.xml&printable=true.
[55] Id.

II. To Prevent Misbranding, USDA Must Amend the Mandatory Meat and Poultry Label to Disclose the Presence of Feces

The Federal Meat Inspection Act and the Poultry Products Inspection Act require USDA to protect consumers from adulterated and misbranded meat and poultry, not only through inspections at the plants, but also through officially approved labels affixed to such meat and poultry. Under the statutes, meat or poultry is misbranded if it does not bear, in addition to the official inspection legends, "such other information as the Secretary [of Agriculture] may require . . . to assure that [the products] will not have false or misleading labeling and that the public will be informed of the manner of handling required to maintain the product in a wholesome condition."[56] Current regulations require the application of the official inspection legend on all meat and poultry products and handling instructions on all raw meat and poultry products. In the absence of truthful disclosures regarding the presence of feces in the products, these labels are false and misleading and unduly confusing to the consumer, constituting misbranding.

The USDA inspection legend, which has been applied to meat for more than a century and to poultry since 1957, is intended to convey to consumers that meat and poultry products are wholesome and fit for eating. Consumers have become accustomed to this guarantee. Yet, the guarantee is a ruse that lulls consumers into a false sense of security about the meat and poultry they purchase and consume.

Consumers deserve truthful, unambiguous labels. Labels should disclose to consumers that USDA has not, and cannot, guarantee any meat or poultry product is free of contamination. To do so honestly and effectively, USDA should unequivocally require producers to warn of the likely presence of feces in meat or poultry.

The time is ripe for such a warning label. In the 1974 case American Public Health Association v. Butz,[57] the court held that USDA inspection labels on meat and poultry that had been inspected and passed were not false and misleading so as to constitute misbranding even though the products did not contain a warning about foodborne pathogens and instructions for safe handling. The court determined that a consumer education campaign was sufficient to address the problems associated with foodborne illness. In support, the court presumed that the presence of salmonella did not make meat or poultry adulterated,[58] that microscopic examination of meat and poultry was unrealistic, and that "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."[59] Under those circumstances, the court held that warning labels were unnecessary. Present circumstances make the Butz ruling inapplicable today.

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[56] 21 U.S.C. §§ 453(h)(12), 601(n)(12).
[57] 511 F.2d 331 (D.C. Cir. 1974).
[58] The conclusion that "the presence of salmonella in meat does not constitute adulteration within the meaning of the [FMIA] was plainly dictum which did not reflect consideration of any factual basis or legal analysis of the adulteration provision of that Act." Seabrook International v. Harris, 501 F. Supp. 1086, 1092 (D.D.C. 1980).
[59] Butz, 511 F.2d at 334.

Since Butz, USDA has conducted a massive and targeted food safety campaign to inform consumers about the handling and cooking of meat and poultry products. USDA instituted a toll-free, nationwide food-safety hotline and conducts myriad food-safety campaigns directed at such specialized audiences as food handlers, institutions, health professionals, and at-risk populations, as well as food handlers in the home.[60] USDA also reversed its position that handling instructions were unnecessary, mandating their application on all raw meat and poultry products in 1994.[61] Additionally, USDA has imposed various microbial testing programs.

Eating habits also have changed over the decades, resulting in reduced personal control over the safety of the food consumed. Compared to their 1974 counterparts, Americans today consume more of their meals in restaurants, eat significantly more "consumer-ready" products, and prepare their own food considerably less often. Americans today consume far more meat and poultry than ever before, thereby increasing their potential exposure to fecal contamination in these products.[62] Thus, the circumstances relied upon by the Butz court are as far as can be from the situation today.

Given the continued unavoidable fecal contamination of meat and poultry, USDA must exercise its authority under the Federal Meat Inspection Act and the Poultry Products Inspection Act to ensure that meat and poultry labels uniformly exclude all misleading language regarding inspection and affirmatively disclose the potential presence of feces. Otherwise, current inspection labels are false and misleading under the Federal Meat Inspection Act and the Poultry Products Inspection Act, constituting misbranding.

USDA should amend sections 317.2(l)(2) and 381.125(b)(2)(i) of the Code of Federal Regulations to exclude from the current mandatory label the sentence that reads, "This product was prepared from inspected and passed meat and/or poultry." USDA should amend sections 317.2(l)(2), 381.125(b)(2)(i), and 381.125(b)(2)(ii) of Title 9 to include in the mandatory label the following as the second-to-last sentence: "This product may be permeated with feces, which cooking does not remove."

III. USDA Should Amend the Authorized Poultry Inspection Legend to Exclude the Word "Wholesome" and to Explicitly Warn About Feces

USDA has regulatory discretion over the text of the poultry inspection legend, which currently reads, "Inspected for wholesomeness by U.S. Department of Agriculture." Although USDA regulations proclaim that this inspection legend informs consumers that the inspected poultry is unadulterated and fit for human consumption, the USDA Food Safety and Inspection Service

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[60] Mandatory Safe Handling Statements on Labeling of Raw Meat and Poultry Products, 58 Fed. Reg. 43,478 (Aug. 16, 1993).

[61] Mandatory Safe Handling Statements on Labeling of Raw Meat and Poultry Products, 59 Fed. Reg. 14,528 (Mar. 28, 1994). In fact, USDA reversed its 1974 opinion on handling instructions to settle a subsequent lawsuit filed to enjoin USDA from affixing the official inspection legend to poultry and meat unless it was accompanied by a warning and handling label. See Mandatory Safe Handling Statements on Labeling of Raw Meat and Poultry Products, 58 Fed. Reg. 43,478, 43,482 (Aug. 16, 1993).

[62] USDA, Food Availability (Per Capita) Data System (Aug. 22, 2012), http://www.ers.usda.gov/data-products/food-availability-%28per-capita%29-data-system.aspx.

internet site suggests a much lower standard, namely that "the chicken is free from visible signs of disease."[63] This is a new and distorted interpretation of the poultry inspection legend.

USDA should not, and cannot, affix a seal that misleads consumers. As shown above, USDA cannot assure that the poultry it inspects is unadulterated, free from fecal contamination, or wholesome. Because fecal contamination is common and even expected, USDA must amend section 381.96 of Title 9 of the Code of Federal Regulations to discontinue the use of the word "wholesome" and explicitly disclose the risk of fecal contamination. The following example inspection legends[64] would protect consumers from unwitting exposure to feces:

[63] Food Safety & Inspection Service, USDA, Chicken from Farm to Table (July 2012), http://www.fsis.usda.gov/PDF/Chicken_from_Farm_to_Table.pdf.
[64] Establishment number P-42 appears only as an example.

CONCLUSION

USDA regulations allow meat and poultry products contaminated by feces to reach consumers' dinner plates so long as the feces are not visible to the human eye. The result is that consumers purchase and consume USDA-approved products that are adulterated and misbranded, in violation of federal law. Accordingly, the Physicians Committee for Responsible Medicine hereby requests that USDA:

1. Declare feces an adulterant and regulate feces as an adulterant.

2. Amend sections 317.2(l)(2), 381.125(b)(2)(i), and 381.125(b)(2)(ii) of Title 9 of the Code of Federal Regulations such that all meat and poultry product labels uniformly disclose the presence of feces.

3. Amend section 381.96 of Title 9 of the Code of Federal Regulations to remove the word "wholesome" from the official inspection legend such that the legend reads as follows: "Inspected by U.S. Department of Agriculture."

Documentation Cited

This attachment excludes documentation for citations to federal statutes, federal regulations, federal cases, the Federal Register, FSIS Directives, and reports or statements published on USDA websites. This attachment includes documentation for the following citations:

- Footnote 4: Cho B, Kim MS, Chao K, Lawrence K, Park B, Kim K. Detection of fecal residue on poultry carcasses by laser-induced fluorescence imaging. *J Food Sci.* 2009;74(3):E154-9.

- Footnote 38: Food Safety News, Poultry Inspectors Protest Inspection Proposal at USDA (Apr. 3, 2012), http://www.foodsafetynews.com/2012/04/poultry-inspectors-protest-inspection-proposal-at-usda/#.UDZKWdWns7k.

- Footnote 39: Altekruse SF, Berrang ME, Marks H, et al. Enumeration of Escherichia coli cells on chicken carcasses as a potential measure of microbial process control in a random selection of slaughter establishments in the United States. *Appl Environ Microbiol.* 2009;75(11):3522-3527.

- Footnote 41: Comment submitted by Amanda Hitt, Director of the Food Integrity Campaign, Government Accountability Project, to Food Safety & Inspection Service, USDA, at 13 (May 25, 2012), http://www.regulations.gov/contentStreamer?objectId=0900006481020a96&disposition=attachment&contentType=pdf.

- Footnote 42: Physicians Committee for Responsible Medicine, Fecal Contamination in Retail Chicken Products (2012), http://www.pcrm.org/health/reports/fecal-contamination-in-retail-chicken-products.

- Footnote 44: Michael Moss, *The Burger That Shattered Her Life*, N.Y. TIMES, Oct. 3, 2009, http://nytimes.com/2009/10/04/health/04meat.html?_r=2&pagewanted=all.

- Footnote 50: College of Biological Sciences, The Ohio State University, Guidelines for Research & Biomedical Waste Disposal (2002).

Footnote 4

Detection of Fecal Residue on Poultry Carcasses by Laser-Induced Fluorescence Imaging

B. Cho, M.S. Kim, K. Chao, K. Lawrence, B. Park, and K. Kim

ABSTRACT: Feasibility of fluorescence imaging technique for the detection of diluted fecal matters from various parts of the digestive tract, including colon, ceca, small intestine, and duodenum, on poultry carcasses was investigated. One of the challenges for using fluorescence imaging for inspection of agricultural material is the low fluorescence yield in that fluorescence can be masked by ambient light. A laser-induced fluorescence imaging system (LIFIS) developed by our group allowed acquisition of fluorescence from feces-contaminated poultry carcasses in ambient light. Fluorescence emission images at 630 nm were captured with 415-nm laser excitation. Image processing algorithms including threshold and image erosion were used to identify fecal spots diluted up to 1:10 by weight with double distilled water. Feces spots on the carcasses, without dilution and up to 1:5 dilutions, could be detected with 100% accuracy regardless of feces type. Detection accuracy for fecal matters diluted up to 1:10 was 96.6%. The results demonstrated good potential of the LIFIS for detection of diluted poultry fecal matter, which can harbor pathogens, on poultry carcasses.

Keywords: fecal residues, fluorescence imaging, food safety, laser induced, poultry carcasses

THE Society for Food Science & Technology

Journal of Food Science

A Publication of the Institute of Food Technologists

Introduction

Ensuring safety of food commodities is a current issue of major importance in the meat industry. Consumption of poultry contaminated with feces can cause serious human illness (Cody and others 1999; Mead and others 1999). Thus inspection regulations of the Food Safety and Inspection Service (FSIS) of the U.S. Dept. of Agriculture (USDA) include a zero-tolerance policy for visible fecal contaminants on poultry products (FSIS 2004).

Common routes of poultry skin contamination are ruptures of the digestive tract during evisceration process that can expel internal content. Even though a human expert inspects the wholesomeness of carcasses on the processing line, trace or dilute fecal contaminants may not be easily discernable from water and skin by the human eye. Previous research has shown potential of multispectral reflectance imaging techniques for detection of fecal matters on poultry carcasses (Park and others 2002, 2005). Results demonstrated that feces residues on poultry carcasses could be detected with approximately 92.5% accuracy using band ratio of images at 565 and 517 nm; however, efforts still need to be made to improve the detection sensitivity for the diluted fecal contaminants to comply with zero-tolerance standards for contaminant-free production.

Recent research conducted at the ARS Food Safety Laboratory (FSL) in Beltsville, Md., U.S.A. exhibited that fluorescence is very sensitive in detecting animal feces on agricultural commodities (Kim and others 2003a, 2003b, 2008). The researchers indicated that multispectral imaging using 2 to 3 fluorescence emission bands was sufficient to detect animal feces on apples. To accomplish fluorescence imaging under ambient lighting conditions, we developed a gated system capable of nano-second (ns) scale time-resolved fluorescence imaging utilizing a tunable pulsed laser to provide proper excitation.

In this study, the feasibility of a laser-induced fluorescence imaging technique is explored for the detection of diluted poultry feces on poultry carcasses. Optimal discrimination parameters, such as gate-delay time, threshold of fluorescence intensity, and image processing algorithm were suggested.

MS 20080992 Submitted 12/8/2008, Accepted 1/16/2009. *Author Cho is with Bioindustrial Machinery Engineering Dept., Chungnam Natl. Univ., 220 Gung-dong, Yuseong-gu, Daejeon, 305-764, Republic of Korea. Authors Kim and Chao are with Food Safety Laboratory, Animal and Natural Resources Inst., Agricultural Research Service, U.S. Dept. of Agriculture, Powder Mill Rd., Building 303, BARC-East, Beltsville, MD 20705, U.S.A. Authors Lawrence and Park are with Quality and Safety Assessment Unit, Richard B. Russell Agricultural Research Center, Agricultural Research Service, U.S. Dept. of Agriculture, 950 College Station Rd., Athens, GA 30605, U.S.A. Author Kim is with Center for Environment & Safety Measurement, Korea Research Inst. of Standards and Science, 1 Doryong-dong, Yuseong-gu, Daejeon, 305-340, Republic of Korea. Direct inquiries to author Cho (E-mail: chobk@cnu.ac.kr).*

Materials and Methods

Sample materials

The carcasses and digestive tracts of 15 chickens, which were grown on soybean protein meal using standard practices until slaughter at the age of 7 wk, were obtained from a poultry processing plant in Cordova, Md., U.S.A. Feed and water were withheld for 10 h prior to the slaughter. The samples were placed in plastic bags, covered with ice, and transported to the laboratory within 2 h. Fecal matter from 4 different parts of the digestive tracts, colon, ceca, small intestine, and duodenum were extracted and diluted 1:5, 1:10, and 1:50 by weight with double-distilled (DD) water. Note that diluted fecal mixtures contained particulates and no attempts were made to dissolve the particulates; however, particulates tended to aggregate toward the middle, and thus the mixtures were gently stirred prior to application on the poultry skin. Using a pipette with approximately 2-mm section of the tip removed to accommodate particulates, undiluted and diluted fecal samples were applied in 50 μL drops to the surface of the poultry carcasses. The mean dry matter contents (with standard deviations in parentheses) of ceca, small intestine, and duodenum were 180 (21), 161 (21), and 149 (18) μg/g, respectively. Note that the dry matter content for colon could not be measured owing to insufficient sample quantity.

doi: 10.1111/j.1750-3841.2009.01103.x

Measurement of fluorescence spectra

Fluorescence characteristics of poultry fecal and organic matters (skin and meat) were investigated with a spectrofluorometer (Fluorolog III, Horiba Industries, Edison, N.J., U.S.A.) with additive-dispersion double grating and 2 Czerny-Turner double monochromators. One monochromator is attached to a 450 W xenon lamp with variable excitation from 220 to 700 nm. The other is attached to a photon counting photomultiplier tube (PMT) capable of acquiring fluorescence emissions from 250 to 900 nm. The system monitors the lamp intensity through a beam splitter with a photon detector and corrects for fluctuations in lamp intensity.

Emission spectra were acquired at 2-nm intervals from 370 to 750 nm with excitation wavelengths at 5-nm increments from 350 to 610 nm. Monochromator slit widths of 2 nm were set for both of excitation and emission with the PMT integration time of 0.1 s. After construction of fluorescence emission–excitation matrices for samples, emission spectra at the excitation maximum wavelength and excitation spectra at the emission maximum wavelength for samples were measured at 1-nm intervals to refine optimal excitation and emission wavelengths. The optimized excitation and emission wavelengths were used for constructing the laser-induced fluorescence imaging system.

Laser-induced fluorescence imaging system (LIFIS)

A schematic diagram and a photo of the LIFIS is shown in Figure 1. It consists of a tunable laser, a beam expander, a C-mount zoom lens, a common aperture adapter, and a fast-gated intensified CCD camera. The excitation laser is a frequency tripled, Nd:YAG laser (10 Hz, 6-ns pulse width) with high pulse energy emitting from 410 to 690 nm (Vibrant VIS, Opotek, Calif., U.S.A.). The 6-mm-dia laser beam was expanded using a pair of divergent lenses to illuminate whole chicken carcasses under investigation at a distance of about 150 cm from the laser. A fast nanosecond-scale gated-intensified CCD camera (Istar, Andor Technology, Mass., U.S.A.) coupled to a C-mount 25-mm lens (Rainbow, Calif., U.S.A.) and a common aperture multispectral adapter (MSAI-04, Optical Insights, Ariz., U.S.A.) was used to collect fluorescence emission. The adapter uses prisms to convert the incoming image into 4 equally sized images in separate quadrants of the focal plane of the camera. Interference filters can be inserted into the aperture for multispectral imaging.

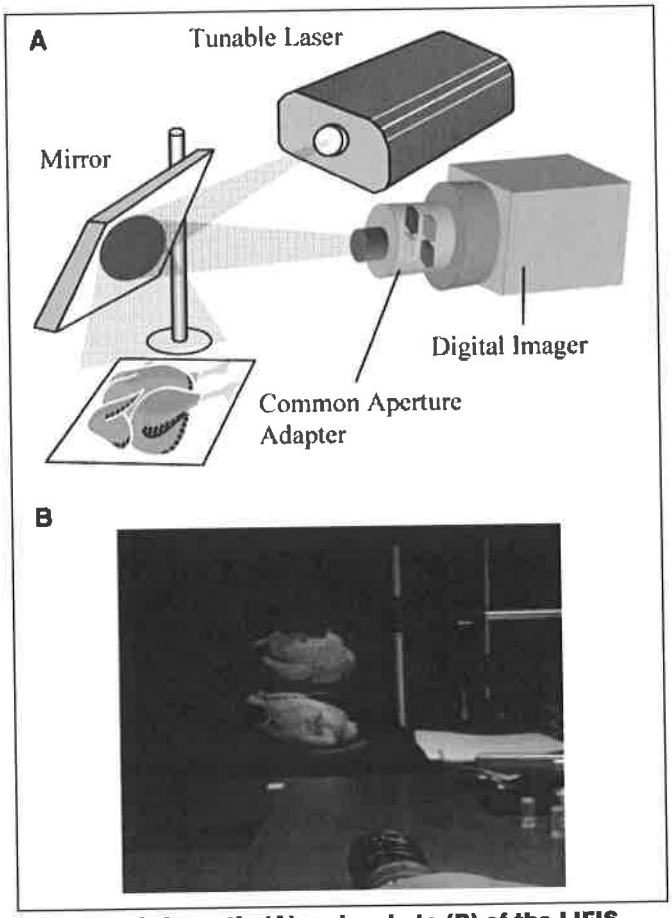

Figure 1 — Schematic (A) and a photo (B) of the LIFIS.

Image acquisition and processing

Visual Basic software (version 6.0, Microsoft, Seattle, Wash., U.S.A.) operating in a MS Windows environment was used to control the imaging system and to acquire image data (512 × 512 pixel). Images were stored as 16-bit signed integers in a sequential binary file. Fifty time-resolved images spanning 50 ns with approximately 1-ns gate width were acquired for each sample. To minimize the variability inherent in using a pulse laser, responses at individual times were averaged over 16 pulses; averaging kept pulse energy variations between time scales to less than 0.5%. Initial system gate-delay time was chosen such that no fluorescence emission from the sample was detected; this image was used for dark current and subtracted from the rest of the images. Energy output of the laser was adjusted to 20 mJ/pulse. However, due to the expansion of the laser beam, the total energy delivered to the target per unit area was less than 2 mJ/mm^2. Under this condition, no property change could be observed in the sample materials.

Image processing was performed for the acquired image data using Matlab software (version 7.0.4, The Mathworks, Natick, Mass., U.S.A.). Selection of optimal gate-delay time was based on F values of analysis of variance (ANOVA) for relative fluorescence intensity (RFI) values of respective gate-delay time between skin and fecal groups. The optimal threshold value of RFI at which the classification accuracy was highest was determined by investigating iterative threshold increments of 0.1% RFI.

Results and Discussion

Three-dimensional fluorescence excitation and emission contour plots for poultry skin and feces were constructed using a spectrofluorometer as shown in Figure 2. The most dominant fluorescence feature of the poultry feces was an emission peak in the red region of the spectrum at about 635 nm with excitation in the blue region (410 to 415 nm) while no apparent emission peak was found in the red region for the poultry skin. Selection of wavelengths and bandwidths of the filters was based on the typical emission characteristics of poultry fecal matter (Figure 3).

To refine optimal excitation and emission wavelengths for the detection of poultry feces, spectra were measured at 1-nm intervals with the excitation monochromator positioned at the excitation wavelengths previously identified as eliciting maximal responses (411 nm); subsequently, excitation spectra were measured with the PMT positioned at the maximal wavelengths identified with the 1-nm interval emission scans (Figure 3). Excitation maxima (peaks) were observed at 411 nm. The excitation spectra for 635- and 692-nm emission maxima exhibited similar characteristics.

Figure 4A shows representative emission spectra of poultry feces and organic matters resulting from excitation at 411 nm. Emission maxima were observed at 580, 625, 635, and 692 nm. The peak fluorescence response of feces is probably directly related to chemical compounds in the feedstuffs and its metabolites produced in the poultry digestive tract; however, the effects of animal digestive processes on feedstuffs were not defined explicitly so far. Kim and others (2003b) proposed that Protoporphyrin IX is a major constituent found in poultry feces that can affect the spectra shapes. Among the emission maxima, fluorescence intensities at 635 nm exhibited relatively greater differences between the feces and organic matters (Figure 4B).

Excitation at 415 nm and emission band at 635 nm were considered for this investigation, and narrow interference filter (10-nm full width at half maximum) centered at 630 nm were selected for LIFIS. The laser is capable of providing excitation at from 410 nm; however, 415 nm was selected to avoid unstable performance of the light source at the extremes of the operating wavelength range. Note that the selection of the emission filters was limited by commercial availability.

Representative ns-scale time-resolved fluorescence emission spectra of poultry feces and skin are shown in Figure 5. The fluorescence peak intensity for the feces and skin was observed at 14 ns. In general, fluorescence responses of untreated feces were greater than responses for skin and diluted fecal matters. However, some scattered spots in the areas for skin showed high fluorescence responses which were greater than responses of diluted fecal matters. A possible explanation for the high fluorescence response of the spots may be the presence of feather roots remaining in skin pores.

Figure 6 illustrates time-resolved fluorescence images spanning from 10 to 50 ns in 5-ns intervals for a poultry carcass artificially contaminated with the diluted and undiluted feces. These images were normalized to the peak intensity. Most of the images showed

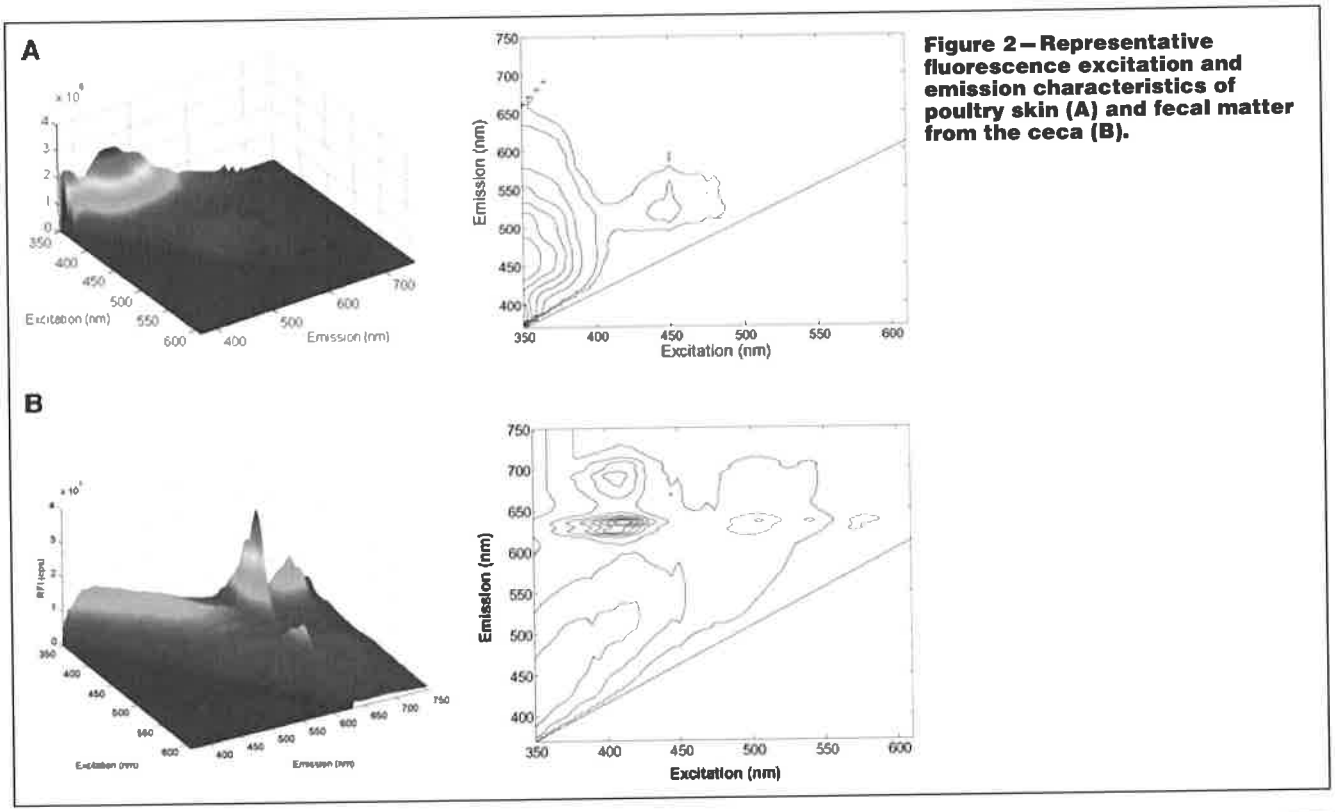

Figure 2—Representative fluorescence excitation and emission characteristics of poultry skin (A) and fecal matter from the ceca (B).

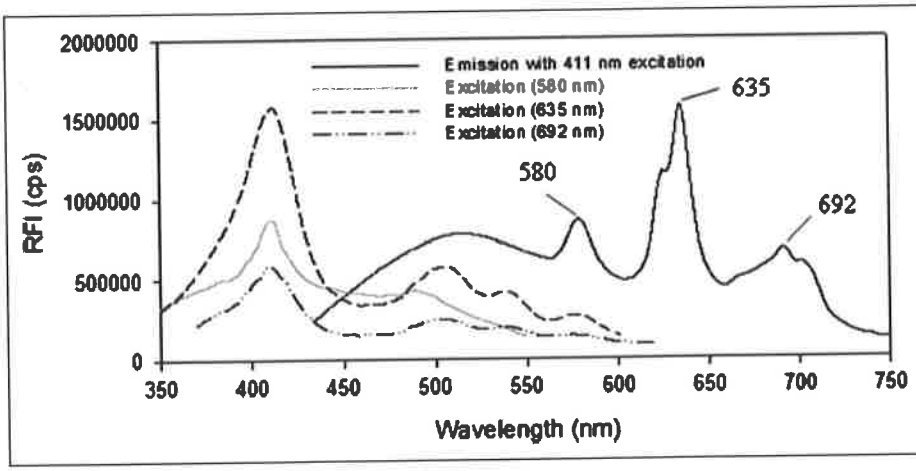

Figure 3—Representative fluorescence excitation and emission spectra of poultry fecal matter from ceca (Kim and others 2006).

the evidence of feces-treated spots on a poultry carcass, but the appearance of the feces spots on the poultry was time dependent. Within the time-resolved fluorescence images, 20- and 25-ns images exhibited relatively greater contrasts between the poultry skin and the feces spots. A detection delay-gate time between 20 and 25 ns may be suitable for the detection of feces contamination on poultry carcass.

F values of one-way ANOVA for RFI values of feces and skin across the gate-delay time were calculated and are shown in Figure 7A. A larger *F* value indicates a more statistically significant mean separation between the 2 groups. The result indicates that the mean of the 2 groups were most significantly separated by a delay-gate time at 22 ns. To find an optimal threshold value for separating feces from skin, classification accuracies were calculated for values across the RFI values. Results illustrated that the highest accuracy (96.6%) was obtained by using a threshold of 1120 RFI value (Figure 7B). As shown in the frequency histogram, the skin parts, the relatively low intensities, are largely grouped together in contrast to the wide spread of a higher intensities for the fecal matters.

On the basis of the discrimination analysis, undiluted and 1:5 diluted fecal matters could be detected with 100% accuracy regardless of feces types. Classification accuracy for 1:10 diluted feces with the dry matter contents of approximately 15 to 18 μg/g was 89.9%. Detection accuracies for ceca and colon (100% for both) were higher than those for small intestine and duodenum (90.8% and 95.8%, respectively). The fluorescence response of 1:50 diluted fecal matters could not be discriminated from skin; hence these were excluded from the analysis.

Figure 8 shows a sequence of processed images beginning with a photo of fecal matters placed on poultry skin. The fecal matters are arranged from top to bottom with no dilution in row 1, and with dilutions of 1:5, 1:10, and 1:50 in rows 2 to 4. The samples shown in columns 1 to 4 (from left to right) are fecal matters from the duodenum, small intestine, ceca, and colon, respectively. As shown in Figure 8A, the diluted fecal matters are not easily discernible by naked eye, except for those from ceca. Figure 8B is the image obtained from using a 22-ns gate-delay time after 5 × 5 binning. Scattered spots that have high fluorescence intensities were observed in the areas for skin. The binary-classification image was obtained by applying the 1120 RFI threshold value to the 22-ns gate-delay time image (Figure 8C). Portions of the highly diluted feces spots are missing, and a few false positives were observed in the sample areas for skin. To eliminate the false positives, a 2 × 1 erosion algorithm was applied. The resultant binary image showed the successful detection of fecal matters diluted up to 1:5 along with partial detection of 1:10 diluted fecal matters without false positive (Figure 8D).

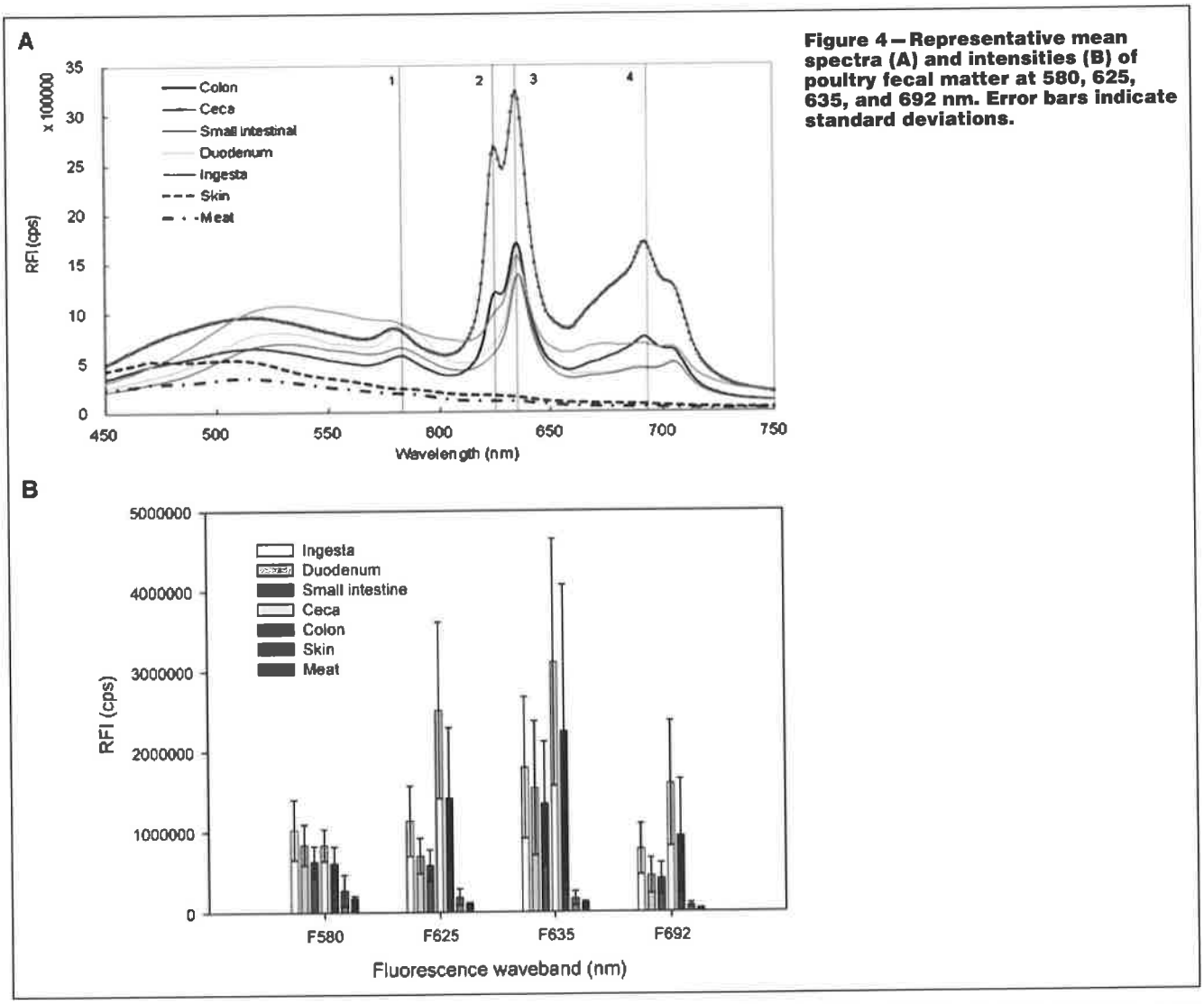

Figure 4—Representative mean spectra (A) and intensities (B) of poultry fecal matter at 580, 625, 635, and 692 nm. Error bars indicate standard deviations.

Conclusions

In this study, the optimization of imaging parameters of a LIFIS was investigated for the detection of diluted fecal matters applied to poultry skin. Fecal matters at dilutions as high as 1:10 could be detected with an accuracy of 96.6% using fluorescence emissions captured with the use of a 415-nm excitation source, 630-nm filter, and a 22-ns gate-delay time with an optimal threshold (for example, RFI 1120). The results demonstrate that the LIFIS has good potential for the detection of diluted feces on poultry carcasses and could be an alternative to the current human inspection method in automated poultry processing plants. To develop robust LIFIS for detecting various types and levels of diluted fecal contaminants, additional researches with more poultry carcasses fed by different feedstuff are warranted especially in an industrial setting.

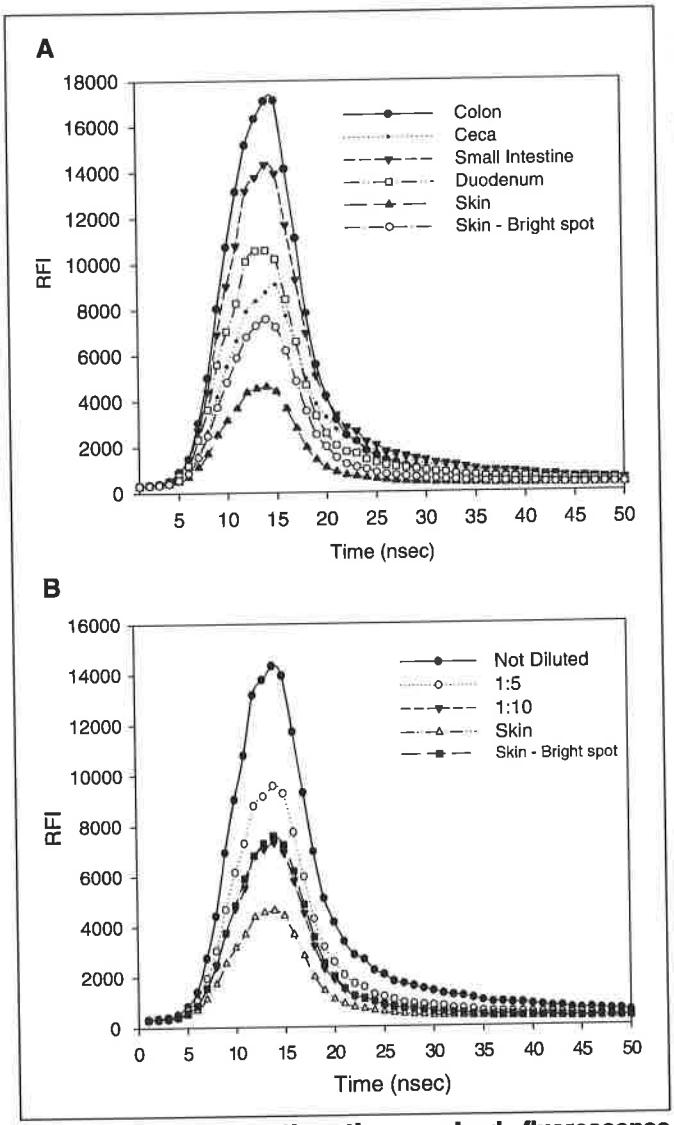

Figure 5—Representative time-resolved fluorescence emission spectra of poultry skin, and (A) undiluted and (B) diluted fecal matters.

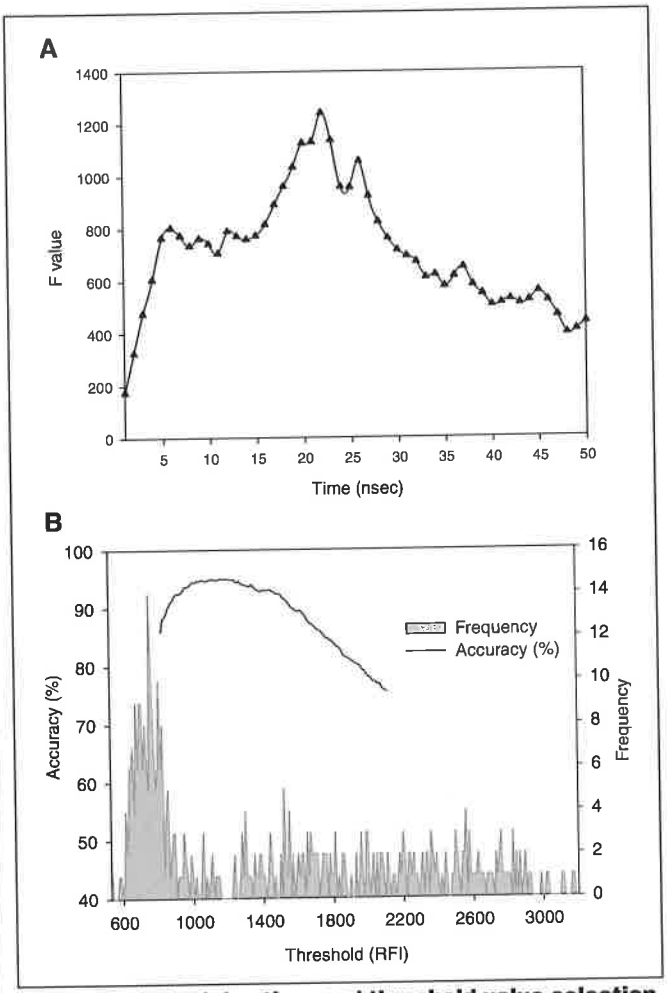

Figure 7—Gate-delay time and threshold value selection. (A) *F* values by delay-gate time used for classification, and (B) detection accuracy as a function of RFI threshold with frequency histogram for RFI values of feces and skin.

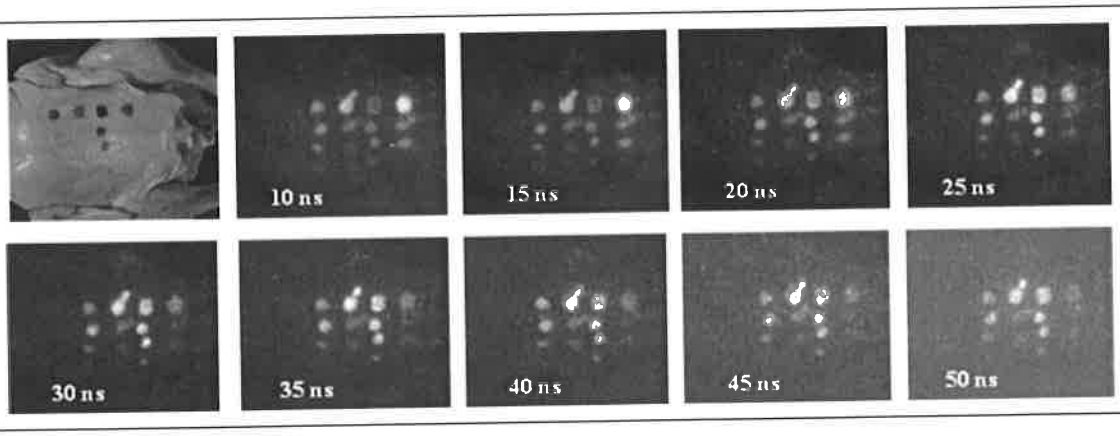

Figure 6—Time-resolved images at 630 nm spanning from 10 to 50 ns in 5-ns interval for a representative poultry artificially contaminated with the fecal dilutions, using 415-nm excitation.

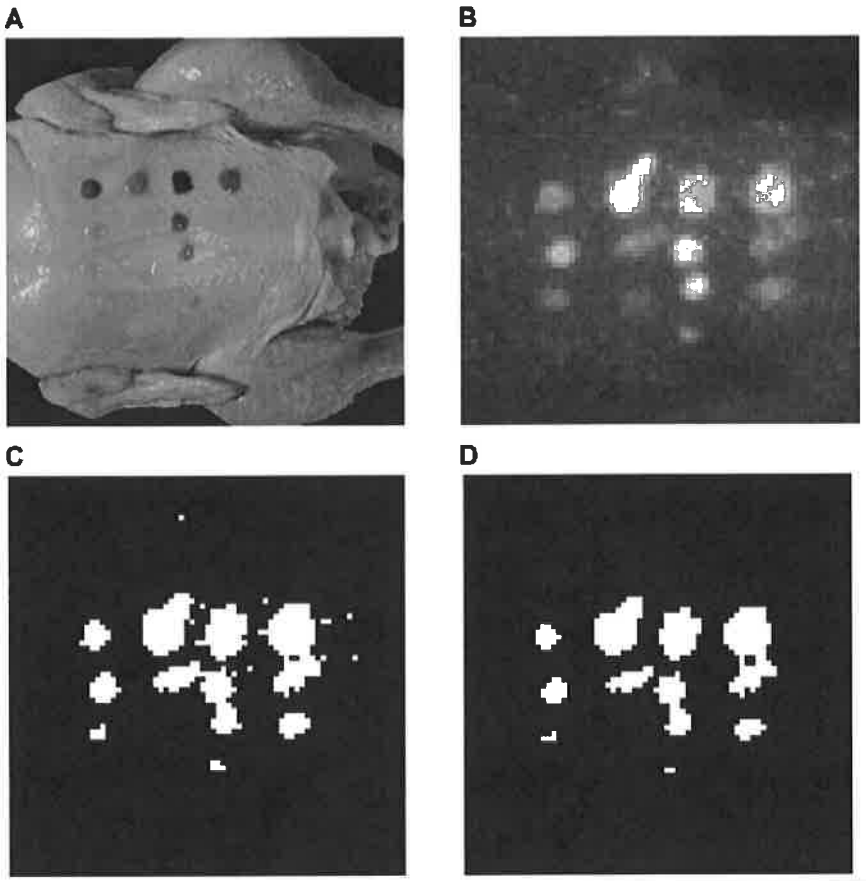

Figure 8—(A) Photo of contaminant on poultry skin; illustration of the image processing sequence: (B) 5 x 5 binned image at 22-ns gate-delay time, (C) binary image from a threshold of 1120 RFI, and (D) binary image with 2 x 1 image erosion.

Acknowledgments

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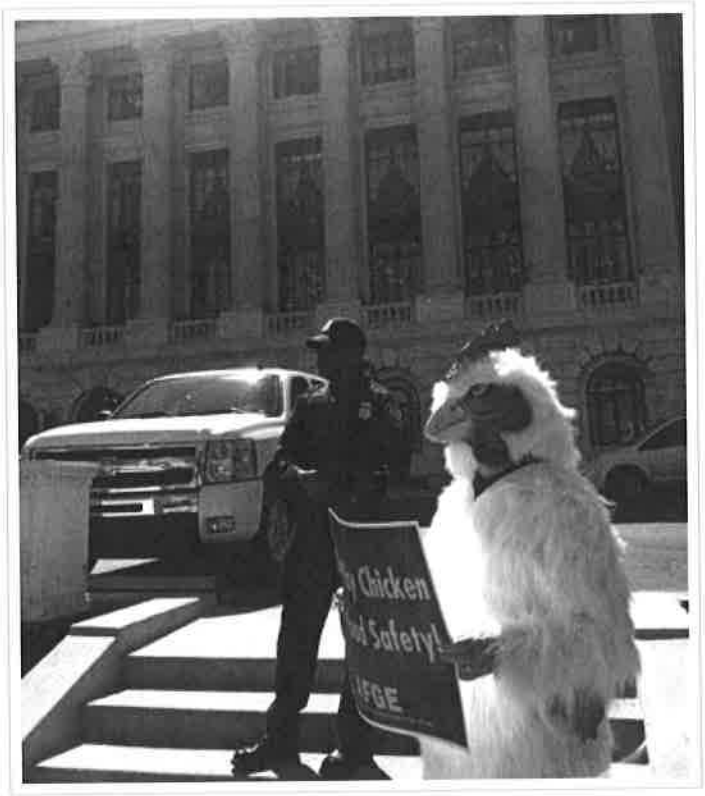
Footnote 38

Food Safety News
Breaking news for everyone's consumption

Poultry Inspectors Protest Inspection Proposal at USDA

By Helena Bottemiller | April 3, 2012

Around 100 poultry inspectors gathered outside the U.S. Department of Agriculture on Monday, right under Agriculture Secretary Tom Vilsack's window, to protest a proposal to expand an inspection system that shifts federal inspectors away from inspecting for quality defects and allows slaughter lines to speed up.



The USDA's Food Safety and Inspection Service is responsible for examining all poultry carcasses for blemishes or visible defects before they are further processed. Under the proposed rule, the agency would transfer much of this quality-assurance task over to the poultry plants so that it can devote more of its employees to evaluating the companies' pathogen-prevention plans and bacteria-testing programs.

It basically moves the federal inspector further down the line, to right before the chiller, to make sure there's no fecal material on the birds before they take the plunge into the cooling tank.

FSIS argues that the system, formally known as the HACCP Based Inspection Models Project, or HIMP, will improve food safety and save taxpayer dollars. The consumer group Food & Water Watch, and the inspectors at the rally, take issue with the entire proposal, arguing that it privatizes inspection and puts consumers at risk. A handful of plants have been a part of the HIMP pilot program for 12 years.

According to a peer-reviewed risk assessment, expanding HIMP would save FSIS $85 to $95 million over the next three years and be a $250 million boost to poultry companies, which will be able to crank up line speeds and process birds at a faster pace, all while reducing an estimated 5,200 poultry-caused illnesses each year.

"Cutting the budget does not justify putting the health and safety of consumers and workers in the balance," said Wenonah Hauter, executive director of FWW. "USDA inspectors receive extensive training to protect public health in poultry facilities, but there is no similar requirement for company employees to receive training before they assume these inspection responsibilities in the proposed privatized inspection system. This short-sided thinking could actually cost the federal government more to deal with a potential increase in foodborne illnesses

caused by unsanitary, defective poultry and meat."

At the protest rally, inspectors held signs that read: "Chicken Inspection Isn't a Speed Sport," "Don't Play Chicken With Safety" and "Speed Kills."

FSIS, for its part, points out that its also the private sector's responsibility — and in the poultry companies' interest — to keep keep carcasses with cosmetic or food safety defects out of commerce.

In a recent interview with Food Safety News, Under Secretary for Food Safety Dr. Elisabeth Hagen pointed out that FSIS' "extensive" HIMP assessment actually compared HIMP and non-HIMP plants, which is something FWW did not do in their analysis.

"What company has an advantage when they put cosmetically unappealing products in the market place? None of them," said Hagen. "There's a lot in the report that Food & Water Watch put out that, there's a lot of detail that I think we can respond to very easily....You could argue that our inspectors are finding things before they're going into commerce. We've still got somebody looking at what's happening in this HIMP system. It's not as if we've completely eliminated that function."

The number one concern expressed among inspectors at the rally was, without question, line speed, and the impact that would have on their ability — or anyone's ability — to inspect the birds whizzing by.

A group of inspectors from Georgia, Florida and Mississippi, who on average have been working in poultry plants for 15 years, told Food Safety News that if line speeds jump from 140 birds per minute, with three inspectors inspecting 35 birds each per minute, to closer to 200 birds per minute, with only one USDA inspector on the line, there will be quality issues: "How much can you see in that period of time!?"

"It's a very very bad idea," said one inspector from Georgia. "It's the speed and it's the quality the public will be receiving."

"There's a public safety risk here," said Clarence Douglas, an inspector from Mississippi. "The speed is a very important issue. We only have a few seconds to look at the birds. It's already tough to inspect as it is. If you speed it up you'll make it even more difficult."

Thomas says he still enjoys chicken and isn't picky about where it comes from, "but I will be if this proposal comes about. It would be a big step back."

Dr. Hagen said that FSIS is simply trying to modernize an outdated poultry inspection system and improve food safety.

"The inspection system was designed at a time when we thought the greatest risk was diseased animals getting into the food supply. We can do better than that now. We know what we need to be focused on is looking at whether the system they've set up is actually doing what it's supposed to do. What are the trends in the testing data? Are they meeting critical control points? These are things that actually make consumers safer," said Hagen. "It's not to say that there's not a role for USDA to play in some of this sorting, but these are primarily marketability issues. Anybody who knows food safety and anybody who's truly interested in moving the ball forward, would agree that we should be focused on things that actually make consumers safer."

Photo by Helena Bottemiller

This story was updated on Apr. 3.

More Headlines from Government Agencies »

Footnote 39

APPLIED AND ENVIRONMENTAL MICROBIOLOGY, June 2009, p. 3522–3527 Vol. 75, No. 11
0099-2240/09/$08.00+0 doi:10.1128/AEM.02685-08

Enumeration of *Escherichia coli* Cells on Chicken Carcasses as a Potential Measure of Microbial Process Control in a Random Selection of Slaughter Establishments in the United States▽

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To evaluate whether the number of *Escherichia coli* bacteria in carcass rinses from chicken slaughter establishments could be monitored for the purpose of microbial process control, we drew a random sample from 20 of 127 large USDA-inspected operations. In 2005, every 3 months, two sets of 10 carcass rinses, 100 ml each, were collected from establishments, netting 80 sample sets from the rehang and postchill stages. *E. coli* and *Campylobacter* numbers and *Salmonella* prevalence were measured. Mixed-effect models were used to estimate variance of mean $\log_{10}$ *E. coli* cell numbers of 10-carcass rinse sample sets. Relationships between *E. coli* and *Campylobacter* and *Salmonella* were examined. For 10-carcass rinse sets, at both the rehang and postchill stages the mean $\log_{10}$ *E. coli* CFU/ml fit the logistic distribution better than the normal distribution. The rehang overall mean $\log_{10}$ *E. coli* was 3.3 CFU/ml, with a within-sample set standard deviation of 0.6 CFU/ml. The overall postchill mean $\log_{10}$ *E. coli* was 0.8 CFU/ml, with 13 establishments having mean $\log_{10}$ *E. coli* CFU/ml values of less than 1.0 and 7 having mean values of 1.2 or more. At the midpoint separating these establishments, a mean $\log_{10}$ *E. coli* CFU/ml of 1.1, the within-sample set standard deviation was 0.5 CFU/ml, with smaller standard deviations as means increased. Postchill sample sets with mean $\log_{10}$ *E. coli* counts less than or equal to 1.1 CFU/ml had lower overall prevalence of *Salmonella* and mean $\log_{10}$ *Campylobacter* CFU/ml than sample sets with higher means. These findings regarding reductions in *E. coli* numbers provide insight relevant to microbial process control.

Regulatory food microbiology standards are defined and enforced with the intent of protecting public health and maintaining consumer confidence in the safety of the food supply. Resource demands (22) and legal constraints (21) have hindered the U.S. Department of Agriculture (USDA) from enforcing its current *Salmonella* performance standard (3). For this reason, in 2004 the USDA requested guidance from its national scientific advisory committee on the possible use of *E. coli* numbers to monitor sanitary conditions during poultry slaughter (12). The committee acknowledged that, if valid, such a performance standard could facilitate inspection of slaughter processing establishments. The committee recommended studies to define how *E. coli* numbers vary in poultry carcass rinses during poultry processing by processing stage, time of year, and geographic region and with respect to foodborne pathogens.

The widespread presence and high numbers of generic *E. coli* bacteria on poultry entering the slaughter establishment (2, 5, 14) are suitable characteristics for an indicator organism used to monitor microbial control processes. The ease and lower cost (5, 13) of *E. coli* enumeration also allow more observations than can be made when comparable resources are allocated for *Campylobacter* or *Salmonella* testing (15).

Regulatory agencies and food manufacturers have recognized the potential utility of *E. coli* numbers as a measure of slaughter process control. For example, USDA's hazard analysis and critical control point rule (3) specifies two criteria for evaluating process control: establishments are to maintain less than 100 CFU of *E. coli* per ml in 80% of poultry carcass rinses and never exceed 1,000 CFU/ml. Surveys have been performed to define precise *E. coli* performance criteria for poultry (5), to monitor microbial reduction during slaughter processing (6), and to validate interventions to reduce microbial numbers on poultry (20).

If generic *E. coli* numbers on poultry carcasses fit a parametric distribution, with a predictable mean and standard deviation, then carcasses could be monitored using a statistical process control plan. For example, if *E. coli* numbers decrease by an acceptable amount during processing to a reasonable level, then the process could be considered to be under control. Or a plan could be designed to monitor for acceptable occurrences of small, medium, and large deviations above a target *E. coli* number (7). If relationships were found between *E. coli* and *Campylobacter* numbers during chicken slaughter as well as *Salmonella* prevalence, they would further support the use of *E. coli* numbers as a measure of process control.

This study of a random sample of 20 large chicken slaughter operations located throughout the United States mea-

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sured microbial numbers at two processing line locations. Once a quarter, 10 carcass rinse samples were collected from both the post-feather-pick (rehang) and postchill locations. Rinses were examined to estimate mean *Salmonella* prevalence and *E. coli* and *Campylobacter* numbers by location within establishments. The primary objective was to assess whether the reduction in *E. coli* numbers between the rehang and postchill stages or numbers at the postchill location might have utility as a measure of process control during chicken slaughter. A related objective was to estimate values of parameters that could be used to design statistical process control plans (7).

MATERIALS AND METHODS

Sampling. All 127 large (i.e., 500 or more employees) USDA federally inspected young chicken slaughter establishments in operation in the autumn of 2004 were eligible for the study. Establishments were stratified by Food Safety and Inspection Service (FSIS) region, and a random sample of about one in six establishments was drawn in each region to yield a sample of 20 establishments. The random sample was drawn using the SAS Procedure Proc Surveyselect (SAS, version 9.1; SAS Institute, Cary NC), without replacement. Selected establishments were located in 13 states (Alabama, Arkansas, California, Delaware, Georgia, Indiana, Missouri, North Carolina, South Carolina, Tennessee, Texas, Virginia, and West Virginia) and represented eight integrated broiler companies. The survey provided a nationally distributed sample of typical chicken slaughter processes in large USDA-inspected operations during fiscal year 2005.

In each establishment, once every 3 months, FSIS personnel collected a set of 10 carcasses at the rehang (postpick) and postchill stages from one flock. Carcasses were collected using commercial kits (Solar Biologicals, Ogdensburg, NY). Each carcass was placed in a specially manufactured plastic bag, and 100 ml of sterile buffered peptone water was added. The collector shook the bag by hand for 1 min and removed the carcass aseptically. The full 100 ml of rinse was typically recovered with little or no excess rinse following the procedure. Vials were packaged in an insulated shipping container lined with six previously frozen 500-ml cold packs and shipped to the Agricultural Research Service (ARS) Bacterial Epidemiology and Antimicrobial Resistance Laboratory in Athens, GA, by overnight courier. Rinse temperature was measured upon receipt at the laboratory. All rinses used in the study arrived at the laboratory at temperatures between 0° and 9°C. In the first weeks of the study, however, rinses from five establishments were discarded because they were received at or above 10°C. In these establishments, rinses were collected 1 year later to provide data for four quarters. Two postchill rinses were lost, yielding 798 postchill carcass rinses.

Microbiology. (i) Generic *E. coli*. *E. coli* bacteria were enumerated by inoculating a 10-fold serial dilution of rinses onto *E. coli* Petrifilms (3 M Corporation, St. Paul, MN). Sterile saline (0.85%) was used for dilution in accordance with manufacturer's instructions. After incubation at 35°C for 24 h, typical *E. coli* colonies were counted.

(ii) *Campylobacter*. Numbers of CFU (CFU/ml) of *Campylobacter* bacteria were estimated by directly plating serial dilutions of carcass rinse on Campy Cefex agar plates (19). In the second, third, and fourth quarters of the study, in order to improve sensitivity of detection for low numbers of *Campylobacter* bacteria at the postchill stage, four 0.25-ml aliquots of undiluted rinse were plated onto four agar plates. Plates were incubated at 42°C for 48 h under the following atmospheric conditions: 5% O_2, 10% CO_2, and 85% N_2. Presumptive *Campylobacter* colonies were confirmed based on cellular morphology and motility under phase-contrast microscopy, followed by latex bead antigen agglutination testing of thermophillic *Campylobacter* (Microgen Bioproducts Ltd., Camberley, Surrey, United Kingdom).

(iii) *Salmonella*. Culture for *Salmonella* was conducted using standard FSIS methods for isolation from poultry rinses (22). A 30-ml aliquot of each carcass rinse was added to sterile buffered peptone water and incubated at 35 ± 2°C for 20 to 24 h. After enrichment, gene amplification (BAX; E. I. du Pont de Nemours and Company, Wilmington, DE) was conducted on lysed cells. The PCR-positive rinses were plated for isolation, as follows: 0.5 ml of preenriched broth was transferred to 10 ml of tetrathionate broth (Becton Dickinson, Sparks, MD), and 0.1 ml was transferred to 10 ml of Rappaport-Vassiliadis R10 broth (Becton Dickinson) and incubated aerobically at 37°C for 24 h. Next, 1 loopful each of tetrathionate broth and Rappaport-Vassiliadis broth was streaked on modified lysine iron agar (Oxoid, Basingstoke, United Kingdom) and brilliant green sulfa agar (Becton Dickinson) and incubated aerobically at 37°C for 24 h. After incubation, a well-isolated colony with typical *Salmonella* sp. morphology was picked from the modified lysine iron agar and brilliant green sulfa agar and screened on triple sugar iron agar (Becton Dickinson) and lysine iron agar (Becton Dickinson) slants. Isolates with typical *Salmonella* biochemical reactions were confirmed to be *Salmonella* based on detection of somatic (Becton Dickinson, Sparks, MD) and flagellar (latex agglutination; Microgen, Camberley, United Kingdom) antigens.

Statistics. To estimate the number of *Campylobacter* and *E. coli* CFU per ml of rinse, duplicate plates were inoculated for each serial dilution of the carcass rinse. The $\log_{10}$ CFU/ml values of both *Campylobacter* and *E. coli* were estimated based on means from duplicate plates. Because the logarithm of zero is undefined, when no cells were present on either zero dilution plate of the rinse sample, the results for *Campylobacter* or *E. coli* were set to 0.25 CFU/ml (i.e., one half of the limit of detection, or 0.5 CFU/ml).

Distribution of $\log_{10}$ *E. coli* numbers. The mean $\log_{10}$ CFU/ml of *E. coli* was determined for each 10-carcass rinse set collected in one establishment at one processing location on 1 day. For both the rehang and postchill rinses, the standardized mean $\log_{10}$ CFU/ml values of *E. coli* for 10-carcass rinse sample sets were calculated for comparison with fitted logistic and normal distributions. The overall mean was subtracted from the sample set mean, and the difference was divided by the predicted standard deviation, adjusted for finite population size. The Kolmogorov-Smirnov test was used to assess goodness of fit of data to normal and logistic distributions (18).

To estimate within-set standard deviations of the 10-carcass sample sets for $\log_{10}$ *E. coli* CFU/ml values, six rehang sample results were excluded as outliers, for a final data set of $\log_{10}$ *E. coli* CFU/ml values at the rehang stage consisting of 794 of 800 observations. To estimate within-set standard deviations of the 10-carcass sample sets at postchill stage, the analysis was restricted to 66 of 80 postchill 10-carcass rinse sample sets in which the mean $\log_{10}$ CFU/ml for *E. coli* exceeded 0.5, i.e., *E. coli* was detected in the majority of carcass rinses. Two rinses were lost during shipping, and two others were excluded as outliers. Thus, the standard deviation and distribution of postchill *E. coli* numbers were based on observations for 656 rinses.

Estimate of variances of $\log_{10}$ CFU/ml *E. coli* numbers within the 10-carcass sample sets at the rehang and postchill stages were obtained using maximum-likelihood estimation (8).

Mixed-effect models estimated standard deviations by the mean $\log_{10}$ *E. coli* CFU/ml of 10-carcass rinse sample sets. The models accounted for nested structure of data: individual rinses, 10-carcass sets, and establishments (11), as reported on USDA's website (23). Linear regression was used to evaluate the standard deviation of $\log_{10}$ *E. coli* CFU/ml with increasing 10-carcass rinse set means. Regression models compared reductions in mean $\log_{10}$ CFU/ml for *Campylobacter* and *E. coli* in flock-matched rehang and postchill sets (4). Analyses were performed with SAS, version 9.1 (SAS, Cary, NC), S-PLUS (Insightful Corporation, Seattle, WA), and WinBugs, version 1.4 (MRC Biostatistics Unit, Cambridge, United Kingdom).

RESULTS

***E. coli* distributions at the rehang and postchill locations.** Overall, 796 of 800 (99.5%) rehang rinses and 691 of 798 (87%) postchill rinses tested positive for *E. coli*. Standardized $\log_{10}$ *E. coli* CFU/ml values of both rehang and postchill 10-carcass rinse sample sets fit the logistic distribution better than the normal distribution due to kurtosis in the observed distributions (Fig. 1). The *P* values for the Kolmogorov-Smirnov test of goodness of fit to the logistic and normal distributions at the rehang stage were 0.017 and 0.003, respectively, and at postchill stage they were 0.059 and 0.015, respectively.

For rehang rinses, the overall mean $\log_{10}$ CFU/ml for *E. coli* was 3.3 CFU/ml (Table 1). The within-set standard deviation of the 10-carcass sample set was approximately 0.6 $\log_{10}$ CFU/ml. Among rehang 10-carcass rinse sample sets, the standard deviations of $\log_{10}$ *E. coli* CFU/ml remained stable as the mean $\log_{10}$ *E. coli* CFU/ml increased (data not shown).

For postchill rinses the overall mean $\log_{10}$ *E. coli* CFU/ml

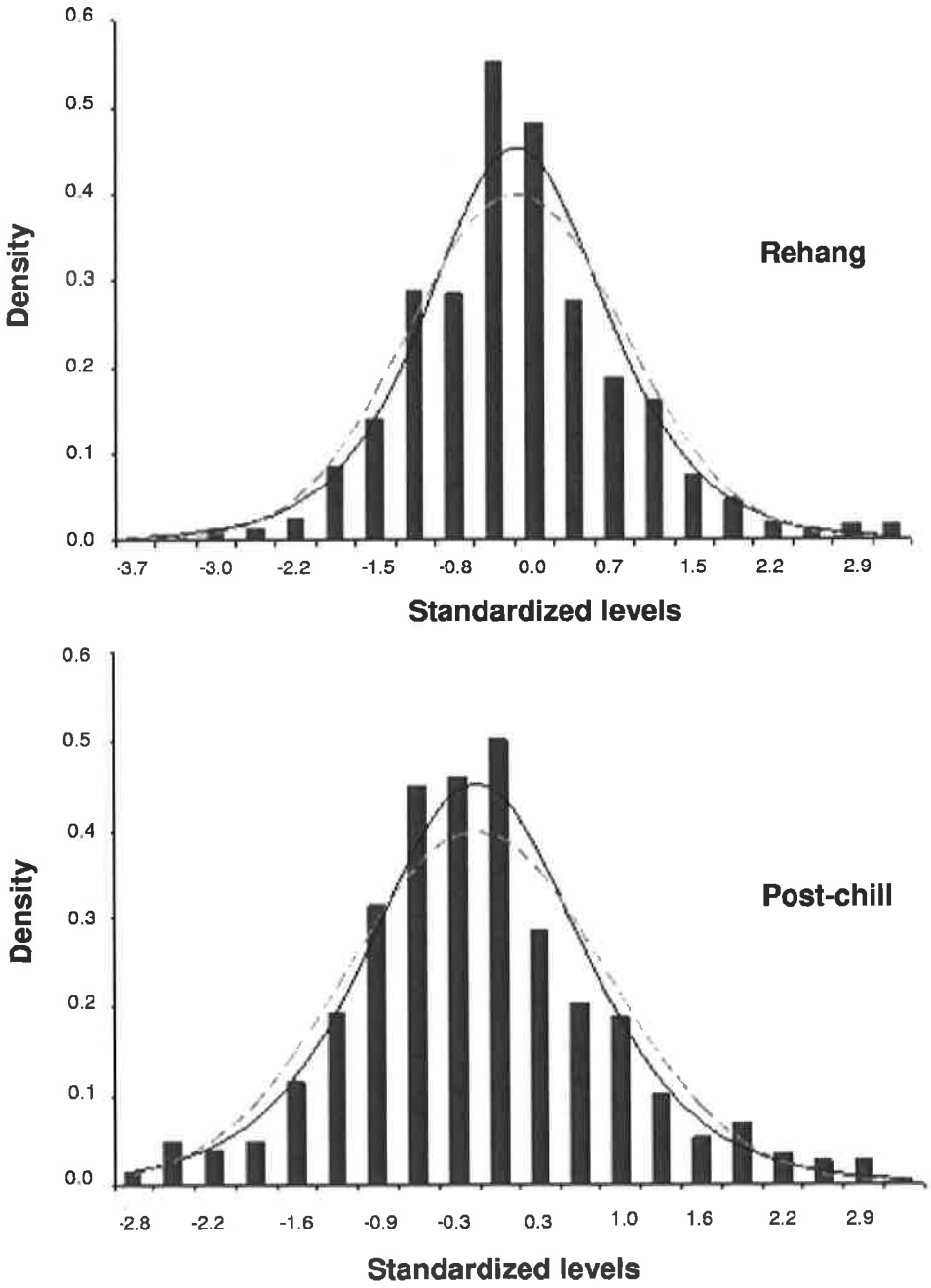

FIG. 1. Standardized mean $\log_{10}$ *E. coli* CFU/ml values of 10-carcass rinse sets collected at rehang and postchill stages with fitted distributions Solid lines, logistic distribution; dotted line, normal distribution.

was 0.8 CFU/ml. Among postchill rinses the standard deviations of $\log_{10}$ *E. coli* CFU/ml values slightly decreased with increases in the mean $\log_{10}$ *E. coli* CFU/ml (data not shown). The within-set standard deviation of the 10-carcass sample sets for *E. coli* at the postchill stage was approximately 0.5 $\log_{10}$ CFU/ml when the 10-carcass rinse sample set mean was 1.1 $\log_{10}$ CFU/ml, a value of potential relevance for process control (below).

Relationships between *E. coli* and other bacteria. The overall prevalence of *Salmonella* at the rehang stage was 71%, and the mean for *Campylobacter* was 2.5 $\log_{10}$ CFU/ml. The overall *Salmonella* prevalence at the postchill stage was 21%, and the mean $\log_{10}$ CFU/ml for *Campylobacter* was 0.02 $\log_{10}$ CFU/ml. In each quarter, the mean $\log_{10}$ CFU/ml for *E. coli* was numerically higher than that for *Campylobacter* at both the rehang and postchill stages.

At postchill, 13 establishments had overall mean *E. coli* numbers below 1.0 $\log_{10}$ CFU/ml, and 7 had mean numbers of 1.2 $\log_{10}$ CFU/ml or more (data not shown). Thus, these establishments fell into two groups separated by a midpoint

TABLE 1. Mean *E. coli* and *Campylobacter* counts as well as *Salmonella* prevalence for rehang and postchill chicken carcass rinses by quarter of collection and for the year

Study quarter	Rehang rinse data				Postchill rinse data			
	No. of rinses	*E. coli* count ($\log_{10}$ CFU/ml)	*Salmonella* prevalence (%)	*Campylobacter* count ($\log_{10}$ CFU/ml)	No. of rinses	*E. coli* count ($\log_{10}$ CFU/ml)	*Salmonella* prevalence (%)	*Campylobacter* count ($\log_{10}$ CFU/ml)
1	200	3.3	72	2.7	200	0.7	29	−0.05
2	200	3.2	76	2.3	199	1.0	20	0.01
3	200	3.3	70	2.7	200	0.9	17	0.35
4	200	3.3	74	2.3	199	0.7	18	−0.23
Overall[a]	800	3.3	71	2.5	798	0.8	21	0.02

[a] October 2004 to October 2005.

postchill mean value of 1.1 $\log_{10}$ *E. coli* CFU/ml. Compared to the seven establishments with postchill mean $\log_{10}$ *E. coli* CFU/ml values greater than 1.1, a larger proportion of the 13 establishments with lower means had postchill mean $\log_{10}$ *Campylobacter* CFU/ml values less than 0.0 and postchill *Salmonella* prevalences less than 20% (Table 2). However, these associations, based on a sample size of 20, were not statistically significant at a P value of <0.05.

Similarly, although not statistically significant, in postchill sample sets, *Salmonella* prevalence and *Campylobacter* numbers were sometimes higher when mean $\log_{10}$ *E. coli* CFU/ml exceeded 1.1. In 32 sample sets with higher *E. coli* numbers, the mean $\log_{10}$ *Campylobacter* CFU/ml was 0.26 compared to 0.14 in 48 sample sets with lower *E. coli* numbers. *Salmonella* prevalence was 27% compared to 17% in the same respective sample sets.

Reduction of *E. coli* and *Campylobacter* numbers. Both mean $\log_{10}$ CFU/ml values for *Campylobacter* and *E. coli* decreased between the rehang and postchill stages (Table 1). In a total of 11 matched 10-carcass sample sets collected from the rehang and postchill stages in one operation on the same day, *Campylobacter* was detected in each rinse. In 10 of these 11 matched sample sets, the mean reduction in *Campylobacter* numbers was greater than that of *E. coli* numbers (Fig. 2).

DISCUSSION

In this study of carcass rinses from 20 randomly selected chicken slaughter establishments, mean $\log_{10}$ *E. coli* CFU/ml values in the rehang and postchill rinse sample sets fit parametric distributions. In addition, mean $\log_{10}$ *E. coli* numbers at the postchill stage were consistent with those reported in other surveys performed around the time of this study (2, 17). A postchill mean $\log_{10}$ *E. coli* CFU/ml value of 1.1 provided a useful reference for the design of a process control plan (7), defining two distinct groups of establishments, those with higher versus lower means. This value also suggested a possible tolerance above the mean for the purpose of process control. With additional information confirming expected *E. coli* numbers during poultry processing, control plans may be developed that define acceptable frequencies of small, medium, and large deviations above the process mean (7) and other quality control measures (e.g., moving averages or the CUSUM method).

A statistical process control plan for poultry slaughter sanitation based on *E. coli* numbers of carcass rinses at the postchill stage might have practical merits for several reasons. The high yield (5) of *E. coli* enumeration compared to labor- and resource-intensive pathogen testing protocols (15) is advantageous for the purpose of statistical process control (7). For example, fewer than half of the postchill

TABLE 2. Overall mean $\log_{10}$ *Campylobacter* CFU/ml and *Salmonella* prevalence in chicken carcass rinses at the postchill stage stratified by plant mean $\log_{10}$ *E. coli* counts

Parameter	No. (%) of plants by the indicated mean $\log_{10}$ *E. coli* CFU/ml		Total no. of plants (%) positive for *E. coli*
	≤1.1	>1.1	
Overall *Campylobacter* count			
$\log_{10}$ CFU/ml ≤0.0	8 (62)	3 (43)	11 (55)
$\log_{10}$ CFU/ml >0.0	5 (38)	4 (57)	9 (45)
Overall *Salmonella* prevalence			
<20%	7 (54)	3 (43)	10 (50)
>20%	6 (46)	4 (57)	10 (50)

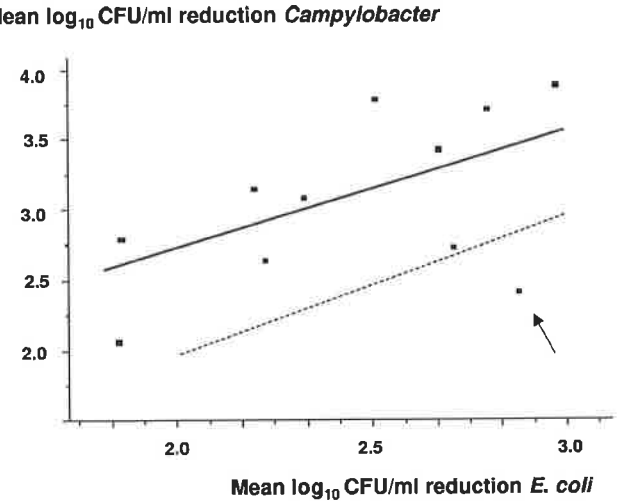

FIG. 2. Reduction of mean $\log_{10}$ *Campylobacter* CFU/ml versus mean $\log_{10}$ *E. coli* CFU/ml values from the rehang to postchill stage for 11 matched 10-rinse sample sets in which *Campylobacter* was detected in all rinses. The arrow denotes one instance with a greater reduction in the $\log_{10}$ *E coli* value than the value for *Campylobacter*. Solid line, fitted linear regression line for data; dotted line, 45° line.

rinses described in the present report tested positive for either *Salmonella* or *Campylobacter*. In contrast, *E. coli* was detected in almost 90% of these rinses. Some variability of *E. coli* numbers was, however, noted across study quarters. More studies are therefore recommended of environmental factors that could affect *E. coli* numbers in poultry rinses.

The evidence regarding relationships between indicator organisms and pathogens on poultry carcasses is equivocal. Although *E. coli*, *Salmonella*, and *Campylobacter* are often present in the chicken gastrointestinal tract (10) and on carcasses, (5) if there are relationships between their presence on carcasses, they may be altered by environmental factors. These factors include the pathogen loads on chickens, which are known to vary by flock (9). The effectiveness of pathogen controls such as feed withdrawal prior to slaughter can also be influenced by host factors, such as the age of the bird (13). As another example, disease conditions within flocks (16) are reported to alter microbial numbers at the postchill stage. In addition, some slaughter plant interventions, such as carcass chilling, can result in differential reductions in *Campylobacter* and *E. coli* numbers (14). Cautious interpretation is therefore advised regarding relationships between *E. coli* levels and food-borne pathogens in this study. Nonetheless, in both establishments and sample sets, overall *Salmonella* prevalence and mean *Campylobacter* numbers were frequently, but not uniformly, higher when the postchill mean log10 *E. coli* CFU/ml exceeded 1.1. To further elucidate relationships between *E. coli* and pathogens, additional surveys with larger sample size are therefore recommended.

We have previously reported that poultry processing significantly reduces *Campylobacter* counts in carcass rinses (1). In this report overall mean *Campylobacter* numbers at both the rehang and postchill stages were lower than those of *E. coli*. Even so, reductions in *Campylobacter* numbers between these processing locations were generally greater than those for *E. coli* when comparisons were possible. Thus, we suggest that, in most instances, processes that lower the *E. coli* level at postchill stage are unlikely to increase *Campylobacter* numbers. Practical reasons for monitoring reductions of *E. coli* over *Campylobacter* include the relative ease of enumeration and lower cost (2).

Limitations of this study included the number of establishments and the times that each establishment was sampled. In addition, human and laboratory resources precluded enumeration of *Salmonella*. A strength of this study was the relatively large number of carcass rinses within sample sets that permitted reasonable estimates of variance. In summary, findings of this study suggest that *E. coli* numbers in postchill chicken carcass rinses may have features of value for process control plans (7). Specifically, *E. coli* numbers were reduced during processing and fit the logistic distribution at the postchill stage, with stable means and defined standard deviations. The study was not designed to evaluate efficacy of processing interventions (20) or the effect of microbial loads in live birds (9). Rather, microbial numbers were measured at the rehang and postchill stages in a randomly selected group of U.S. chicken processing operations. Additional studies are recommended of *E. coli* numbers in poultry carcass rinses, environmental factors that could affect these numbers, and possible relationships with pathogens.

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We report no conflicts of interest related to our contributions to this study.

This study complies with federal and institutional animal use guidelines and policies.

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Footnote 41

GOVERNMENT ACCOUNTABILITY PROJECT
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May 29, 2012

Docket Clerk
U.S. Department of Agriculture (USDA), FSIS
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Washington, DC 20250-3700

(Submitted via www. Regulations.gov)

RE: Docket FSIS-2011-0012:Modernization of Poultry Slaughter Inspection

The Government Accountability Project (GAP) is providing the following comments, which contain affidavits from federal poultry inspectors/whistleblowers, all of which challenge the U.S. Department of Agriculture's (USDA) proposed Modernization of Poultry Inspection System – based on the piloted poultry inspection system known as the HAACP-Based Inspection Models Project (HIMP). Additionally, GAP's comments expose weaknesses in the USDA's assessment of the HIMP pilot's efficacy and challenge the Agency's approach to rule-making.

Just some of the concerns that GAP's comments express:

Under the new proposal, line speeds will be greatly increased. One federal inspector is going to be responsible for safeguarding **over 10,000 birds per hour**. These rates are so fast, that inspectors simply cannot look at every bird.

Under traditional inspection methods, inspectors can see all sides (and the inside) of the bird. But inspectors at HIMP plants **can only see the backside of the bird** – not the front (where the breast meat is) that may clearly show tumors or scabs. Nor can HIMP inspectors see the inside of the bird, where fecal matter and other disease-causing abnormalities are found.

In each Inspectors' case, the Agency allowed the plant to move its "Critical Control Point (CCP)" – the main purpose of which is to identify and catch potential food safety problems – to a point further down the conveyor line, which was ***after*** a key "Inspection Station." This has the effect of **taking away the inspectors' ability to see non-compliances or issue Noncompliance Records (NRs)**, documentation showing a plant CCP's failure to prevent important regulatory violations. Multiple NRs can lead to increased enforcement action against the plant.

Federal inspectors at HIMP plants are made incapable of, or discouraged from, holding the plants accountable for contaminated poultry. One whistleblower said the inspectors were told by their USDA supervisor to "give [plants] a break" for violations, seemingly so that the plants with high violation numbers wouldn't be removed from the HIMP program. Another whistleblower pointed out that even if they are able to detect problems amidst breakneck line speeds during "Carcass Inspection," inspectors at his/her plant are not permitted to stop the line.

HIMP inspectors, being short-staffed, frequently are **unable to complete all of their inspection duties**, which has serious consequences for public health. For example, if there are not enough inspectors to do sanitation checks, rodents or garbage could contaminate the slaughter or production areas.

The Agency's own data from the HIMP pilot project demonstrates that **Carcass Inspectors are unable to detect, and therefore cannot protect consumers from the vast majority of carcasses with food safety defects.**

The Agency does not explain why certain data are missing or why time periods for comparisons are not uniform. Without reasonable explanations for these discrepancies, **it is impossible to conclude that these data were not cherry-picked** because they were particularly advantageous for the Agency's agenda.

The Agency's assertion that HIMP plants produce less NR's than Traditional plant are based on faulty assumptions. The Agency provided no information to demonstrate that documentation policies and opportunities for documenting violations were the same in HIMP and non-HIMP plants.

HIMP is being promoted **for economical efficiency, not for the benefit of public health**. The steamrolling of this proposal has precluded the type of public discussion that could result in increased allocations for FSIS instead of decreased protections for consumers, workers, and poultry animals.

Sincerely,

Amanda Hitt

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(Submitted via www. Regulations.gov)

RE: Docket FSIS-2011-0012: Modernization of Poultry Slaughter Inspection, Proposed Rule

The Government Accountability Project (GAP) appreciates the opportunity to comment on the United States Department of Agriculture Food Safety Inspection Service' (USDA/FSIS's) proposal and the supporting documents which report on the Agency's experience under its HACCP-based Inspection Models Project (HIMP). The Government Accountability Project is the nation's leading whistleblower protection organization. Through litigating whistleblower cases, publicizing concerns and developing legal reforms, GAP's mission is to protect the public interest by promoting government and corporate accountability. Founded in 1977, GAP is a non-profit, non-partisan advocacy organization based in Washington, D.C.

GAP has attached to these comments a number of whistle-blowing disclosures made by FSIS inspectors who are currently working or have worked in one of the Agency's HIMP pilot plants. [ATTACHMENT 1]. Their eyewitness testimony is essential to providing the public with a more informed view of what the Agency's proposal will mean for consumers of poultry products.. The federal inspector disclosures represent approximately 80 of experience in HIMP poultry establishments in 4 different states in 5 plants. Among these disclosures is the statement of a current federal inspector who worked as a plant supervisor in the poultry industry for 10 years before leaving to work for USDA/FSIS. [1] Excerpts from the statements are included throughout these comments.

Despite the threat of retaliation, inspectors provided these affidavits for the benefit of the public's health and right to know. The following are but some of the reasons these inspectors have come forward.

> "[B]ased on my many years of experience as a HIMP inspector, I know that the claims the government is making about the HIMP program are not true. [Affidavit 1];
> "[T]he government's plan to implement the pilot "HIMP" inspection program in all poultry plants would be a mistake with very serious negative consequences. I believe that more unwholesome and potentially harmful products will reach consumers. . ." [Affidavit 2];

[1] This is the first in a series of disclosures that GAP will publish which were made by current or former employees for the meat or poultry industries about working in the industry.

"The Agency says that its proposal to make HIMP the primary inspection system is based on food safety objectives. However, from what I have seen, I do not know how they can make that claim."[Affidavit 3];
"[B]ased on my direct experience, the government's plan to bring the HIMP inspection system to all poultry plants would be against the best interests of consumers and taxpayers." [Affidavit 4];
" USDA's proposed rule. . . .creates the opportunity for serious threats to public health and safety." [Affidavit 5];
"[T]he Agency's plan to implement [its proposal] is a very serious mistake. . . and if most consumers knew about how HIMP functions, they would not want it implemented either." [Affidavit 6];
"[B]ased on my direct experience [as a supervisor in a poultry plant for over 10 years] I believe that the proposed rule poses a significant danger to the public's health and safety [because] the fewer USDA inspectors that are available to inspect actual product, the more the plants will try to cut corners and pressure their employees to maintain productivity at any and all costs." [Affidavit 7].

INTRODUCTION

GAP joins other concerned groups in urging the Department of Agriculture to withdraw its proposed rule which will largely abandon government inspection of poultry.

Although the proposal says the system will be voluntary, Agency plans to cut back inspection resources for plants that do not opt in to the proposed system effectively make the program mandatory. In response to program incentives and market forces, the vast majority of commercial poultry slaughtering establishments will turn inspection over to in-plant employees and will increase production line speeds.

The new poultry proposal will result in increasingly unsafe and unwholesome poultry products reaching consumers -all of which will carry a USDA seal indicating that they were inspected and passed by government inspectors. The new plan not only puts consumers at risk. In addition to occupational safety threats that the new plan poses for inspectors, poultry line workers will be at increased risk for injury, and poultry animals will undoubtedly be subjected to more abuse and inhumane treatment

The Fox Guarding the Henhouse

The concept of the fox guarding the henhouse is, understandably, an affront to common sense. Yet, this is precisely what the new poultry rule proscribes. It is unrealistic to expect that companies will forfeit profits in order to provide protections for consumers when, under this proposal, they will no longer be required to do so. The vast majority of commercial poultry plants will be subject to less government oversight and consumers will have little market power to demand that current levels of food safety and quality be maintained as the industry engages in a race to the bottom.

Inspectors working in HIMP plants report that, rather than trying to maintain the same level of product inspection as provided by federal inspectors under the traditional inspection system, plant managers cut corners and try to get around the regulations.

> [S]uspicious looking birds are "reworked" instead of discarded like in the traditional system, even though their carcasses may have signs of disease that could be harmful if not distasteful to consumers . . . I often find reworked birds with fecal contamination because the plant

workers do not have enough time to correctly process the birds and are missing many things."[Affidavit 5].

As company employees replace government inspectors on the lines, managers of HIMP plants fail to train their employees so that they are knowledgeable enough to do their jobs. Managers also run line speeds so fast that even willing employees fail, and they punish employees who try to prevent unsafe or unwholesome product from going out to consumers.

> "[C]ompany employees are not well trained. The higher management employees, those who are responsible for directing the program in the plant, cannot even identify the poultry diseases that affect the carcasses that we see every day on the slaughter line. So it is not a surprise that the company sorters, those who are responsible for looking at every carcass to determine if it is safe and wholesome, often overlook things. . . . Even when it appears they are trying, they just cannot keep up because the line speeds are now so high."[Affidavit 3].

> "It is my experience that plants are mostly concerned with production and the maintenance of the production line at high speeds. . . . I have yet to see a plant properly train their employees in poultry sorting, and I have seen plant leadership fire those who bring food safety or quality assurance issues to their attention.
> . . . "The piloting of the HIMP system was useful in that it made it very clear that plants do not care about protecting consumers and should not be trusted to come up with their own inspection plans."[Affidavit 6]

> "I've seen [plant] sorters attempt to slow down or stop the line to move birds to the reprocessing line, only to be rebuked by their supervisors. In my plant, some of the sorters really try to look at all of the birds. Others, though, seem to not care or to have given up on doing their job." [AFFIDAVIT 1].

Inspectors also report that when plants have to conduct product checks by sampling, plant employees try to game the system:

> "If I report a problem at the verification inspection, like detection of fecal contamination, septicemia or toxemia, the Veterinarian and I must observe the plant quality control employees perform several checks and retests to ensure that the problem is fixed and that corrective action (like finding the source of the problem and resolving the issue) has been taken. . . . In my opinion, the plant's checks and retests are not conducted thoroughly. It is just a game -- they prepare the sample birds for the rechecks to ensure they will not fail, taking much more care with these birds than they do with the majority of the birds to make sure they are free of contamination and disease and the initial problems persist." [Affidavit 2].

One inspector who has not worked in a HIMP plant, but worked as a supervisor for a poultry company for over 10 years before becoming a federal inspector, described managerial and supervisory motivations in industrial poultry slaughter plants. His statement explains what inspectors have seen in the HIMP plants and what the public can expect as all of the major poultry producers adopt the proposed inspection system.

> "It is my experience that the fewer USDA inspectors that are available to inspect actual product, the more the plants will try to cut corners and pressure their employees to maintain productivity at any and all costs.

. . . plant employees had it drilled into their heads that productivity and maintaining the production line was their chief responsibility, not making sure the poultry was safe to eat. In fact, we were encouraged to hide diseased or dirty chicken carcasses from the USDA inspectors in the plant and process it out to consumers. All plant supervisors and managers had walkie-talkies and we would inform each other where inspectors were and where they were heading so that we could be prepared and prevent them from seeing any number of the food safety violations we committed. A constant refrain on the radio was, "USDA inspector on the floor."

. . . . As supervisors, we never questioned the plant manager's directives; we just did what we were told to do. The impression we got was that anyone who did not toe the line would be yelled at, fired, or most likely both

. . . . When we knew that we had a bad, diseased, or unwholesome-looking flock that might get pulled off the line by the USDA inspector we would mix a "good" flock with the bad flock and turn up the speed of the evisceration line so that it would be more difficult for the inspector to catch the bad birds. . . . We were in a constant battle with the USDA inspectors.

. . . When the USDA was not present, we would re-label boxes of poultry product so that boxes of product would have their "use by" dates changed so that we could meet the specific requirements of an order.

. . . The constant pressure to "run, run, run" the production line against any and all other concerns was my only thought to avoid getting fired. Every minute that the plant was not running the line, thousands of dollars would be lost and not only the slaughter side, but the production end of things would be held up as well. We were told that these employees would then be paid for doing nothing, which was unacceptable. I know that the expansion of the HIMP proposal is so dangerous because of my experience working for the plant. If plants are placed in charge of the inspection process, there will be no inspection at all." [Affidavit 7].

Dangerous Pathogens in Poultry

Contaminated poultry is the USDA-regulated product with the most significant public health impact. According to the Centers for Disease Control (CDC), Salmonella is the foodborne pathogen responsible for the greatest number of hospitalizations and deaths.[2] Additionally, researchers at the University of Florida Emerging Pathogens Institute found that *Campylobacter* and *Salmonella* in poultry were responsible for more hospitalizations and deaths, and greater costs of illness, than any other single pathogen/food combination.[3] The public is generally aware that acute symptoms can be caused by foodborne pathogens, but researchers are just beginning to understand that the long-term health consequences from food poisoning may even outweigh those of the more immediate problems.[4]

Agency officials have repeatedly claimed that the impetus for the proposal is public health. But USDA's estimates of public health benefits to be expected under this proposal are weakly supported and are meager - illnesses from poultry might be reduced by 1.9% and no reduction is anticipated in *Campylobacter* illnesses, In fact, USDA acknowledges that implementation of the program may lead

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[2] CDC 2011 Estimates of Foodborne Illness. http://www.cdc.gov/foodborneburden/2011-foodborne-estimates.html

[3] Table ES-2. The top 10 pathogen-food combinations in terms of annual disease burden, by combined rank. Ranking the Risks: The 10 Pathogen-Food Combinations with the Greatest Burden on Public Health. Michael B. Batz, Sandra Hoffmann and J. Glenn Morris, Jr. University of Florida Emerging Pathogens Institute. 2011. Pg. 9.

[4] The Long-Term Health Outcomes of Selected Food Pathogens. Tanya Roberts, Barbara Kowalcyk, Patricia Buck. The Center for Foodborne Illness Research & Prevention.2009.

to increased illnesses. [5] This is not a reasonable basis for USDA's proposal to radically alter its inspection system and, in effect, transfer the majority of inspection activities over to industry employees.

"Modernization" fails from pilot to proposal

This ill-conceived plan should be rejected for several reasons. First, the Agency bases its public health projections on information from its HIMP pilot project. However, information from the HIMP pilot, including the Agency's own data, indicates that HIMP is an inferior form of inspection (despite the Agency's repeatedly unrealistic and misleadingly optimistic claims, which are addressed in Section 2 of these comments.)

Second, as bad as HIMP is, the proposal includes changes that will make the new inspection system even worse for consumers. The proposed inspection system retains the worst characteristics of the HIMP pilot then decreases protections even further. Additionally, unlike the HIMP pilot program, which was limited to plants slaughter of young animals, there is no limitation on the type or age of poultry that can be slaughtered under the proposed inspection system, despite the fact that older animals are more likely to be diseased. It is unreasonable to assume (and the Agency has provided no justification for its assumption) that results under the HIMP pilot will be similar under the proposed inspection system once the standards and the regular government checks are eliminated.

Third, the new features of the proposal will enable the Agency to diminish food safety inspection activities. There are numerous reasons to assume that this will happen. One of the primary claimed benefits of the proposal is the significant budgetary savings for USDA as it cuts over 10 % of its inspection force. These savings were included in the Agency's 2013 budget even before the Agency received comments on the proposal. We are very concerned that as Agency staffing in poultry plants dwindles, inspection activities will be significantly less than under the HIMP pilot because the Agency has repeatedly refused to commit to maintaining similar, specific levels of food safety activities under the new system. The Agency has already allowed staffing levels to decrease in some HIMP plants, to the detriment of the inspectors' abilities to maintain the level of oversight promised to the public when the Agency implemented this pilot.

> "In the plant where I normally work (which is under the model HIMP system) . . . we are stretched far too thin and as a result, many times are unable to complete the inspection tasks that we are supposed to complete or even have a bathroom break. It bothers me that we do not have the manpower to be able to do our jobs . . . [Affidavit 5]
>
> "Several years ago, we had a Verification Inspector and a team leader on the slaughtering floor at all times. Now, the team leader and Verification Inspector covers not only the slaughter floor but also huge processing floor, which can easily be larger than a football field. Additionally, with the Public Health Information System (PHIS) being implemented, the Verification Inspector now spends much of his time off the floor entering data in the office." [Affidavit 1].

[5] There are several different estimates provided by USDA, but this seems to be the one the Agency believes is the most reliable of the lot. FSIS Risk Assessment for Guiding Public Health-Based Poultry Slaughter Inspection. USDA/FSIS, Office of Public Health and Science. Updated November 2011. Pg. 11

"The Agency has been short-staffed for many years at various plants and there have been timed (sic) we had to delay certain inspection duties until late into the shift, the next shift or even the following day. I have heard of other plants so short-staffed that they cannot complete sanitation inspection. This is a concern because, depending on the plant's commitment to sanitation, mold, debris from the slaughter process, or eve rodent issues may be present. On many occasions, we have had to monitor production either late in shift or until the next shift arrives. This worries me greatly because much of the cutting is done on the production-side the plant. When we are present, we have seen many plant employees accidentally drop product and utensils like knives and scissors on the floor and neglect to sanitize the equipment or rinse the meat before it is returned to the production line." [Affidavit 6].

SECTION 1 - DIMINISHED GOVERNMENT INSPECTION UNDER THE HIMP PILOT AND THE PROPOSED INSPECTION SYSTEMS

Whistleblower inspectors reveal the stark contrast between traditional plants and those based on the HIMP model. Many of their concerns are about line speed, the inability to effectively inspect the carcasses, and the inability to stop the line for defects.

Inspection under the Traditional Inspection System

"Under traditional inspection, there are several inspectors on the evisceration lines . . . with each inspector observing approximately 35 birds per minute." [Affidavit 5].

"Our inspection was characterized by a "hands on" mentality. . . [We] are able to see all angles of the birds as they go by and look at the inside and outside of the birds. This is important because fecal contamination . . . is oftentimes found inside the birds." [Affidavit 2].

"Inspectors working in a traditional plant are trained to be sure to look inside the bird, as well as the front and the back, and also look at the organs in order to make a determination that the carcass is not carrying dangerous disease conditions or fecal contamination. Inspectors in a traditional plant condemn, and remove from the line, those carcasses that exhibit signs of disease or fecal contamination. [Affidavit 3].

Inspection under HIMP and the Proposed Inspection Systems

Under HIMP and the proposed inspection system, federal employees rotate between two different roles. When in the Carcass Inspector (CI) position, inspectors are stationed at a fixed point, at or near the end of the establishment's evisceration line, looking at carcasses. When in the Verification Inspector (VI) position, inspectors roam throughout the plant, doing food safety tasks, inspecting plant facilities and taking product samples.

The Agency seriously misleads consumers by claiming that under the HIMP pilot and the proposed inspection systems, company employees are only taking over the line inspectors' responsibilities of "sorting" for bruises, feathers, and other "cosmetic defects," and that CIs retain all of the other functions of line inspectors in traditional plants. The Agency also claims that CIs have the same authority as line inspectors in a traditional plant. These are falsehoods. Additionally, while inspectors examine around 35 birds per minute under traditional inspection, under HIMP and the proposed inspection systems, they are required to do the impossible – "inspect" 175 birds per minute.[6]

[7] HIMP Evaluation, Pg. 23

> "I am expected to "inspect" over 150 birds per minute. It just cannot be done. . . I know I cannot detect all of the carcasses with Food Safety defects, and it is reasonable to assume that some are going out to the public."[Affidavit 3].
>
> "We cannot stop the line if we are concerned and have been admonished by our supervisors if we do." [Affidavit 6].

Under HIMP and the Agency's proposal, (CIs) are not able to look at the organs. Also, CIs are not required to inspect the inside or front of the carcass, both of which are necessary for detecting food safety and wholesomeness defects, and some have been admonished for doing so. The Agency claims to have a "zero tolerance" policy for two Food Safety defects in poultry: Septicemia/Toxemia (classified under HIMP as FS-1) and Fecal Contamination (classified under HIMP as FS-2).[7] Yet, under HIMP and the proposed system, most inspectors only look at the back of the bird as it quickly moves by on the line and so are far less able to detect food safety defects in each carcass.

> "USDA inspectors are trained to look for and prevent food safety violations of the poultry products that are produced. Under HIMP we were prevented from using our knowledge to fully protect consumers. . . We were told to "verify from the outside" and to be sure of what we saw before stopping the line. This seemed absurd to me, because you cannot be sure of a food safety violation until you "inspect" the bird." [Affidavit 4].
>
> "[U]nder HIMP, we are not permitted to look inside the bird, meaning we are likely to miss any defects or diseases that don't show up on the outside back of the bird. . . . our authority has diminished substantially." [Affidavit 1];
>
> When we only see the "back" of the bird we cannot see the widely consumed "breast tissue" of the birds, which is a common site . . . blisters, tumors, or excessive feathers stuck to the bird carcass." [Affidavit 2].

The proposed inspection systems further decreases other protections that are part of the HIMP pilot program. Under HIMP, VIs collect and closely examine 10 birds for food safety defects, every hour, and also examine at least two of the 10-bird samples for wholesomeness defects. Given the decreased role of federal line inspectors, these 10-bird samplings are the only hands-on verification of poultry carcasses under HIMP. There are no scheduled food safety or wholesomeness checks included in the Agency's proposal and in its discussions with consumer organizations, the Agency was unwilling to commit to any specific number of scheduled checks. Also, while HIMP included government standards for defects that rendered carcasses unwholesome, under the proposal, each establishment will be able set its own standards for wholesomeness.

Finally, under the proposed inspection system, the Agency also reduces other standards and controls used in the traditional and HIMP pilot inspection systems. These include sampling for generic *E. coli*, time and temperature standards, and restrictions on the use of carcass washes and chemical interventions.

SECTION 2 – THE EVIDENCE OF AN INDEFENSIBLE SYSTEM

The Agency proposal and supporting documents claim that CIs in HIMP plants are able to "properly inspect each carcass"[8] and can detect fecal contamination and Septicemia/Toxemia[9]. The Agency's

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[8] HIMP Evaluation pg. 5.
[9] HIMP Evaluation, pg. 14; Fed. Reg. Pg. 4415.

data, to the contrary, indicates that CIs can barely detect these defects and cannot do so at a level that is adequate to protect public health.

Fecal Contamination - – USDA Data Shows That Most Fecal Contamination Cannot Be Detected by HIMP Inspectors

During the mechanical evisceration process, eviscerators may puncture intestines which may lead to fecal contamination inside and/or on the outside of the carcass. Fecal contamination carries pathogens such as *Salmonella* and *Campylobacter* and is therefore considered a Food Safety defect. Most CI's under HIMP and the proposed system, however, cannot look inside or at the front of the bird (discussed above), and are therefore unable to prevent fecally-contaminated birds that are potential carriers of deadly pathogens from going out to consumers.

The consumer organization Food and Water Watch recently received government documents under the Freedom of Information Act (FOIA) from a number of HIMP plants.[10] The records pertaining to violations of Agency's zero tolerance policy for fecal contamination indicate the exact location on a carcass where fecal contamination was found. Our analysis revealed that the fecal contamination on at least 150 out of 191 would not have been detectable by CIs because the contamination was inside or on the front of the bird. But, given the accelerated line speeds, CIs would even be likely to miss contamination found on the back of the bird, particularly if it was confined to a small area.

USDA's own two-year analysis of HIMP data, contained in the Evaluation of HACCP Inspection Models Project (HIMP) ("the HIMP Evaluation"), indicates that *CIs were incapable of detecting fecal contamination on 88 out of 89 birds with fecal contamination going down the line.*[11] Inspectors in the VI position, who were able to examine both the inside and the whole outside of the bird, found fecal contamination on the poultry at approximately 90 times the rate as CIs were able to find it.

While these numbers are already abysmal, they are based on the assumption that the rate at which VIs found fecal contamination was representative of the level at which it occurred -which may not be the case. In HIMP plants, only eight samples, consisting of 10 birds each, are collected per shift and there is no evidence that such a small sample size is truly representative of the quality of production throughout the shift. Further, HIMP inspector-whistleblowers told us that plant employees took greater care when they knew a VI sample would soon be taken, so the VI findings are likely an underestimation of the rate at which fecally-contaminated birds were actually produced by the plants.

> "[W]e often find many more birds with fecal contamination at VI than at CI." [Affidavit 6].
>
> "[W]ith 10, 000 or more birds going down the line in an hour, there is not much of a chance that the VI will find such defects even if many birds violate the regulations." [Affidavit 3].
>
> "The plant seems to note when I'm getting ready to do VI testing. I've gotten up on the stand to pull my ten bird sample, and watched the quality of the birds improve for the next two minutes or so after I get on the stand. . . .It's clear that the plant is trying to manipulate the VI tests. I've found ways to combat this, like waiting longer to pull my 10 bird sample after

[10] http://www.foodandwaterwatch.org/food/foodsafety/privatized-poultry-inspection-usdas-pilot-project-results/

[11] The analysis shows that Verification Inspectors, through sampling, detected fecal contamination on 0.08% of the carcasses while CI's detected fecal contamination on only 0.0009% of the carcasses. TABLE 3-2. Comparison of Fecal Detection Rates for Carcass and Verification Inspectors. HIMP Evaluation, pg. 15; and Fed. Reg. pg. 4415.

> getting on the stand, but it's a constant battle to stay one step ahead of the plant." [Affidavit #2].
>
> "These Verification Inspections are also supposed to be random to get an accurate reading for potential infectious diseases, contaminations or OCPs. What eventually happened was that when the plant supervisors saw us preparing for a "random" sample, they would slow the line down and pull out any suspicious looking birds, and fewer and fewer NRs were written from the VI station. The plant supervisors would even instruct the sorters to pull suspicious looking birds off the line before our VIs. As a result, the samples were not an accurate reflection of what was going down the line. Our supervisor did not see the plant supervisors do this, and when we told him, he said that he would have to see it himself before he could take action, which he never ending up doing." [Affidavit #4].

Since verification sampling is done only occasionally, the vast majority of carcasses with fecal contamination, which cannot be spotted by the CI, continue along the production lines:

> "During VI, a USDA inspector will pull in ten bird samples from the production line to examine closely for diseases or adulteration every hour. At VI, we could write NRs for Food Safety violations. I would continue to find fecal contamination on the inside of the birds, so I knew that birds that were not collected for the sample might be going down the line contaminated and out to the consumer." [Affidavit #4].

Based on the data provided by the Agency, it is reasonable to calculate that CIs failed to detect over a quarter of a million carcasses with fecal contamination in the 20 HIMP plants within the two-year period of data collection.[12] These contaminated birds continued down production lines on their way to consumers. Given that the Agency's VI data is an underestimate, as discussed above, it is reasonable to assume that many more birds with food safety violations continued down evisceration and production lines because of the CIs' inability to detect them.

Septicemia/Toxemia -- USDA Data Shows That Most Diseased Carcasses That Pose Public Health Threats Cannot Be Detected by HIMP Inspectors

Septicemia and toxemia are systemic conditions that are classified as Food Safety defects by the Agency. The two conditions show similar signs and are considered as one category, "sept/tox", by the Agency.[13] Under Agency regulations, carcasses exhibiting symptoms must be condemned.[14]

In the Agency's current training for inspectors on how to identify sept/tox when performing postmortem inspection of poultry carcasses, four of the six symptoms identified are in the organs or inside the carcass of the bird.[15] The Training also says that the conditions may affect the bird either rapidly or more gradually. Finally, it instructs, "It is important to remember that no single carcass will show all of these signs."

Despite these clear instructions to inspectors based on veterinary pathology, the Agency now claims that CIs do not need to examine the organs and do not need to look inside the carcass. However, the

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[12] 2, 994 x 89 = 266, 466.
[13] Poultry Postmortem Inspection. FSIS. 3/7/09. Pg. 14.
http://www.fsis.usda.gov/employees/Slaughter_Inspection_Training/index.asp
[14] 9 CFR § 381.83
[15] Poultry Postmortem Inspection. FSIS. 3/7/09. Pg. 13.
http://www.fsis.usda.gov/employees/Slaughter_Inspection_Training/index.asp

Agency's own data demonstrates that the CIs in HIMP plants are even less able to detect sept/tox than they are to detect fecal contamination. *The data indicates that CI's detect only approximately 1 of every 200 birds with sept/tox,*[16] *which means that 199 of every 200 birds with sept/tox are continuing down production lines and on to consumers.*

Based on the government data alone, it is reasonable to estimate that over 6000 chickens with sept/tox were undetected by CIs and continued down production lines to consumers. Again, this data is based on the assumption that the level of sept/tox discovered by VIs is representative of the level of sept/tox in production, which is unlikely s discussed above, since plant employees improve performance when they see the VI preparing to take a 10-bird sampe.

Covering for Industry Food Safety Problems

Based on the history of HIMP, if the proposal is adopted in over 200 poultry plants, as estimated, it will result in much more sept/tox and fecal contamination on poultry products. Consumers would be wrong to assume that the Agency will be rigorously scrutinizing the program and demanding improvements by industry. Another lesson from the HIMP pilot is that rather than forcing the plants to improve, USDA will change the rules to benefit the industry and avoid responsibility for known problems.

A 2002 Government Accountability Office report on HIMP warned that "the number of non-compliance records resulting from fecal material increased significantly at several plants after they shifted from traditional inspections to [HIMP]." HIMP inspector-whistleblowers who worked at the plants when they transitioned from traditional inspection to HIMP confirmed that fecal contamination increased.

Under HIMP, plants are to have critical control points (CCPs) along the production line to remove any defective birds prior to the CI station. If a CI found a bird with fecal contamination, the plant's CCPs had failed and the CI was authorized to write a NR. The inspectors reported that some plants wanted to leave the program because they were getting so many NRs that they could be subject to increased enforcement action.

USDA's solution? Change the rules so the plants would no longer be written up.

In violation of the Agency's philosophy that, under HIMP, it was the plant's responsibility to ensure that it only presented to the CI carcasses that were likely to pass inspection, USDA allowed the plants to move their CCPs for fecal contamination and sept/tox to points AFTER the CI. Once plants did so, the CI could no longer hold them accountable for any food safety defects they were able to detect. Industry learned well. The Agency's supporting documentation for the proposal reports that, of the 20 young chicken establishments, 8 have moved the CCP for FS-1 (Sept/Tox) and 20 have moved the CCP for FS-2 (fecal material) to a position after the CI.[17]

> "We were finding so many fecal contamination that the rumors in the plant were that the plant was considering leaving the HIMP pilot program. It seems like our USDA supervisor, maybe from pressure from the district office, was concerned that the plant might leave the system

[16] Comparison of Sep/Tox (sic) Detection Rates for Carcass and Verification Inspectors. Table 3-1. HIMP Evaluation, pg. 15; Fed. Reg. pg. 4415.
[17] HIMP Evaluation, pg. 10.

because we were told to combine several NRs into one NR and told to "give them a break" for the violation. When the fecal violations keep coming, the CCP was moved to *after* the inspection station. According to our supervisor, and the HIMP guidelines, we were not permitted to write NRs when the CCP was after the inspection station" [Affidavit 4].

"I've sometimes found 4 or 5 birds with fecal contamination within a timeframe of 15 minutes and still cannot issue an NR to the plant. Because there is room to place the inspector station after the plants' CCP, I believe that the CCP was moved solely to prevent the plant from being documented for non-compliances." [Affidavit 1];

"When we first came under the HIMP system, the CCP for fecal contamination was located before the inspection station and we were writing NRs for fecal contamination 5-6 times a shift, which was much more than under the traditional inspection system. When this kept happening, the plant was permitted to have the CCP *after* the inspection station." [Affidavit 2].

"Multiple NRs for a particular issue can lead to increased enforcement action against the plant and, therefore, the threat of an NR provides a good incentive for the plant to produce safe product. . . .

[W]e were issuing the plant a lot of NRs because fecal contamination was passing their CCPs and reaching the CI station. . . Then plant managers were worried they would be subject to enforcement action and some of them started thinking about leaving the program.

Soon after that. FSIS allowed the plants to move the CCP to a point *after* the CI position. So now, if the CI finds birds with fecal contamination, no NR is written. It is not that the plant prevented any of that fecal contamination; we just stopped issuing NRs for it." [Affidavit 3].

OCP – The Agency is Relinquishing Control of Wholesomeness

Diseases, conditions, and symptoms that render poultry unwholesome but "are less important to food safety" [18] are termed Other Consumer Protections (OCPs). These include cancers, infectious diseases, and inedible organs (such as intestines or lungs). OCPs also include bruises, scabs, mutilations and fractures; so, in addition to being unwholesome for consumers, they may also indicate that animals were abused prior to or during slaughter. Although poultry produced under this proposal will continue to carry the USDA "INSPECTED FOR WHOLESOMENESS" seal, and despite its statutory mandate under the Poultry Products Inspection Act (PPIA), the Agency is generally abdicating continued accountability for wholesomeness to private industry.

Under HIMP, inspectors are generally not capable of seeing or preventing OCP defects from reaching consumers because they are only allowed to see the back of the carcasses. Also inspectors are generally, prohibited from intervening[19] because the Agency established specific (albeit, quite permissive) levels of unwholesome products that the industry could release to the public before the Agency would intervene on OCP's.[20] Finally, and most significantly, under HIMP (as well as the proposal), it is only when "the establishment or FSIS inspection personnel observe the presence of

[18] Fed. Reg. 4422.

[19] HACCP Based Inspection Models Project (HIMP) Young Chicken Inspection, FINAL DRAFT 8. 12/24/04, pg. 6. ("HIMP Draft 8")

[20] HIMP Draft 8, pg. 9-13.

persistent, unattended removable animal diseases or trim and dressing defects on poultry carcasses or parts", that the Agency will take action to "require the establishment to take appropriate actions."[21]

> "Whereas in the traditional system, inspectors will pull birds from the line or ask an inspector's "helper" assigned to them to trim any suspicious parts of the birds, in the HIMP system we were instructed to avoid stopping the production line and the message we received was to be generally less involved because "sorters" that work for the plants would remove any suspicious looking birds." [Affidavit 4].

> "When we are on CI duty, it is difficult to determine the wholesomeness of birds because they are going by so fast and even if we could see every bird at that speed and we detect problems, we are not permitted to stop the line . . . When I am at a CI station, I can observe the final trim station where plant employees known as "trimmers" are supposed to look for OCP characteristics and trim them off the birds. There is no way that these employees can catch all of the birds with OCPs when the production line is going that fast. OCPs are not considered a food safety issue by the Agency, but I have seen bruises that exhibit signs of advanced bacterial development. For example, bruises often ooze slime when the trimmers cut them off. I have seen bruises that, when cut off, ooze red, green, brown, and, when very old, black slime." [Affidavit 6].

Federal inspectors who have worked in traditional plants and have had the ability and authority to prevent these defects from going to consumers object to having "their hands tied" under HIMP and the proposed inspection system. As stated by Dr. Randy Daily, a USDA veterinarian who has been a supervisor in a HIMP plant for 11 years and is, generally, a supporter of the proposal:
"Our inspectors have a natural desire to want to have diseased tissues removed from the food chain. The current inability to take action on diseased tissues in the HIMP inspection system produces a continual source of frustration for the inspection team."[22]

Inspectors, in their own words, have voiced concerns about OCP's. While many of their accounts of OCP's are unsavory, some inspector disclosures reveal potential food safety concerns, such as the presence of fecal matter on the carcasses:

> "I believe that unsafe and unwholesome birds will be more likely to reach consumers . . .[U]nder the HIMP program. . . I have seen birds whose bodies were at least half covered with inflammatory process, an amount indicative of [a systemic condition], and been told that because part of the bird can be salvaged through trimming, the inflammatory process is only localized." [Affidavit 1].

> "At verification inspection, . . . [w]e find many OCP issues but cannot write NRs for these findings unless the plant exceeds its allowable limit or "performance standard" for a specific OCP in a 25-day period. For example, we would not be able to write an NR for blisters unless 52.5% of the birds during VI had blisters for seven days within a 25- day period." [Affidavit 6].

> "The definition of fecal contamination has also changed and narrowed. I have been told that "if it's not smearing" it's not fecal contamination and must be classified as ingesta (or stomach contents) for which FSIS has a greater tolerance and is an [OCP]. . . Several times I have

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[21] Fed. Reg. pg. 4423.

[22] Comment by Dr. Randy Daily at www.Regulations.gov

spotted what I know smells like fecal contamination and have had to let it go because it does not smear." [Affidavit 5].

"[I]f the fecal contamination is not touching the bird's skin, it is not considered fecal contamination. We often see birds going down the line with intestines still attached [OCP-5], which are full of fecal contamination. If there is no fecal contamination on the bird's skin, however, we can do nothing to stop that bird from going down that line. It is more than reasonable to assume that once the bird gets into the chill tank (a large vat of cold water), that contamination will enter the water and contaminate all of the other carcasses in the chiller. That's why it is sometimes called "fecal soup." I think we should be able to prevent birds with intestines full of feces from continuing down the line toward the chiller . . . more than 20.8% of the birds would have to have intestines still attached, for 6 days within a 25-day moving window, for their system to be deemed out of control. Otherwise, we do nothing." [Affidavit 3].

One of the primary arguments for distancing federal inspectors from matters involving quality defects is a free market approach. The government maintains that once the government no longer monitors quality, companies will do so in order to protect their brands. However, all evidence suggests that the market will not take care of the problem.

There is an increasing market for chicken parts and processed chicken that enables companies to profit, even from unwholesome product. As stated by Dr. Daily:

"today's consumer rarely sees raw poultry product in a form where they can determine its wholesomeness. Today's products are battered, breaded, marinated etc. to the point where the consumer is no longer able to recognize diseased tissue even if they knew what to look for."[23]

Inspectors under HIMP have seen that the companies allow line speeds to run so fast that their employees cannot remove all of the OCP defects. Additionally, under HIMP, the VIs inspect several samples of 10-birds every shift for OCP defects. Given the allowable limits, plants can manipulate their controls once they know they will pass the standards for the shift, and do so, rather than ensuring that they maintain higher levels of wholesomeness.

"I've noticed that the plant will usually do better quality control at the beginning of the shift, then start to degrade and allow more feathers and other OCP defects to pass through the sorting station after the 4th test or so, when the numbers are such that the plant is confident it will pass for the day." [Affidavit 2].

HIMP results obtained by Food and Water Watch also indicate that rather than trying to minimize defects, establishments will alter production only enough to meet the standard:

For the OCP category pertaining to blisters, bruises, mutilations, fractures, scabs and skin diseases, (OCP 2), which has an allowable limit of 52.5%, only one of the 11 plants for which FWW was able to obtain records, had less than 25% of these defects in their poultry carcasses; 4 plants approached a 30% defect level, 5 plants hovered around 40% and one plants had nearly 50%.

For the OCP category pertaining to "extraneous material, feathers, lung, oil gland, trachea, bile" (OCP 4), which has an allowable limit of 80%, only 2 broiler plants had an OCP rate of

[23] Daily, public comment.

less than 53% and the rest had rates between 63-72%. The three turkey plants did even worse, with rates of 54.8%, 95.7% and 99.52%.

It is clear that the industry will not maintain the levels of wholesomeness that are provided by government inspectors. Immediately after the proposal was published, the industry cartooned about the fact that USDA will no longer be controlling the amount of bruises and scabs that go out to the consumer. [ATTACHMENT 2].

The Agency's proposal reduces government oversight even further than under the HIMP pilot inspection system. Under the proposal, establishments will determine how best to address OCP defects and how best to document that they are meeting the general standard of "ready-to-cook" poultry.[24] This will mean that they can determine what, when, how often and where to monitor for OCP defects. Also, the proposal suggests that federal eyewitness verification of establishment products will be largely replaced by review of company paperwork. The proposal states that "Under this proposed rule, FSIS would verify that an establishment's poultry products comply with the ready-to-cook poultry definition by reviewing the records maintained by the establishment to document that its products are ready-to-cook poultry." It seems that review of company paperwork will be the primary way that inspectors will verify the level of OCPs that companies are releasing to the public. Under this proposed rule, FSIS would verify that an establishment's poultry products comply with the ready-to-cook poultry definition by reviewing the records maintained by the establishment to document that its products are ready-to-cook poultry." It seems that review of company paperwork will be the primary way that inspectors will verify the level of OCPs that companies are releasing to the public.

By carefully designing, monitoring, and documentation programs, companies will be able to limit government oversight of wholesomeness even more. The Agency's false reassurance that CIs will "also inspect carcasses for trim and dressing defects and removable animal diseases"[25] is meaningless, as discussed above, because CIs only see the back of the bird and line speeds will be greatly increased. Further, in contrast to the HIMP program, the agency is not committing to any specific level of scheduled VI verifications under the proposal.

Failing to provide standards and decreased VI verifications in the proposed inspection system is a cynical way for the Agency to avoid following statutes mandating that USDA-inspected product be wholesome. It will inevitably result in only very occasional intervention on behalf of consumers. As stated in Dr. Randy Dailey's public comment:

> "[t]he current language used (persistent unattended) presents an extremely vague standard for the IIC [Inspector in Charge] and the establishment to use as guidance. Without a standard to use as a point of reference there will be great variation in how this language is interpreted and applied through [out the country]."

Vague standards inhibit inspectors from challenging supervisory instructions that threaten public health. FSIS programs have been repeatedly criticized by the Government Accountability Office (GAO) and the USDA's own Office of Inspection General (USDA/OIG) because vague standards have been interpreted differently in different locations and have often been ineffective. Moreover, vague standards provide fodder for plant managers who want to frustrate government regulation by continuously challenging and threatening to sue FSIS in-plant supervisors (this is so common that the Agency advises veterinarians to obtain private insurance to cover such an eventuality).

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[24] Fed. Reg. 4423.

[25] Id.

Salmonella Data Call the Agency's Prediction of Public Health Benefits From the Proposed Inspection System Into Question

Since the disease burden of *Salmonella* is one of the public health problems that USDA must address, it is reasonable that the Agency consider relative levels of *Salmonella* in poultry produced under the different inspection systems, before determining which system to use. USDA's proposal presents some data about *Salmonella* rates in some HIMP poultry plants and also claims that *Salmonella* rates will likely be lower in plants under the proposal, but how the Agency reached its conclusion is not clear.

The Agency's prediction of public health benefits are discussed in its 2011 FSIS Risk Assessment for Guiding Public Health-Based Poultry Slaughter Inspection ("RA"), which concludes "the greatest effect on *Salmonella* and *Campylobacter* prevalence and related illness would occur when inspection duties were concentrated on increased unscheduled offline procedures."[26] But the RA provides little raw data, few explanations of how it was analyzed, and is largely silent on the assumptions upon which it is based.

The most basic problem is that the RA is based on the assumption that the Agency's *Salmonella* verification data is representative of the performance of the plants. (Other problems with the RA are discussed in Section 3 of these comments). This assertion has been refuted repeatedly by the Center for Foodborne Illness Research and Prevention's CEO and Director of Research, Dr. Barbara Kowalcyk, whose doctoral work included a focus on biostatistics. The Agency is well aware of Dr. Kowalcyk's concern but continues to use *Salmonella* data improperly.

There are many questions the Agency would have to answer before it can be assumed that the RA is correct and can be used to direct Agency actions to reduce pathogen levels, including:

> *If the unscheduled procedures were more frequent under HIMP and this was so significant, why did the non-HIMP comparison plants have better Salmonella results in 2009 and 2010, than the HIMP plants did?*

The Agency data shows that *Salmonella* rates were lower in HIMP plants than in the 64 comparison plants in the years 2006-2008 but that rates were higher in the HIMP plants in 2009-2010.[27] It is clear from the data that plants under both traditional and HIMP inspection systems lowered their *Salmonella* rates considerably between 2006 and 2010. Since the Agency reports no changes to the HIMP or traditional inspection systems during that time, it is reasonable to assume that another factor may have caused such a significant decrease in *Salmonella* levels in all plants. For example, the Agency says that there are currently 144 broiler plants that use on-line reprocessing technology, which is designed to lower salmonella rates.[28] However, there is no indication in the RA that the Agency identified or controlled for this or any other factor in its analysis.

If the data is correct and if the trend continued, it would indicate that the traditional inspection system currently leads to the lowest *Salmonella* levels. This would be very important for the Agency and the public to consider in identifying the inspection level with the greatest potential public health benefit.

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[26] Id. Pg. 4420.

[27] Table 6: Salmonella Percent Positive Rates for HIMP and Non-HIMP Broiler Establishments. Id. Pg. 4418.

[28] Id. Pg. 4412. We requested information from the Agency on how many of the HIMP and non-HIMP comparison plants added this technology by year, to see if that might suggest a correlation, but the Agency would not provide that information.

Were the salmonella results cherry-picked, and if not, why are there significant gaps in the data?

The Agency admits that *Salmonella* data was only collected in 10 of the 20 HIMP broiler plants in 2010.[29] Data from the Agency's *Salmonella* testing program, acquired by Food and Water Watch, shows that, *Salmonella* was collected in only 14 HIMP plants in 2006, 17 HIMP plants in 2007[30], and 15 HIMP plants in 2008.

The Agency also provided no comparison on *Salmonella* results in the turkey plants. Our analysis of the Agency's *Salmonella* data from 1/1/2006 through 9/20/2007, shows that the HIMP plants had a *Salmonella* rate of 8.9%, while the non-HIMP plants had a rate of 6.5%.

Finally, the Agency's own analysis of *Salmonella* data from the 20 plants that joined the HIMP pilot demonstrates that *Salmonella* levels actually increased in 14 of the plants when they came under the HIMP program.[31] [ATTACHMENT 3]. If plant performance under this proposal tracks HIMP performance in this way, even an initial increase in *Salmonella* levels in the 194 plants that the Agency assumes will adopt this system would create a significant public health problem.

Were the reductions in Salmonella levels due, merely, to the fact that the procedures were unscheduled, or were reductions due to the particular unscheduled procedures in addition to the scheduled procedures that were performed?

Finally, the RA concludes that more unscheduled procedures are the key to lowering *Salmonella* levels. However, there is not enough information presented to conclude that this would be the case even if the Agency drops all of the *scheduled* food safety verifications, which might be a necessary base- these were the only inspection tasks that were conducted in HIMP plants more than in traditional plants.[32] This is important because there are *no* scheduled food safety checks in the Agency's proposed system. Therefore, the Agency's "assum[ption] that off-line inspection activities after the voluntary implementation of the new inspection system will parallel off-line inspection activities in current HIMP establishments,"[33] is without foundation.

SECTION 3 – THE AGENCY'S FAULTY AND UNRELIABLE PUBLIC PROCESS

USDA/FSIS has attempted to bypass the public process because this ill-conceived proposal is unsupportable. For ten years, the USDA has conducted the HIMP pilot program, a precursor to the proposed inspection system. In those 10 years, the Agency has been unable to collect evidence to reliably demonstrate that HIMP is superior to USDA's traditional poultry inspection system. It's *Evaluation of the HACCP Inspection Models Project (HIMP),* is replete with falsehoods, cherry-picked data, and illegitimate analyses. Also, since the premises on which the proposal is based are debatable, public scrutiny would likely have necessitated the adoption of an alternative proposal.

Precluding Public Consideration

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[29] Id. Pg. 4419.

[30] Between 1/1/07 and 9/20/07.

[31] Previously provided to the Safe Food Coalition.

[32] Table 1. CY2010 Ratios of Inspection Procedures per Establishment in HIMP to Non-HIMP plants. Fed. Reg. Pg. 4416.

[33] RA, Pg. 8.

The Agency has prevented meaningful public consideration and participation before adoption of this proposal by:

*Publishing the proposal in the Federal Register before consulting with its National Advisory Committee on Meat and Poultry Inspection (NACMPI). The Agency held a meeting with NACMPI, only upon the insistence of consumer groups, then informed members that their comments would be included with all other individual comments and would be given no consideration;

*publishing the proposal without sending it to Occupational Health and Safety Agency or the Department of Labor for guidance on worker safety issues, prior to publication;

*publishing complex statistical analysis but little raw data in extensive supporting documents, then initially provided only a 90-day comment period;

*refusing, for the first time in over 10 years, requests by consumer organizations for a public meeting, during which the Agency could explain and allow members of the public to ask questions about the proposal and supporting materials.

*including the anticipated cost savings from the proposal in its 2013 proposed budget to Congress, long before the public comment period for the proposal was closed.

*repeatedly misleading members of Congressional appropriations committees by testifying that the supporting documents, in particular, the 2011 *Risk Assessment for Guiding Public Health Risk-Based Poultry Slaughter Inspection (*RA), had been peer reviewed. When asked for the a copy of the peer review, the Agency admitted that there was none, but then claimed that the 2011 Risk Assessment was very similar to the 2008 *Risk Assessment,* which *was* peer reviewed. However, the docket for the proposal contains neither the 2008 *Risk Assessment* nor a peer review of that RA. The docket contains only the "Reply to Peer Review Comments for the [*2005] Risk Assessment for Guiding Public Health Risk-Based Poultry Slaughter Inspection.*[34] This document warns that, since the 2008 RA was a substantial revision of the 2005 RA, many of the comments "are not germane" to the 2008 RA.[35]

False Claims

The Agency admits that "[i]n slaughter establishments, fecal contamination of carcasses is the primary avenue for contamination by pathogens."[36] Inexplicably, it also claims that the new system will allow CIs to perform a "critical appraisal,"[37] of each carcass despite the fact that carcass inspection will be the same under the proposed system as it is under HIMP. The American Heritage dictionary defines "critical" as "[c]haracterized by careful, exact evaluation and judgment."[38] However, as demonstrated by inspector statements and Agency data above, HIMP rules prohibit CIs from examining parts of the bird where adulteration is most likely to be detected, and CIs are unable to detect and prevent the vast majority of carcasses with fecal contamination and other food safety defects from continuing down production lines on their way to consumers.

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[34] http://www.fsis.usda.gov/Science/Risk_Assessments/index.asp#poultry

[35] Reply to Peer Review Comments for FSIS Risk Assessment for Guiding Public Health Risk-Based Poultry Slaughter Inspection.
http://www.fsis.usda.gov/regulations_&_policies/Poultry_Slaughter_Inspection/index.asp

[36] Fed. Reg. Pg. 4417.

[37] Id. Pg. 4411.

[38] The American Heritage® Dictionary of the English Language, Fourth Edition copyright ©2000 by Houghton Mifflin Company. Updated in 2009. Published by Houghton Mifflin Company. All rights reserved. http://www.thefreedictionary.com/critical.

The Agency claims that "HIMP establishments have consistently performed better under HIMP than they did under non-HIMP inspection systems."[39] However, as discussed above, the Agency's own *Salmonella* data from 1998-2007 demonstrates that 14 of the 20 HIMP plants had better *Salmonella* results under the traditional inspection system than under HIMP, and the average of all 20 of the plants was better under the traditional system than under HIMP. In making this claim, the Agency also fails to recognize that 7 of the original 20 plants dropped out of the HIMP pilot. Their performance may contradict the Agency's claim.

Cherry Picking Data

The Agency claims that its evaluations are "based on data for the calendar years CY2006 through CY2010, with exceptions where only more recent data are available".[40] The Agency does not explain why certain data are missing or why time periods for comparisons are not uniform. Without reasonable explanations for these discrepancies, it is impossible to conclude that these data were not cherry-picked and chosen specifically because they were particularly advantageous for the Agency's agenda. It also indicates that less than rigorous analytical methods were used in the Evaluation and raises additional questions about the reliability of the Agency's other evaluations, assessments and conclusions.

The Agency has computerized records of all inspection tasks scheduled and performed, yet the Agency only analyzed data from CY2010 when comparing the Ratio of Inspection Procedures per Establishment in HIMP to Non-HIMP.[41]

The Agency compares findings:

by VIs of OCP defects between January 1, 2009 and December 31, 2010;[42]

by VIs of Food Safety defects between April 1, 2009 and March 31, 2011;[43] and

by CIs of Food Safety defects between April 1, 2009 and March 31, 2011.[44]

While these time periods are not very different, it is possible that the slight shifts were made to conceal results that would be less supportive, or that would even contradict Agency claims.

Faulty Assumptions

The Agency concludes [based on its evaluation of the HIMP study . . . that establishments operating under the HIMP inspection system performed better than establishments operating under non-HIMP inspection systems with respect to rates of food safety and OCP defects.[45] This claim is faulty for several reasons. First, the Agency provides *no* data of food safety or OCP defect levels from current non-HIMP establishments (although it could have collected and presented these data). Instead, it compares the current performance of HIMP plants with the lowest levels of performance that were

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[39] Fed. Reg. Pg. 4414.
[40] Id. Pg. 4415.
[41] Id. Pg. 4416.
[42] Id. Pg. 4418
43 Id. Pg. 4418
[44] Id. Pg. 4415.
[45] Id. Pg. 4419.

found, before 2000, during the baseline collection in plants that later joined the HIMP pilot.[46] The Agency fails to explain how the performance level of the bottom four plants that entered the HIMP program, is representative of approximately 200 *other* plants more than a decade later.

The Agency concludes that "HIMP establishments are likely have lower levels of pathogens than non-HIMP establishments"[47] because there were less non-compliance records (NRs) for fecal contamination written in HIMP plants. But there are many reasons to doubt that the number of NRs in HIMP plants reflects the true level of fecal contamination on the carcasses. Aforementioned inspector statements made clear that CIs were instructed to "give the plants a break," combine several violations on one NR, and stop writing NRs for fecal contamination once the plants moved their critical control points to specifically avoid such documentation. Inspectors also stated that plant employees temporarily improve their performance when they know that the VI is about to take a 10-bird sample, which could result in a NR if fecal contamination is found. Inspector statements also make clear that at least some HIMP plants were short-staffed, which sometimes prevents inspectors from documenting violations. The Agency provided no information to demonstrate that documentation policies and opportunities for documenting violations were the same in HIMP and non-HIMP plants. Finally, we have recently acquired records of NRs written, roughly, within the last year, from two HIMP plants and two non-HIMP plants. [ATTACHMENT 4]. To the best of our knowledge, all of the plants are Large plants with two production lines and two production shifts. The non-HIMP plants have 19 and 23 NRs, respectively, and the HIMP plants have 93 and 173 NRs, respectively. These dramatic comparisons only add to our concern that NRs may not be good indicators of the level of food safety defects on carcasses.

Debatable Premises

We do not believe that this proposal is the result of its anticipated public health benefits, which are minimal at best and weakly supported. The Agency's discussion of the "alternatives considered" suggests that there are two primary assumptions that are the driving forces behind this proposal. First, the Agency assumes that because industry evisceration technology is now capable of increased line speeds, the Agency must allow industry to run lines much faster and must "accommodate the demand of the industry for additional IPP [Inspection Program Personnel],"[48] Second, the Agency assumes that "[r]esource constraints would not allow for this" while maintaining the traditional inspection system.[49]

The Primacy and Consequences of Increased Line Speeds

A primary assumption underlying FSIS' proposal is that there is no alternative to increased production line speeds (except taking no action at all) because all other considerations *must* be adjusted to accommodate the new technologies that allow for faster evisceration of poultry. This will inevitably lead, not only to more adulterated poultry reaching consumers, but also to increased worker injuries. While the Agency requested that the National Institute for Occupational Safety and Health (NIOSH), conduct a study in 5 plants, this is a very small sample.[50] Further, the study involves non-HIMP plants that are operating under waivers from line speed restrictions. There is no information that suggests that these plants are operating at speeds of 175 birds per hour that are authorized under the proposal. Slaughterhouse workers, and in particular, poultry slaughter works are already subject to high levels of

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[46] Evaluation of HIMP, Appendix A. Pg. 39.
[47] Fed. Reg. Pg. 4418.
[48] Id. Pg. 4446-7
49 Id.
[50] Id. 4423-4.

repetitive stress injuries and lines speeds that will nearly double, can only lead to additional crippling of workers.

Increased line speeds will also inevitably lead to more inhumane treatment of the animals, for several reasons. Workers will inadvertently maim animals as they desperately try to keep up with lines speeds that will nearly double under the proposal. Increasing worker frustration could lead to the types of abuse that have been documented previously in undercover videos. With fewer inspectors in the plants, the government will have even less oversight of these abuses. And with the Agency's new hands off approach to OCP defects, industry will have less incentive to prevent injury to the animals.

Line speeds are not being increased so that the poultry industry can meet increasing consumer demand, which has remained somewhat level. Instead they are being increased to allow the industry to "operate more efficiently".[51] Large corporations that own multiple plants will be able to close some and still produce the same volume. Poultry plant closures will mean worker layoffs and community disruption, especially in locations where the plant is the largest employer.

The "Necessity" of Cutting FSIS' Budget
The Agency's proposal presents a cost/benefit analyses of several alternatives,[52] but neglects to provide an analysis of the one that would seem to hold the most promise – adding an extra off-line inspector in each poultry plant to conduct additional food safety activities within the traditional inspection system.

The steamrolling of this proposal has precluded the type of public discussion that could result in increased allocations for FSIS rather than decreased protections for consumers, workers, and poultry animals. The Agency estimates that it would need $33 million annually in order to add an additional inspector to each poultry plant.[53] Instead of doing away with traditional inspection, consumers might argue that USDA or congressional appropriators should decrease corporate subsidies or bailouts and allocate those funds to FSIS instead. For example, in 2011, when there was a glut of chicken on the market, USDA made a special purchase of $40 million in chicken products. Rather than bailing the poultry industry out for overproduction, USDA should be improving the level of food safety in meat and poultry products.

For all of the aforementioned reasons, we call upon the Agency to withdraw this proposal.

Sincerely,

Amanda Hitt
Director of the Food Integrity Campaign

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[51] Fed. Reg. Pg. 4450.
[52] Fed Register Pg. 4446-7.
[53] Table 17. Comparisons of the Considered Alternatives to the Proposed Poultry Slaughter Rule. Fed. Reg. Pg. 4446.

Footnote 42

- FOR PHYSICIANS
- HEALTH AND NUTRITION
  - Action Alerts
  - Breaking Medical News
  - Health Topics
  - Cancer Resources
  - Diabetes Resources
  - Food for Life Classes
  - Healthy School Lunches
  - Vegetarian and Vegan Diets
  - Reports and Surveys
  - Clinical Research Studies
  - Health Care Professionals
- ETHICAL RESEARCH & EDUCATION
- MEDIA CENTER
- LEGISLATIVE FOCUS
- CLINICAL RESEARCH
- EDUCATIONAL LITERATURE
- MEMBERSHIP
- SHOP

Fecal Contamination in Retail Chicken Products

A Report from the Physicians Committee for Responsible Medicine
April 2012

Fecal contamination is surprisingly common on chicken products in grocery stores. In this study, scientists with the Physicians Committee for Responsible Medicine tested chicken products sold by 15 grocery store chains in 10 U.S. cities for the presence of feces. A certified, independent analytical testing laboratory in Chicago, Ill., tested for the presence of *E. coli* as evidence of fecal contamination. Chicken products from every city and every grocery store chain tested positive for fecal contamination. Overall, 48 percent of chicken samples tested positive.

Fecal Contamination of Chicken Products in 10 U.S. Cities

City	Grocery Store	Chicken Products with Fecal Contamination
Charleston, S.C.	Harris Teeter	33%
	Publix	33%
Chicago, Ill.	Dominick's	33%
	Jewel-Osco	67%
Dallas, Texas	Albertsons	33%
	Kroger	100%
Denver, Colo.	Albertsons	50%
	Safeway	67%
Houston, Texas	H-E-B	17%
	Randalls	17%
Miami, Fla.	Publix	50%
	Winn-Dixie	83%
Milwaukee, Wis.	Pic 'n Save	17%
	Piggly Wiggly	50%
Phoenix, Ariz.	Fry's	50%
	Safeway*	0%
San Diego, Calif.	Albertsons	17%
	Ralphs	83%
Washington, D.C.	Giant	83%
	Safeway	67%

** Indicates a store where retesting was performed; retesting found that 60 percent of the samples were positive for fecal contamination.*

Background

In the conditions of typical poultry farms and transportation, chickens defecate on themselves and one another and commonly stand in feces. Feces are also present in intestines at the time of slaughter. As a result, feces are common in poultry farms, transport vehicles, and slaughter plants.

A typical large processing plant may slaughter more than a million birds per week.[1] There, chickens are stunned, killed, bled, and sent through scalding tanks, which help remove feathers but also act as reservoirs that transfer feces from one carcass to another. After scalding, feathers and intestines are mechanically removed. Intestinal contents can spill onto machinery and contaminate the muscles and organs of the chicken and those processed afterward.

The eviscerated carcasses are then rinsed with chlorinated water and checked for visible fecal matter. However, some slaughter lines process as many as 140 birds per minute, allowing inspectors minimal time to examine each carcass for visible feces.[2]

After the visual check for fecal matter, carcasses are typically chilled in ice water, effectively a communal bath in which feces spread from bird to bird. After chilling, a chicken may be cut up, allowing for further fecal spread from carcass to implements. The remains are then packaged, carrying fecal bacteria to consumers. Feces consist of undigested food, dead cells, hepatically excreted compounds, parasites, and live bacteria, which may be benign or pathogenic. Feces on retail products are of concern to consumers for both esthetic and health reasons, but fecal traces are typically not visible.

To assess the efficacy of procedures to limit fecal contamination, the U.S. Department of Agriculture requires poultry slaughter and processing establishments to test for levels of *E. coli*, a bacterium that is a highly specific indicator of fecal contamination. According to the USDA's *Guidelines for Escherichia coli Testing for Process Control Verification in Poultry Slaughter Establishments*, facilities must test one chicken per 22,000 slaughtered or perform at least one test per week.[3]

This study assessed the frequency of fecal contamination on retail chicken products in 10 U.S. cities.

Methods

PCRM purchased chicken products—whole chickens, breasts, drumsticks, thighs, or wings—from stores in 10 cities in nine states. Twelve samples of chicken were initially purchased in each city for a total of 120 samples.

The grocery store chains sampled were Albertsons, Dominick's, Fry's, Giant, Harris Teeter, H-E-B, Jewel-Osco, Kroger, Pic 'n Save, Piggly Wiggly, Publix, Ralphs, Randalls, Safeway, and Winn-Dixie.

Brands tested included Perdue, Pilgrim's, Sanderson Farms, Covington Farms, Eating Right, Foster Farms, Gerber's Poultry, Harris Teeter, Harvestland, H-E-B, Hill Country Fare, Murray's, Nature's Promise, Open Nature, Smart Chicken, Piggly Wiggly, Publix, Red Bird Farms, Roundy's, Safeway, Safeway O Organics, Springer Mountain Farms, Super G, Supervalu, and Wild Harvest Natural.

The products were purchased, and store packaging was left undisturbed. The packages were placed unopened in coolers with ice packs and immediately shipped overnight to EMSL Analytical Inc., a certified, independent analytical testing laboratory in Chicago, Ill. Using detection methods standard for food testing, EMSL tested for the presence of *E. coli*.[4] As noted above, *E. coli* is a specific indicator of fecal contamination and is used by slaughter and processing plants to check for fecal contamination of food products and water, following USDA requirements.

Results

Testing revealed that 48 percent of all chicken samples tested positive for feces. Among skinless breasts, 49 percent of products were contaminated, compared with 28 percent of breasts with skin intact, indicating that skin removal did not reduce fecal contamination in the samples tested.

Of the antibiotic-free chicken samples, 46 percent tested positive for fecal contamination, while 48 percent of conventional samples tested positive.

Of the 20 stores sampled, one (Safeway, Phoenix, Ariz.) had no detectable fecal bacteria in six samples. To determine whether this was an aberrant result based on sampling, 10 additional samples were purchased and tested by EMSL Analytical Inc. Of these 10 samples, six tested positive for fecal contamination, suggesting previous findings

were the result of sampling, rather than to an absence of feces in the store.

Discussion

The results show that feces are common on chicken products. Although variability was evident from store to store, it appears that consumers bring feces into their kitchens on roughly half of the retail chicken products purchased, regardless of the region or brand. This variability appears to be due to sampling, rather than to differences in procedures followed by different stores or brands.

Retail chicken products are rarely tested for feces. Instead, testing is commonly performed during slaughter and processing to assess the effectiveness of practices intended to limit fecal spread. A 2009 USDA study found that 87 percent of chicken carcasses tested positive for *E. coli* after chilling and just prior to packaging.[5]

The current findings suggest that skinless chicken is at least as likely as to be contaminated as chicken with skin left intact. Likewise, antibiotic-free products appear to be as likely as "conventional" chicken to be contaminated. Nearly 50 percent of both types of products tested positive for fecal traces.

Conclusion

Overall, roughly half of the chicken samples purchased in supermarkets were contaminated with feces, which originate in chickens' intestines, but are easily spread during rearing, transport, slaughter, and processing. In turn, feces carried on chicken products into the home are easily transferred to countertops, cutting boards, utensils, refrigerators, and family members.

While consumers are counseled by the USDA to apply high cooking heat to poultry products, this treatment simply cooks the feces along with the muscle tissue and does nothing to remove it from the ingested product.

In summary, feces are present on approximately half of chicken products at retail stores in locations across the United States.

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The Burger That Shattered Her Life

By MICHAEL MOSS

Stephanie Smith, a children's dance instructor, thought she had a stomach virus. The aches and cramping were tolerable that first day, and she finished her classes.

Then her diarrhea turned bloody. Her kidneys shut down. Seizures knocked her unconscious. The convulsions grew so relentless that doctors had to put her in a coma for nine weeks. When she emerged, she could no longer walk. The affliction had ravaged her nervous system and left her paralyzed.

Ms. Smith, 22, was found to have a severe form of food-borne illness caused by E. coli, which Minnesota officials traced to the hamburger that her mother had grilled for their Sunday dinner in early fall 2007.

"I ask myself every day, 'Why me?' and 'Why from a hamburger?' "Ms. Smith said. In the simplest terms, she ran out of luck in a food-safety game of chance whose rules and risks are not widely known.

Meat companies and grocers have been barred from selling ground beef tainted by the virulent strain of E. coli known as O157:H7 since 1994, after an outbreak at Jack in the Box restaurants left four children dead. Yet tens of thousands of people are still sickened annually by this pathogen, federal health officials estimate, with hamburger being the biggest culprit. Ground beef has been blamed for 16 outbreaks in the last three years alone, including the one that left Ms. Smith paralyzed from the waist down. This summer, contamination led to the recall of beef from nearly 3,000 grocers in 41 states.

Ms. Smith's reaction to the virulent strain of E. coli was extreme, but tracing the story of her burger, through interviews and government and corporate records obtained by The New York Times, shows why eating ground beef is still a gamble. Neither the system meant to make the meat safe, nor the meat itself, is what consumers have been led to believe.

Ground beef is usually not simply a chunk of meat run through a grinder. Instead, records and interviews show, a single portion of hamburger meat is often an amalgam of various grades of meat from different parts of cows and even from different slaughterhouses. These cuts of meat are particularly vulnerable to E. coli contamination, food experts and officials say. Despite this, there is no federal requirement for grinders to test their ingredients for the pathogen.

The frozen hamburgers that the Smiths ate, which were made by the food giant Cargill, were labeled "American Chef's Selection Angus Beef Patties." Yet confidential grinding logs and other Cargill records show that the hamburgers were made from a mix of slaughterhouse trimmings and a mash-like product derived from scraps that were ground together at a plant in Wisconsin. The ingredients came from slaughterhouses in Nebraska, Texas and Uruguay, and from a South Dakota company that processes fatty trimmings and treats them with ammonia to kill bacteria.

Using a combination of sources — a practice followed by most large producers of fresh and packaged hamburger — allowed Cargill to spend about 25 percent less than it would have for cuts of whole meat.

Those low-grade ingredients are cut from areas of the cow that are more likely to have had contact with feces, which carries E. coli, industry research shows. Yet Cargill, like most meat companies, relies on its suppliers to check for the bacteria and does its own testing only after the ingredients are ground together. The United States Department of Agriculture, which allows grinders to devise their own safety plans, has encouraged them to test ingredients first as a way of increasing the chance of finding contamination.

Unwritten agreements between some companies appear to stand in the way of ingredient testing. Many big slaughterhouses will sell only to grinders who agree not to test their shipments for E. coli, according to officials at two large grinding companies. Slaughterhouses fear that one grinder's discovery of E. coli will set off a recall of ingredients they sold to others.

"Ground beef is not a completely safe product," said Dr. Jeffrey Bender, a food safety expert at the University of Minnesota who helped develop systems for tracing E. coli contamination. He said that while outbreaks had been on the decline, "unfortunately it looks like we are going a bit in the opposite direction."

Food scientists have registered increasing concern about the virulence of this pathogen since only a few stray cells can make someone sick, and they warn that federal guidance to cook meat thoroughly and to wash up afterward is not sufficient. A test by The Times found that the safe handling instructions are not enough to prevent the bacteria from spreading in the kitchen.

Cargill, whose $116.6 billion in revenues last year made it the country's largest private company, declined requests to interview company officials or visit its facilities. "Cargill is not in a position to answer your specific questions, other than to state that we are committed to continuous improvement in the area of food safety," the company said, citing continuing litigation.

The meat industry treats much of its practices and the ingredients in ground beef as trade secrets. While the Department of Agriculture has inspectors posted in plants and has access to production records, it also guards those secrets. Federal records released by the department through the Freedom of Information Act blacked out details of Cargill's grinding operation that could be learned only through copies of the documents obtained from other sources. Those documents

illustrate the restrained approach to enforcement by a department whose missions include ensuring meat safety and promoting agriculture markets.

Within weeks of the Cargill outbreak in 2007, U.S.D.A. officials swept across the country, conducting spot checks at 224 meat plants to assess their efforts to combat E. coli. Although inspectors had been monitoring these plants all along, officials found serious problems at 55 that were failing to follow their own safety plans.

"Every time we look, we find out that things are not what we hoped they would be," said Loren D. Lange, an executive associate in the Agriculture Department's food safety division.

In the weeks before Ms. Smith's patty was made, federal inspectors had repeatedly found that Cargill was violating its own safety procedures in handling ground beef, but they imposed no fines or sanctions, records show. After the outbreak, the department threatened to withhold the seal of approval that declares "U.S. Inspected and Passed by the Department of Agriculture."

In the end, though, the agency accepted Cargill's proposal to increase its scrutiny of suppliers. That agreement came early last year after contentious negotiations, records show. When Cargill defended its safety system and initially resisted making some changes, an agency official wrote back: "How is food safety not the ultimate issue?"

The Risk

On Aug. 16, 2007, the day Ms. Smith's hamburger was made, the No.3 grinder at the Cargill plant in Butler, Wis., started up at 6:50 a.m. The largest ingredient was beef trimmings known as "50/50" — half fat, half meat — that cost about 60 cents a pound, making them the cheapest component.

Cargill bought these trimmings — fatty edges sliced from better cuts of meat — from Greater Omaha Packing, where some 2,600 cattle are slaughtered daily and processed in a plant the size of four football fields.

As with other slaughterhouses, the potential for contamination is present every step of the way, according to workers and federal inspectors. The cattle often arrive with smears of feedlot feces that harbor the E. coli pathogen, and the hide must be removed carefully to keep it off the meat. This is especially critical for trimmings sliced from the outer surface of the carcass.

Federal inspectors based at the plant are supposed to monitor the hide removal, but much can go wrong. Workers slicing away the hide can inadvertently spread feces to the meat, and large clamps that hold the hide during processing sometimes slip and smear the meat with feces, the workers and inspectors say.

Greater Omaha vacuums and washes carcasses with hot water and lactic acid before sending them to the cutting floor. But these safeguards are not foolproof.

"As the trimmings are going down the processing line into combos or boxes, no one is inspecting every single piece," said one federal inspector who monitored Greater Omaha and requested anonymity because he was not authorized to speak publicly.

The E. coli risk is also present at the gutting station, where intestines are removed, the inspector said

Every five seconds or so, half of a carcass moves into the meat-cutting side of the slaughterhouse, where trimmers said they could keep up with the flow unless they spot any remaining feces.

"We would step in and stop the line, and do whatever you do to take it off," said Esley Adams, a former supervisor who said he was fired this summer after 16 years following a dispute over sick leave. "But that doesn't mean everything was caught."

Two current employees said the flow of carcasses keeps up its torrid pace even when trimmers get reassigned, which increases pressure on workers. To protest one such episode, the employees said, dozens of workers walked off the job for a few hours earlier this year. Last year, workers sued Greater Omaha, alleging that they were not paid for the time they need to clean contaminants off their knives and other gear before and after their shifts. The company is contesting the lawsuit.

Greater Omaha did not respond to repeated requests to interview company officials. In a statement, a company official said Greater Omaha had a "reputation for embracing new food safety technology and utilizing science to make the safest product possible."

The Trimmings

In making hamburger meat, grinders aim for a specific fat content — 26.6 percent in the lot that Ms. Smith's patty came from, company records show. To offset Greater Omaha's 50/50 trimmings, Cargill added leaner material from three other suppliers.

Records show that some came from a Texas slaughterhouse, Lone Star Beef Processors, which specializes in dairy cows and bulls too old to be fattened in feedlots. In a form letter dated two days before Ms. Smith's patty was made, Lone Star recounted for Cargill its various safety measures but warned "to this date there is no guarantee for pathogen-free raw material and we would like to stress the importance of proper handling of all raw products."

Ms. Smith's burger also contained trimmings from a slaughterhouse in Uruguay, where government officials insist that they have never found E. coli O157:H7 in meat. Yet audits of Uruguay's meat operations conducted by the U.S.D.A. have found sanitation problems, including improper testing for the pathogen. Dr. Hector J. Lazaneo, a meat safety official in Uruguay, said the problems were corrected immediately. "Everything is fine, finally," he said. "That is the reason we are exporting."

Cargill's final source was a supplier that turns fatty trimmings into what it calls "fine lean textured

beef." The company, Beef Products Inc., said it bought meat that averages between 50 percent and 70 percent fat, including "any small pieces of fat derived from the normal breakdown of the beef carcass." It warms the trimmings, removes the fat in a centrifuge and treats the remaining product with ammonia to kill E. coli.

With seven million pounds produced each week, the company's product is widely used in hamburger meat sold by grocers and fast-food restaurants and served in the federal school lunch program. Ten percent of Ms. Smith's burger came from Beef Products, which charged Cargill about $1.20 per pound, or 20 cents less than the lean trimmings in the burger, billing records show.

An Iowa State University study financed by Beef Products found that ammonia reduces E. coli to levels that cannot be detected. The Department of Agriculture accepted the research as proof that the treatment was effective and safe. And Cargill told the agency after the outbreak that it had ruled out Beef Products as the possible source of contamination.

But federal school lunch officials found E. coli in Beef Products material in 2006 and 2008 and again in August, and stopped it from going to schools, according to Agriculture Department records and interviews. A Beef Products official, Richard Jochum, said that last year's contamination stemmed from a "minor change in our process," which the company adjusted. The company did not respond to questions about the latest finding.

In combining the ingredients, Cargill was following a common industry practice of mixing trim from various suppliers to hit the desired fat content for the least money, industry officials said.

In all, the ingredients for Ms. Smith's burger cost Cargill about $1 a pound, company records show, or about 30 cents less than industry experts say it would cost for ground beef made from whole cuts of meat.

Ground beef sold by most grocers is made from a blend of ingredients, industry officials said. Agriculture Department regulations also allow hamburger meat labeled ground chuck or sirloin to contain trimmings from those parts of the cow. At a chain like Publix Super Markets, customers who want hamburger made from whole cuts of meat have to buy a steak and have it specially ground, said a Publix spokeswoman, Maria Brous, or buy a product like Bubba Burgers, which boasts on its labeling, "100% whole muscle means no trimmings."

To finish off the Smiths' ground beef, Cargill added bread crumbs and spices, fashioned it into patties, froze them and packed them 18 to a carton.

The listed ingredients revealed little of how the meat was made. There was just one meat product listed: "Beef."

Tension Over Testing

As it fed ingredients into its grinders, Cargill watched for some unwanted elements. Using metal

detectors, workers snagged stray nails and metal hooks that could damage the grinders, then warned suppliers to make sure it did not happen again.

But when it came to E. coli O157:H7, Cargill did not screen the ingredients and only tested once the grinding was done. The potential pitfall of this practice surfaced just weeks before Ms. Smith's patty was made. A company spot check in May 2007 found E. coli in finished hamburger, which Cargill disclosed to investigators in the wake of the October outbreak. But Cargill told them it could not determine which supplier had shipped the tainted meat since the ingredients had already been mixed together.

"Our finished ground products typically contain raw materials from numerous suppliers," Dr. Angela Siemens, the technical services vice president for Cargill's meat division, wrote to the U.S.D.A. "Consequently, it is not possible to implicate a specific supplier without first observing a pattern of potential contamination."

Testing has been a point of contention since the 1994 ban on selling ground beef contaminated with E. coli O157:H7 was imposed. The department moved to require some bacterial testing of ground beef, but the industry argued that the cost would unfairly burden small producers, industry officials said. The Agriculture Department opted to carry out its own tests for E. coli, but it acknowledges that its 15,000 spot checks a year at thousands of meat plants and groceries nationwide is not meant to be comprehensive. Many slaughterhouses and processors have voluntarily adopted testing regimes, yet they vary greatly in scope from plant to plant.

The retail giant Costco is one of the few big producers that tests trimmings for E. coli before grinding, a practice it adopted after a New York woman was sickened in 1998 by its hamburger meat, prompting a recall.

Craig Wilson, Costco's food safety director, said the company decided it could not rely on its suppliers alone. "It's incumbent upon us," he said. "If you say, 'Craig, this is what we've done,' I should be able to go, 'Cool, I believe you.' But I'm going to check."

Costco said it had found E. coli in foreign and domestic beef trimmings and pressured suppliers to fix the problem. But even Costco, with its huge buying power, said it had met resistance from some big slaughterhouses. "Tyson will not supply us," Mr. Wilson said. "They don't want us to test."

A Tyson spokesman, Gary Mickelson, would not respond to Costco's accusation, but said, "We do not and cannot" prohibit grinders from testing ingredients. He added that since Tyson tests samples of its trimmings, "we don't believe secondary testing by grinders is a necessity."

The food safety officer at American Foodservice, which grinds 365 million pounds of hamburger a year, said it stopped testing trimmings a decade ago because of resistance from slaughterhouses. "They would not sell to us," said Timothy P. Biela, the officer. "If I test and it's positive, I put them in a regulatory situation. One, I have to tell the government, and two, the government will trace it back to them. So we don't do that."

The surge in outbreaks since 2007 has led to finger-pointing within the industry.

Dennis R. Johnson, a lobbyist for the largest meat processors, has said that not all slaughterhouses are looking hard enough for contamination. He told U.S.D.A. officials last fall that those with aggressive testing programs typically find E. coli in as much as 1 percent to 2 percent of their trimmings, yet some slaughterhouses implicated in outbreaks had failed to find any.

At the same time, the meat processing industry has resisted taking the onus on itself. An Agriculture Department survey of more than 2,000 plants taken after the Cargill outbreak showed that half of the grinders did not test their finished ground beef for E. coli; only 6 percent said they tested incoming ingredients at least four times a year.

In October 2007, the agency issued a notice recommending that processors conduct at least a few tests a year to verify the testing done by slaughterhouses. But after resistance from the industry, the department allowed suppliers to run the verification checks on their own operations.

In August 2008, the U.S.D.A. issued a draft guideline again urging, but not ordering, processors to test ingredients before grinding. "Optimally, every production lot should be sampled and tested before leaving the supplier and again before use at the receiver," the draft guideline said.

But the department received critical comments on the guideline, which has not been made official. Industry officials said that the cost of testing could unfairly burden small processors and that slaughterhouses already test. In an October 2008 letter to the department, the American Association of Meat Processors said the proposed guideline departed from U.S.D.A.'s strategy of allowing companies to devise their own safety programs, "thus returning to more of the agency's 'command and control' mind-set."

Dr. Kenneth Petersen, an assistant administrator with the department's Food Safety and Inspection Service, said that the department could mandate testing, but that it needed to consider the impact on companies as well as consumers. "I have to look at the entire industry, not just what is best for public health," Dr. Petersen said.

Tracing the Illness

The Smiths were slow to suspect the hamburger. Ms. Smith ate a mostly vegetarian diet, and when she grew increasingly ill, her mother, Sharon, thought the cause might be spinach, which had been tied to a recent E. coli outbreak.

Five days after the family's Sunday dinner, Ms. Smith was admitted to St. Cloud Hospital in excruciating pain. "I've had women tell me that E. coli is more painful than childbirth," said Dr. Phillip I. Tarr, a pathogen expert at Washington University in St. Louis.

The vast majority of E. coli illnesses resolve themselves without complications, according to the Centers for Disease Control and Prevention. Five percent to 10 percent develop into a condition

called hemolytic uremic syndrome, which can affect kidney function. While most patients recover, in the worst cases, like Ms. Smith's, the toxin in E. coli O157:H7 penetrates the colon wall, damaging blood vessels and causing clots that can lead to seizures.

To control Ms. Smith's seizures, doctors put her in a coma and flew her to the Mayo Clinic, where doctors worked to save her.

"They didn't even think her brain would work because of the seizuring," her mother said. "Thanksgiving Day, I was sitting there holding her hand when a group of doctors came in, and one looked at me and just walked away, with nothing good to say. And I said, 'Oh my God, maybe this is my last Thanksgiving with her,' and I stayed and prayed."

Ms. Smith's illness was linked to the hamburger only by chance. Her aunt still had some of the frozen patties, and state health officials found that they were contaminated with a powerful strain of E. coli that was genetically identical to the pathogen that had sickened other Minnesotans.

Dr. Kirk Smith, who runs the state's food-borne illness outbreak group and is not related to Ms. Smith, was quick to finger the source. A 4-year-old had fallen ill three weeks earlier, followed by her year-old brother and two more children, state records show. Like Ms. Smith, the others had eaten Cargill patties bought at Sam's Club, a division of Wal-Mart.

Moreover, the state officials discovered that the hamburgers were made on the same day, Aug. 16, 2007, shortly before noon. The time stamp on the Smiths' box of patties was 11:58.

On Friday, Oct. 5, 2007, a Minnesota Health Department warning led local news broadcasts. "We didn't want people grilling these things over the weekend," Dr. Smith said. "I'm positive we prevented illnesses. People sent us dozens of cartons with patties left. It was pretty contaminated stuff."

Eventually, health officials tied 11 cases of illness in Minnesota to the Cargill outbreak, and altogether, federal health officials estimate that the outbreak sickened 940 people. Four of the 11 Minnesota victims developed hemolytic uremic syndrome — an unusually high rate of serious complications.

In the wake of the outbreak, the U.S.D.A. reminded consumers on its Web site that hamburgers had to be cooked to 160 degrees to be sure any E. coli is killed and urged them to use a thermometer to check the temperature. This reinforced Sharon Smith's concern that she had sickened her daughter by not cooking the hamburger thoroughly.

But the pathogen is so powerful that her illness could have started with just a few cells left on a counter. "In a warm kitchen, E. coli cells will double every 45 minutes," said Dr. Mansour Samadpour, a microbiologist who runs IEH Laboratories in Seattle, one of the meat industry's largest testing firms.

With help from his laboratories, The Times prepared three pounds of ground beef dosed with a strain of E. coli that is nonharmful but acts in many ways like O157:H7. Although the safety instructions on the package were followed, E. coli remained on the cutting board even after it was washed with soap. A towel picked up large amounts of bacteria from the meat.

Dr. James Marsden, a meat safety expert at Kansas State University and senior science adviser for the North American Meat Processors Association, said the Department of Agriculture needed to issue better guidance on avoiding cross-contamination, like urging people to use bleach to sterilize cutting boards. "Even if you are a scientist, much less a housewife with a child, it's very difficult," Dr. Marsden said.

Told of The Times's test, Jerold R. Mande, the deputy under secretary for food safety at the U.S.D.A., said he planned to "look very carefully at the labels that we oversee."

"They need to provide the right information to people," Mr. Mande said, "in a way that is readable and actionable."

Dead Ends

With Ms. Smith lying comatose in the hospital and others ill around the country, Cargill announced on Oct. 6, 2007, that it was recalling 844,812 pounds of patties. The mix of ingredients in the burgers made it almost impossible for either federal officials or Cargill to trace the contamination to a specific slaughterhouse. Yet after the outbreak, Cargill had new incentives to find out which supplier had sent the tainted meat.

Cargill got hit by multimillion-dollar claims from people who got sick.

Shawn K. Stevens, a lawyer in Milwaukee working for Cargill, began investigating. Sifting through state health department records from around the nation, Mr. Stevens found the case of a young girl in Hawaii stricken with the same E. coli found in the Cargill patties. But instead of a Cargill burger, she had eaten raw minced beef at a Japanese restaurant that Mr. Stevens said he traced through a distributor to Greater Omaha.

"Potentially, it could let Cargill shift all the responsibility," Mr. Stevens said. In March, he sent his findings to William Marler, a lawyer in Seattle who specializes in food-borne disease cases and is handling the claims against Cargill.

"Most of the time, in these outbreaks, it's not unusual when I point the finger at somebody, they try to point the finger at somebody else," Mr. Marler said. But he said Mr. Stevens's finding "doesn't rise to the level of proof that I need" to sue Greater Omaha.

It is unclear whether Cargill presented the Hawaii findings to Greater Omaha, since neither company would comment on the matter. In December 2007, in a move that Greater Omaha said was unrelated to the outbreak, the slaughterhouse informed Cargill that it had taken 16 "corrective

actions" to better protect consumers from E. coli "as we strive to live up to the performance standards required in the continuation of supplier relationship with Cargill."

Those changes included better monitoring of the production line, more robust testing for E. coli, intensified plant sanitation and added employee training.

The U.S.D.A. efforts to find the ultimate source of the contamination went nowhere. Officials examined production records of Cargill's three domestic suppliers, but they yielded no clues. The Agriculture Department contacted Uruguayan officials, who said they found nothing amiss in the slaughterhouse there.

In examining Cargill, investigators discovered that their own inspectors had lodged complaints about unsanitary conditions at the plant in the weeks before the outbreak, but that they had failed to set off any alarms within the department. Inspectors had found "large amounts of patties on the floor," grinders that were gnarly with old bits of meat, and a worker who routinely dumped inedible meat on the floor close to a production line, records show.

Although none were likely to have caused the contamination, federal officials said the conditions could have exacerbated the spread of bacteria. Cargill vowed to correct the problems. Dr. Petersen, the federal food safety official, said the department was working to make sure violations are tracked so they can be used "in real time to take action."

The U.S.D.A. found that Cargill had not followed its own safety program for controlling E. coli. For example, Cargill was supposed to obtain a certificate from each supplier showing that their tests had found no E. coli. But Cargill did not have a certificate for the Uruguayan trimmings used on the day it made the burgers that sickened Ms. Smith and others.

After four months of negotiations, Cargill agreed to increase its scrutiny of suppliers and their testing, including audits and periodic checks to determine the accuracy of their laboratories.

A recent industry test in which spiked samples of meat were sent to independent laboratories used by food companies found that some missed the E. coli in as many as 80 percent of the samples.

Cargill also said it would notify suppliers whenever it found E. coli in finished ground beef, so they could check their facilities. It also agreed to increase testing of finished ground beef, according to a U.S.D.A. official familiar with the company's operations, but would not test incoming ingredients.

Looking to the Future

The spate of outbreaks in the last three years has increased pressure on the Agriculture Department and the industry.

James H. Hodges, executive vice president of the American Meat Institute, a trade association, said that while the outbreaks were disconcerting, they followed several years during which there were fewer incidents. "Are we perfect?" he said. "No. But what we have done is to show some continual

improvement."

Dr. Petersen, the U.S.D.A. official, said the department had adopted additional procedures, including enhanced testing at slaughterhouses implicated in outbreaks and better training for investigators.

"We are not standing still when it comes to E. coli," Dr. Petersen said.

The department has held a series of meetings since the recent outbreaks, soliciting ideas from all quarters. Dr. Samadpour, the laboratory owner, has said that "we can make hamburger safe," but that in addition to enhanced testing, it will take an aggressive use of measures like meat rinses and safety audits by qualified experts.

At these sessions, Felicia Nestor, a senior policy analyst with the consumer group Food and Water Watch, has urged the government to redouble its effort to track outbreaks back to slaughterhouses. "They are the source of the problem," Ms. Nestor said.

For Ms. Smith, the road ahead is challenging. She is living at her mother's home in Cold Spring, Minn. She spends a lot of her time in physical therapy, which is being paid for by Cargill in anticipation of a legal claim, according to Mr. Marler. Her kidneys are at high risk of failure. She is struggling to regain some basic life skills and deal with the anger that sometimes envelops her. Despite her determination, doctors say, she will most likely never walk again.

Gabe Johnson contributed reporting.

Footnote 50

THE OHIO STATE UNIVERSITY
COLLEGE OF BIOLOGICAL SCIENCES
GUIDELINES FOR RESEARCH & BIOMEDICAL WASTE DISPOSAL
2002 REVISION

TYPE OF WASTE	RECOMMENDED PROCEDURES FOR SAFE DISPOSAL
ANIMAL RESEARCH SOLID WASTE: CONTAMINATED OR UNCONTAMINATED CARCASS, ORGANS, FECES, TISSUE OR BEDDING	1. PLACE WASTE IN ORANGE BIOHAZARD BAG. 2. PLACE SEALED AND SECURED BIOHAZARD BAG INTO RED LINED BIOHAZARD BURN BOX AND CALL EHS (292-1284) FOR PICK UP AND DISPOSAL.
CELL/MICROBE RESEARCH SOLID WASTE: PLASTIC PETRI AND TISSUE CULTURE VESSELS INCLUDING MEDIA, CONTAMINATED GLOVES, MATS, TOWELS ETC.	1. STERILIZATION IS OPTIONAL. AFTER STERILIZATION, CULTURES CAN BE POURED INTO SANITARY DRAINS. 2. VESSELS CONTAINING LIQUID WHETHER CONTAMINATED OR NOT ARE PLACED IN ORANGE BIOHAZARD BAGS WHICH ARE TAPED AND TIED SECURELY TO PREVENT ANY LEAKAGE. 3. FULL BIOHAZARD BAGS AND ANY EMPTY VESSELS ARE PLACED IN RED LINE BIOHAZARD BURN BOXES WHICH ARE SECURED WITH WATERPROOF TAPE
AQUEOUS LIQUID WASTE BLOOD, URINE, CELL OR MICROBIAL CULTURES	1. AUTOCLAVE OR CHEMICALLY STERILIZE. 2. DISCARD IN SANITARY DRAIN.
SHARPS CONTAMINATED OR UNCONTAMINATED (SEE PAGE 2 FOR DEFINITION OF "SHARPS".)	1. PLACE CONTAMINATED SHARPS IN RIGID PLASTIC SHARPS CONTAINERS WHICH MUST BE SEALED WHEN FILLED. 2. UNCONTAMINATED SHARPS ONLY MAY BE PLACED IN STURDY CARDBOARD CONTAINERS WHICH THEN ARE SECURELY TAPED. IT IS SUGGESTED THAT ALL PIPETS (GLASS OR PLASTIC) BE REPACKED INTO THEIR ORIGINAL BOXES AFTER USE. 3. FILLED SHARPS BOXES AND CARDBOARD BOXES MUST BE PUT INTO RED LINED BIOHAZARD "BURN BOXES". NOTE: DO NOT PLACE LOOSE SHARPS INTO BURN BOXES. EVEN PLASTIC PIPET TIPS CAN CAUSE LINER TO PUNCTURE WHEN HEAVIER ITEMS ARE LOADED ON TOP OF THEM.
CARCINOGENIC OR CHEMOTHERAPEUTIC AGENTS	1. PLACE WASTE INTO 4 MIL POLYETHYENE BAGS DESIGNED FOR CYTOTOXIC WASTE DISPOSAL AS SOLD IN CYTOXIC SPILL KIT. 2. SEAL SPILL BAGS AND DISPOSE IN RED LINED BURN BOX.
EMPTY GLASS OR METAL REAGENT CONTAINERS	1. EMPTY AND RINSE THROUGHLY (AT LEAST 3X). DO NOT BREAK GLASS. BROKEN GLASS IS TREATED AS SHARPS. 2. PLACE IN HALLWAY FOR WEDNESDAY PICK-UP BY CUSTODIAN.
LIQUID ORGANIC WASTE	1. SOLVENTS ARE PUT INTO METAL OR PLASTIC SOLVENT SAFETY CAN. THE AMOUNT AND IDENTITY ARE RECORDED ON TAG PROVIDED BY EOHS. 2. AQUEOUS CHEM WASTE THAT CANNOT BE POURED DOWN A SINK CAN BE MIXED WITH ORGANICS. 3. CALL EOHS WHEN CAN ARE FULL FOR AN EXCHANGE.
GENERAL CHEMICALS HARMLESS AS WELL AS TOXIC, CORROSIVE, REACTIVE, OR IGNITABLE AGENTS	1. DISPOSE IN ACCORDANCE WITH EOHS CHEMCIAL GUIDELINE. 2. YOU WILL BE ASKED TO IDENTIFY ALL CHEM AND SEGREGATE BY HAZARD CLASSIFICATION.
RADIOACTIVE WASTE	1. FOLLOW RADIATION SAFETY INSTRUCTION DISPOSAL OF RAD.
ORDINARY RUBBISH	1. NON HAZARDOUS WASTE ONLY; NEVER PIPETS, PIPET TIPS, PETRI OR TISSUE CULTURE CONTAINERS.

II. IMPORTANT TELEPHONE NUMBERS:

OFFICE OF ENVIRONMENTAL & OCCUPATIONAL
HEALTH & SAFETY (EOHS) 292-1284
NIGHTTIME 911
OFFICE OF RADIATION SAFETY 292-1284
BIOSCIENCES ANIMAL FACILITY 292-3370
BIOSCIENCES SAFETY COORDINATOR ..... 292-3419 (JEREMY SMITH)
BUILDING COORDINATOR ..... 292-3419 / 292-8772

III. DEFINITIONS:

INFECTIOUS AGENTS: CLASS 2 ETIOLOGIC AGENTS. IT IS RECOMMENDED THAT CLASS 1 BE TREATED AS CLASS 2. CLASS 3 ETIOLOGIC AGENTS REQUIRE ADDITIONAL PRECAUTIONS. SEE CDC GUIDELINES.

CONTAMINATED WASTE HAS BEEN IN CONTACT WITH INFECTIOUS AGENTS OR CONTAINS HAZARDOUS CHEMICAL AGENTS.

DECONTAMINATED WASTE HAS BEEN TREATED TO KILL INFECTIOUS AGENTS OR CLEANED TO REMOVE HAZARDOUS CHEMICALS.

HAZARDOUS WASTE: CONTAMINATED WASTE PLUS UNCONTAMINATED SHARPS.

SHARPS: ANY ITEM CAPABLE OF CAUSING PUNCTURE WOUNDS OR CUTS. THIS INCLUDES DISCARDED HYPODERMIC SYRINGES, CANNULAS, NEEDLES, SCALPEL BLADES, COVERSLIPS, MICROSCOPE SLIDES, ALL GLASS OR PLASTIC PIPETTES (INCLUDING PASTEUR PIPETTES), PLASTIC PIPETTE TIPS, BROKEN GLASS, AND METAL SHARDS. SYRINGES ARE NOT RESHEATHED, CLIPPED, OR BROKEN BEFORE DISCARD.

IV. WASTE CONTAINERS AND THEIR DISPOSAL

TYPE OF APPROVED WASTE CONTAINER	1 BIOHAZARD AUTOGLAVE BAG	2 PLASTIC SHARPS CONTAINER	3 BIOHAZARD BURN BOX (RED LINED)	4 STURDY CARDBOARD BOX	5 SOLVENT SAFETY CANS
WHERE TO OBTAIN THE CONTAINERS	OFF CAMPUS SUPPLIER (CHARGE)	HOSPITAL STORES OR OFF CAMPUS	EHS OR BIOSCI LOADING DOCK	SAVE SHIPPING BOXES RECYCLE	LAB STORES OR OFF CAMPUS
HOW TO DISPOSE OF FILLED CONTAINER	PLACE IN BURN BOX	PLACE IN BURN BOX	SECURE PROPERLY PLACE IN HALLWAY CALL EHS	TAPE SECURELY PLACE IN BIOHARD BURN BOX	CALL EHS FOR EXCHANGE

V. ADDITIONAL NOTES ON HAZARDOUS WASTE POLICIES:

A. FLAMMABLE SOLVENT WASTE STORAGE. A SUITABLE SOLVENT STORAGE CABINET MUST BE USED FOR ALL CONTAINERS OF FLAMMABLE SOLVENT GREATER THAN ½ GALLON IN SIZE, OR IF THE TOTAL VOLUME OF ALL FLAMMABLE SOLVENTS AMOUNTS TO MORE THAN TWO GALLONS KEPT IN ONE ROOM.

B. SPILLS. OSHA HAZARD COMMUNICATION REGULATIONS REQUIRE MANUFACTURERS TO PROVIDE PURCHASERS AND USERS OF HAZARDOUS CHEMICALS WITH MATERIAL SAFETY DATA SHEETS. THESE MSDS'S INCLUDE PHYSICAL AND CHEMICAL PROPERTIES AND KNOWN ACUTE OR CHRONIC HEALTH EFFECTS INCLUDING CARCINOGENICITY, EXPOSURE LIMITS AND EMERGENCY AND FIRST AID PROCEDURES. IT IS THE RESPONSIBILITY OF THE RESEARCHER NOT ONLY TO BE AWARE OF SUCH HAZARDS BUT ALSO TO INFORM AND EDUCATE ALL THOSE WHO MIGHT COME IN CONTACT WITH THAT HAZARD. EACH HAZARD HAS ITS PECULIARITIES AND EACH SPILL HAS ITS OWN RESOLUTION. LEARNING EACH HAZARD AND ITS EMERGENCY RESOLUTION MUST BE STANDARD ORIENTATION FOR EVERYONE WHO COULD BE EXPOSED TO THAT HAZARD. ALSO IT IS NECESSARY TO AVOID THINKING A SPILL IS RESOLVED AFTER IT IS OFF THE LAB BENCH OR FLOOR. IF A HAZARD IS DISPOSED UNTHINKINGLY INTO A NORMAL TRASH RECEPTACLE, ANY UNKNOWING HOUSEKEEPER IS AT RISK. MSDS'S SHOULD BE CONSULTED FOR SPECIFIC INSTRUCTIONS. ONLY BRIEF GUIDELINES ARE GIVEN HERE.

HAZARDOUS CHEMICAL SPILLS SHOULD BE REPORTED IMMEDIATELY TO THE OFFICE OF ENVIRONMENTAL & OCCUPATIONAL HEALTH AND SAFETY. THEY WILL ISSUE INSTRUCTIONS AND SEND SPECIAL ASSISTANCE IF NECESSARY.

CYTOTOXIC DRUG SPILLS REQUIRE SPECIAL PRECAUTIONS TO ISOLATE. INEXPENSIVE CD SPILL KITS WITH DOUBLE-LATEX GLOVES, GOGGLES, RESPIRATORS AND SPILL MATS ARE AVAILABLE.

MERCURY SPILLS REQUIRE SPECIFIC PRECAUTIONS TO AVOID INHALATION, INGESTION OR ABSORPTION. THE OFFICE OF ENVIRONMENTAL & OCCUPATIONAL HEALTH AND SAFETY (292-1284) SHOULD BE NOTIFIED IMMEDIATELY AND A MERCURY SPILL TEAM WILL BE DISPATCHED.

C. PROHIBITION OF CHROMIC ACID AS GLASS CLEANER. DUE TO EXTREME TOXICITY OF CHROMATE AND THE EXPENSE OF THEIR DISPOSAL, NO-CHROMIX OR SIMILAR SUBSTITUTE SHOULD REPLACE THIS OUTDATED PRACTICE. PRESS HERE FOR MSDS FOR CHROMIUM TRIOXIDE AND OTHER CH SALTS.

D. COLLEGE OF BIOLOGICAL SCIENCES LABORATORY GLOVE POLICY. LABORATORY GLOVES ARE NOT TO BE WORN IN LOBBIES, REST ROOMS, ADMINISTRATIVE OFFICES, LIBRARIES, VENDING AREAS, ELEVATORS, COLLEGE GLASSWARE FACILITY, OR STORES. IT IS ASSUMED THAT ONE IS WEARING GLOVES FOR PROTECTION FROM A LAB HAZARD. THAT HAZARD IS MOST PROBABLY ON THE OUTSIDE OF THE GLOVE. FOR THIS REASON, LAB GLOVES SHOULD NOT LEAVE THE IMMEDIATE LAB AREA TO PREVENT CONTAMINATION OF DOOR KNOBS, ELEVATOR SWITCHES, AND OTHER PUBLIC AREAS. IF GLOVES ARE WORN TO PROTECT CLEAN GLASSWARE FROM GREASE OR FINGERPRINTS, THEY BECOME IMMEDIATELY CONTAMINATED WITH GREASE FROM HUNDREDS OF BUILDING OCCUPANTS AS SOON AS AN ELEVATOR BUTTON OR DOOR PULL IS TOUCHED THUS DEFEATING THE PURPOSE OF THE GLOVES. CONTAMINATED GLOVES SHOULD BE DISCARDED IN RED LINED BIOHAZARD BURN BOXES.

V. ADDITIONAL NOTES ON HAZARDOUS WASTE POLICIES: CONTINUED

E. BURN BOXES (INCINERATOR BOXES). 18" X 18" X 28" CARDBOARD INCINERATOR BOXES MARKED INFECTIOUS WASTE-BIOHAZARD IN RED PLUS 6.5 MIL RED PLASTIC LINERS ARE AVAILABLE FROM THE WASTE CAGE ON THE LOADING DOCK OF THE BUILDING OR FROM THE OFFICE OF ENVIRONMENTAL AND OCCUPATIONAL HEALTH AND SAFETY. BOXES AND LINERS ARE FREE.

THE BOXES MUST BE BUILT USING PLASTIC STRAPPING TAPE OR CARTON TAPE. MASKING TAPE IS NOT ACCEPTABLE AS IT QUICKLY LOSES ITS STRENGTH WHEN DAMP. PLACE THE BOX UPSIDE DOWN WITH THE BIOHAZARD SYMBOL INVERTED THEN FOLD BOTTOM FLAPS INWARD SO THAT THE FLAP WITH THE BOX MANUFACTURER'S LABEL IS VISIBLE. TAPE SECURELY. FLIP THE BOX OVER AND INSERT LINER.

WHEN REASONABLY FULL WITH THE WEIGHT NOT EXCEEDING 35 POUNDS, THE RED LINER IS SECURELY TIED OFF USING STRONG TAPE. SHOULD THE SEALED BOX BE INVERTED ACCIDENTALLY IN TRANSIT, THIS TAPED RED LINER CAN PREVENT LEAKAGE ONLY IF IT IS TIGHTLY CLOSED! THE BOX LID IS THEN FOLDED DOWN SO THAT THE RED IDENTIFICATION SQUARE IS VISIBLE, AND SECURED WITH PLASTIC STRAPPING OR BOX BUILDING TAPE. MARK THE BOX WITH YOUR LABORATORY ROOM NUMBER.

FILLED BOXES SHOULD BE PLACED IN THE HALL OUTSIDE YOUR LABORATORY DOOR. IF YOU DESIRE A REGULAR COLLECTION, YOU MUST CALL EHS AT 292-1284. WASTE CURRENTLY IS COLLECTED ON TUESDAYS AND THURSDAYS.

AS IT IS VERY EXPENSIVE FOR THE UNIVERSITY TO INCINERATE THESE BOXES, DO NOT USE BURN BOXES FOR NONHAZARDOUS WASTE JUST BECAUSE THEY ARE FREE TO YOU!!!

F. PLASTIC SHARPS CONTAINERS ARE DISPOSABLE RIGID PLASTIC CONTAINERS WITH "LOCKING" TOPS IN SIZES UP TO 8 GALLONS. THEY ARE MARKED "BIOHAZARD-CONTAMINATED" AND ARE AVAILABLE FROM LAB STORES OR FROM SCIENTIFIC SUPPLY HOUSES. SHARPS: ANY ITEM CAPABLE OF CAUSING PUNCTURE WOUNDS OR CUTS. THIS INCLUDES DISCARDED HYPODERMIC SYRINGES, CANNULAS, NEEDLES, SCALPEL BLADES, COVERSLIPS, MICROSCOPE SLIDES, ALL GLASS OR PLASTIC PIPETTES (INCLUDING PASTEUR PIPETTES), PLASTIC PIPETTE TIPS, BROKEN GLASS, AND METAL SHARDS. SYRINGES SHOULD NOT BE RESHEATHED, CLIPPED, OR BROKEN.
THERE IS NO NEED TO AUTOCLAVE THE CONTENTS OF SHARPS CONTAINERS. WHEN FILLED, A SHARPS CONTAINER IS CLOSED WITH ITS LOCKING LID AND THEN PLACED IN A BURN BOX CONTAINING A RED PLASTIC LINER. THE PLASTIC LINERS MUST BE PROTECTED FROM SHARPS SINCE LEAKS FROM A BURN BOX CREATE OBVIOUS ALARM.

G. WASTE SOLVENT CANS. PLASTIC OR METAL SOLVENT WASTE DISPOSAL CANS ARE AVAILABLE FROM LAB STORES OR OUTSIDE SUPPLIERS. CANS SHOULD BE USED FOR ALL DISCARDED SOLVENTS INCLUDING CHLOROFORM, ACETONE, ETHYL ETHER, METHANOL, FORMALDEHYDE, PHENOL, TOLUENE, METHYL CHLOROFORM, OR XYLENE. KEEP TRACK OF THE KIND AND AMOUNTS OF ORGANIC COMPOUNDS ADDED TO A CAN AND RECORD ON THE TAGS PROVIDED BY EOHS. FULL CANS WILL BE EMPTIED AND RETURNED BY EOHS. NOTE: HEAVY METALS, {Hg, Pb, Ag, As, Ba, Sl, Cr, Cd}, SULFIDES, CYANIDES, OR CONC. MINERAL ACIDS OR BASES 5<pH>9 ARE NOT TO BE DISCARDED IN SOLVENT WASTE CANS BUT AS HAZARDOUS WASTE ON SEPARATE MANIFEST.

H. ANIMAL CARCASS OR TISSUE DISPOSAL. NO ANIMAL CARCASS OR TISSUE IS TO BE DISCARDED THROUGH NORMAL REFUSE DISPOSAL CHANNELS. ALL ANIMAL TISSUE OR CARCASSES USED IN EXPERIMENTAL STUDIES INCLUDING CLASSROOM LABS ARE TO BE PROCESSED BY THE ANIMAL LABORATORY FACILITY (ULAR)USING RED LINED BURN BOXES.

V. ADDITIONAL NOTES ON HAZARDOUS WASTE POLICIES: CONTINUED

I. PROPER DISPOSAL OF REFRIGERATOR UNITS, FREON AND COMPRESSOR OIL.

1. IF THE UNIT IS IN A ROOM THAT CARRIES A RADIATION SIGN, CALL RADIATION SAFETY AT 292-1284 TO HAVE THE EQUIPMENT CHECKED FOR CONTAMINATION. IF THE UNIT IS COLD, THEY WILL PLACE A TAG ON IT CERTIFYING IT FOR DISPOSAL.
2. DECONTAMINATE ANY BIOLOGICAL RESIDUE AND FILL OUT DECONTAMINATION FORM. THE REFRIGERATOR NEEDS TO LOOK CHEMICALLY AND BIOLOGICALLY CLEAN.
3. OBTAIN REFRIGERATION DISPOSAL PROTCOL SHEET FROM PHYSCIAL FACILITIES AT 292-1512. FILL IN PERTINANT INFORMATION AND SEND IT ALONG WITH A 100W TO PHYSICAL FACILITIES. THEY WILL CHARGE ~ $50 TO ARRANGE PICK-UP AND HAVE A CERTIFIED TECHNICIAN REMOVE AND RECYCLE ALL FREON AND OIL. THEY WILL PLACE THEIR TAG ON THE COMPRESSOR STATING THAT THE UNIT IS CLEARED OF ENVIRONMENTAL CONTAMINANTS.
4. IF THE UNIT IS PART OF DEPARTMENTAL INVENTORY, SEND SURPLUS PROPERTY RELEASE FORM TO SURPLUS MATERIALS DISPOSAL & RECYCLING TO GET EQUIPMENT LEGALLY REMOVED FROM DEPARTMENTAL INVENTORY.

J. HARD TRASH DISPOSAL 

HARD TRASH IS ANYTHING TOO LARGE, TOO BULKY, TOO HEAVY OR TOO SOLID TO BE COMPACTED IN REFUSE TRUCKS WITHOUT DAMAGING THE REFUSE EQUIPMENT.

IF HARD TRASH MATERIAL IS PART OF DEPARTMENTAL INVENTORY, SEND SURPLUS PROPERTY RELEASE FORM TP SURPLUS MATERIALS DISPOSAL AND RECYCLING TO GET EQUIPMENT LEGALLY REMOVED FROM INVENTORY.

CALL HARD TRASH REMOVAL AT 292-0892 TO ARRANGE FOR DISPOSAL PICK-UP. THE COLLEGE BUILDING'S LOADING DOCKS ARE NOT DUMP SITES. PLEASE DO NOT DUMP UNWANTED TRASH ON ANY LOADING DOCK EXPECTING IT TO MAGICALLY DISAPPEAR WITHOUT CALLING FOR PROPER DISPOSAL.

K. FLUORESENT LIGHT TUBES AND BALLASTS

CAREFULLY TRANSPORT TO BIOSCIENCE BUILDING LOADING DOCK CAGE PLACING THEM INTO DESIGNATED CARDBOARD BOXES. CALL EHS AT 292-1284 FOR PICK-UP.

L. BATTERIES

SILVER, LITHIUM, MERCURY, NiCAD OR LEAD ACID BATTERIES SHOULD NOT BE DUMPED INTO NORMAL TRASH STREAM AS THEY CAUSE DUMPSITE TOXICITY. CALL EHS AT 292-1284 FOR PICK-UP TO HAVE THESE HEAVY METALS PROPERLY RECYCLED.

V. ADDITIONAL NOTES ON HAZARDOUS WASTE POLICIES: CONTINUED

M. ASBESTOS AWARENESS

ASBESTOS IS PRESENT IN MOST BUILDINGS CONSTRUCTED PRIOR TO THE EARLY 1980'S USUALLY IN THE FORM OF PLUMBING INSULATION, FLOOR TILES, CHEMICAL FUME HOODS, THE CEMENT DUCT WORK CONNECTING CHEMICAL FUME HOODS, CHEMICAL RESISTANT COUNTER TOPS, OR SPRAYED FIRE RETARDANT ON BUILDING SUPPORTS. IN THIS ENCAPSULATED FORM, IT PRESENTS LITTLE OR NO HAZARD.

HOWEVER, PLUMBING OR RENOVATION WORK CAN DISTURB ASBESTOS CREATING AIRBORNE HAZARDS. THEREFORE, IN OLDER BUILDINGS ALL REPAIR AND RENOVATION WORK AREAS MUST BE INSPECTED FOR THE PRESENCE OF ASBESTOS BEFORE WORK BEGINS. IF ASBESTOS IS FOUND, ABATEMENT BY CERTIFIED ASBESTOS REMOVER MUST PRECEDE ANY WORK. HELP IN DETERMINING THE NEED FOR ABATEMENT CAN BE OBTAINED FROM EHS AT 292-1284.

ANY VIOLATION OF ASBESTOS DISPOSAL RULES IS SERIOUS. OSU EHS IS VIGILANT OF ANY EXPOSURE. IF LARGE SCALE VIOLATIONS OCCUR, BOTH THE OHIO EPA AND OHIO DEPARTMENT OF HEALTH CAN BECOME INVOLVED. THESE AGENCIES DEAL WITH VIOLATIONS WITH DUE SERIOUSNESS INCLUDING LARGE FINES.

QUESTIONS MAY BE DIRECTED TO :

JEREMY SMITH, COLLEGE SAFETY OFFICER, 292-3419 OR THE COLLEGE OFFICE, 292-8772.