

## COMMENTS

# Pathogen Reduction Through “HACCP” Systems: Is Overhaul of the Meat Inspection System All It’s Cut Out To Be?

Now, sometimes food makes us sick because it’s undercooked. But sometimes, families have been exposed to illnesses because some meat and poultry shipped to our supermarket shelves contained invisible and deadly bacteria. The reason was shocking and simple: For all our technological advances, the way we inspect meat and poultry had not changed in 90 years. Even though we know that killers such as salmonella can only be seen with a microscope, inspectors were still checking on meat and poultry by look, touch, smell. We relied on an overworked cadre of government inspectors rather than working with the industry and challenging it to keep food safe . . . . [T]he United States Department of Agriculture has worked with industry, scientists, farmers, parents and consumers to completely revamp our meat and poultry inspection system, to revolutionize the way our nation protects food safety . . . . Parents should know that when they serve a chicken dinner they’re not putting their children at risk. Parents should know that when a teenager borrows the car to get a fast food hamburger, the hamburger should be the least of their worries. Our new food safety initiative will give families the security to know that the food they eat is as safe as it can be.<sup>1</sup>

### INTRODUCTION

In July 1996, the new Pathogen Reduction; Hazard Analysis and Critical Control Points (“HACCP”)<sup>2</sup> rule became final.<sup>3</sup> The purpose of the rule was not to replace or eliminate the current meat-inspection

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<sup>1</sup> President William Clinton, Radio Address By the President to the Nation (July 6, 1996).

<sup>2</sup> Pronounced “hass-up.”

<sup>3</sup> Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems, 61 Fed. Reg. 38,806 (1996) (to be codified at 9 C.F.R. § 304).

system, but rather to modernize the current system and make it much safer.<sup>4</sup> As the President stated, the United States Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS) worked together with consumer groups, industry representatives, agricultural producers, scientists and members of Congress to develop the revamped system. The USDA believes it has produced a rule which is "reasonable, but effective, sensible, but tough."<sup>5</sup> The ultimate objective of the new rule is to ensure that American families have the safest meat-and-poultry-inspection system possible.<sup>6</sup> In the wake of so many food-poisoning tragedies, the new rule brings a sigh of relief for many, especially for those who have lost loved ones. Furthermore, the new rule is considered long overdue in an industry traditionally perceived as putting profit before safety. Although the President and the USDA announced this rule with much fanfare, its creation did not come easily. After great debate over several key provisions of the rule, both the industry and consumer groups ultimately had to compromise on several positions. Therefore, for those in the industry and for consumer groups, the final rule is not the great panacea.

This comment first examines, in part I, the current meat-inspection system (pre-HACCP). Part II discusses how meat becomes contaminated. Part III is an exploration of the primary causative organism, the *Escherichia coli* (*E. coli*) bacteria. Part IV examines the 1993 outbreak as the triggering event to the reformation of meat inspection. Parts V and VI examine the provisions of HACCP, the enacted requirements for the meat industry, and the new role of the government. Part VII examines those provisions of the rule subject to substantial debate, and how it was necessary for the industry and consumers to compromise on certain provisions to develop the new rule. Part VIII examines the rule's effects on industry liability. Part IX discusses what HACCP left out, and the possible future of meat inspection.

### I. SEE, TOUCH, SMELL

In 1906, muckraking author Upton Sinclair exposed the foul conditions of the nation's slaughterhouses in his book "The Jungle."<sup>7</sup> It de-

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<sup>4</sup> *The White House: Press briefing by Larry Haas, Daniel Glickman, Sally Katzen*, M2 Presswire, July 8, 1996, available in LEXIS, Nexis Library, Newsl. File.

<sup>5</sup> *Id.*

<sup>6</sup> *Id.*

<sup>7</sup> Walter Hamilton, *Federal Meat Safety Programs Inspected*, DAILY NEWS, Feb. 28, 1993, at B1.

tailed the unsanitary conditions of our country's meat-packing plants.<sup>8</sup> The exposé was the catalyst for the first federal meat-industry reforms.<sup>9</sup> Since then, the government has maintained an inspection program that has relied on a system of visual inspections, often referred to as the "organoleptic<sup>10</sup> method."<sup>11</sup> Carcasses are scanned for: (1) noticeable abscesses or abrasions, which can signal disease or infected animals<sup>12</sup> and (2) contamination by hair, wood chips or fecal matter.<sup>13</sup> Generally, this inspection process depends on approximately 5,000 USDA inspectors.<sup>14</sup> It is estimated that inspectors have approximately two seconds to examine a poultry carcass and 30 seconds to look over a 2,000 to 3,000 pound beef carcass.<sup>15</sup> The current system does not require laboratory tests or microbiological testing for pathogens.<sup>16</sup> Currently, pathogenic testing has not been required primarily because it is costly and time-consuming.<sup>17</sup> In an era of abundant technological advances, this antiquated inspection process is one that critics have long said "was an accident waiting to happen."<sup>18</sup> The current "see, touch, and smell" system is based on the premise that identifying and destroying overtly diseased animals will prevent human illness.<sup>19</sup> With the recent emergence of the rare strain of *E. coli* O157:H7,<sup>20</sup> this premise is clearly no longer valid. This new bacteria thrives in the intestinal tracts of cattle without affecting the animal.<sup>21</sup> However, if ingested by humans, the bacteria can be fatal.<sup>22</sup> USDA inspectors have ex-

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<sup>8</sup> *Id.*

<sup>9</sup> Angela Zimm, "Poke and Sniff" Meat Inspection Gives Way to More Technologically Advanced Methods, 11 WARFIELD'S BUS. REC. 9 (1996).

<sup>10</sup> Organoleptic: making an impression on an organ of special sense; capable of receiving a sense impression. DORLAND'S ILLUSTRATED MED. DICTIONARY 1190 (28th ed. 1994).

<sup>11</sup> Zimm, *supra* note 9.

<sup>12</sup> Hamilton, *supra* note 7.

<sup>13</sup> Denise Gellene, *USDA Inspections Come Under Fire*, L.A. TIMES, Feb. 5, 1993, at D1.

<sup>14</sup> *Id.*

<sup>15</sup> Jim Specht, *Food-Safety Groups Again Call for Better Meat Inspections*, Gannett News Service, Nov. 9, 1995, available in LEXIS, Nexis Library, Newsl. File.

<sup>16</sup> Gellene, *supra* note 13. A pathogen is a parasite capable of causing disease in its host. JACQUELYN G. BLACK, MICROBIOLOGY PRINCIPLES AND APPLICATIONS 387 (2nd ed. 1993).

<sup>17</sup> *Id.*

<sup>18</sup> *Id.*

<sup>19</sup> Hamilton, *supra* note 7.

<sup>20</sup> A rare and virulent strain of *E. coli* bacteria. See *infra* Part III.A.

<sup>21</sup> *Id.*

<sup>22</sup> *Id.*

amed animals severely infected with *E. coli* and, finding no apparent signs of disease, have approved the animals' meat for issue into commerce.<sup>23</sup> Hence, with the emergence of new bacterial strains, this age-old inspection system has proven with increasing frequency to fail the public and the industry. When outbreaks occur, industry costs can include product recall, litigation and settlement, higher premiums for product-liability insurance, and a devastating loss of reputation.<sup>24</sup> More importantly, societal costs include serious illness or the loss of invaluable lives.

## II. MEAT CONTAMINATION

Aside from inadvertent contamination of meat that may occur at the time of slaughter, meat may also become contaminated later in processing by improper sanitary procedures or negligence. In 1995, numerous USDA inspectors, concerned about the unsanitary and unsafe practices, prepared reports on the conditions of meat-handling establishments.<sup>25</sup> In September of that same year, 75 inspectors disclosed their findings to the consumer group, Government Accountability Project (GAP). On November 9, 1995, GAP released a report that consisted of these whistle-blower<sup>26</sup> disclosures. The report, titled "Fighting Filth on the Kill Floor: A Matter of Life and Death for American Families," documented unsanitary conditions, direct product contamination, and record falsifications.<sup>27</sup> After analyzing dozens of USDA reports, GAP found that the use of modern technology<sup>28</sup> often contributes to contamination.<sup>29</sup> Meat processing procedures frequently allow feces, internal organs and other contaminants to accumulate on processing-plant floors.<sup>30</sup> Meat moved by conveyor belts would occasionally fall off the belt onto the floor. Plant workers often simply

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<sup>23</sup> *Id.*

<sup>24</sup> Kathryn Salensky, *The War Against Food-Borne Pathogens*, 15 PUGET SOUND BUS. J. 4 (1995).

<sup>25</sup> *FSIS Budget, Inspector's Shortfalls Subject of Consumer Press Conference*, FOOD CHEMICAL NEWS, Nov. 13, 1995 [hereinafter *FSIS Budget*].

<sup>26</sup> "Whistle-blower" is an employee who refuses to engage in illegal and/or wrongful activities of his employer or fellow employees. Employer retaliation is often statutorily prohibited. BLACK'S LAW DICTIONARY 1101 (6th ed. 1991); *See, e.g.*, ALA. CODE § 25-8-57 (1996), N.Y. LABOR LAW § 740 (Consol. 1996).

<sup>27</sup> *FSIS Budget, supra* note 25.

<sup>28</sup> Such as conveyor belts.

<sup>29</sup> Specht, *supra* note 15.

<sup>30</sup> *Id.*

rinsed off the contaminants.<sup>31</sup> In some of the worst cases, meat that fell on the floor was returned to the assembly line without rinsing. Furthermore, unwashed transport containers used primarily for tainted meat were often used for outgoing fresh meat.<sup>32</sup>

### III. THE *ESCHERICHIA COLI* BACTERIA

#### A. Pathogenicity

*E. coli* are a group of bacteria normally found in the intestines of warm-blooded animals, including humans.<sup>33</sup> *E. coli* can also be found in water contaminated by animal or human feces.<sup>34</sup> Under normal conditions, these symbiotic microorganisms are harmless. In fact, a certain number are needed as part of the normal flora of the human and animal digestive systems.<sup>35</sup> *E. coli* bacteria include thousands of different strains.<sup>36</sup> One subgroup called "entero pathogenic *E. coli*," however, can cause food-borne illnesses. Within this harmful subgroup exists a rare and virulent strain, *E. coli* O157:H7.<sup>37</sup> This rare serotype<sup>38</sup> first attracted attention in 1982, when it was identified as the causative agent in two outbreaks of human gastrointestinal illness.<sup>39</sup> Like other strains, *E. coli* O157:H7 colonizes in the intestinal tracts of animals.<sup>40</sup> When an animal is slaughtered, the spilled intestinal contents can contaminate the muscle tissue of the animal.<sup>41</sup> If the meat is then ground (e.g., to produce hamburger meat), the infectious organisms are blended into the meat product. *E. coli* O157:H7 can survive both refrigeration and freezer storage, and can multiply very slowly at 44 degrees<sup>42</sup> Fahrenheit.<sup>43</sup> Even in low numbers, *E. coli* O157:H7 produces infections in the more susceptible human populations: infants, the eld-

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<sup>31</sup> *Id.*

<sup>32</sup> *Id.*

<sup>33</sup> *Escherichia coli Update: E. coli O157:H7*, FSIS BACKGROUNDER (USDA, Washington D.C.), Jan. 1993, at 1.

<sup>34</sup> *Id.*

<sup>35</sup> BLACK, *supra* note 16, at 388.

<sup>36</sup> NATIONAL LIVE STOCK & MEAT BOARD, *E. COLI O157:H7 FACT SHEET* (1993).

<sup>37</sup> *Id.*

<sup>38</sup> A strain of an organism. BLACK, *supra* note 16, at G27.

<sup>39</sup> *E. coli Spread is Worrying Officials*, WASH. POST, Jan. 7, 1997, at B17.

<sup>40</sup> FSIS BACKGROUNDER, *supra* note 33.

<sup>41</sup> *Id.*

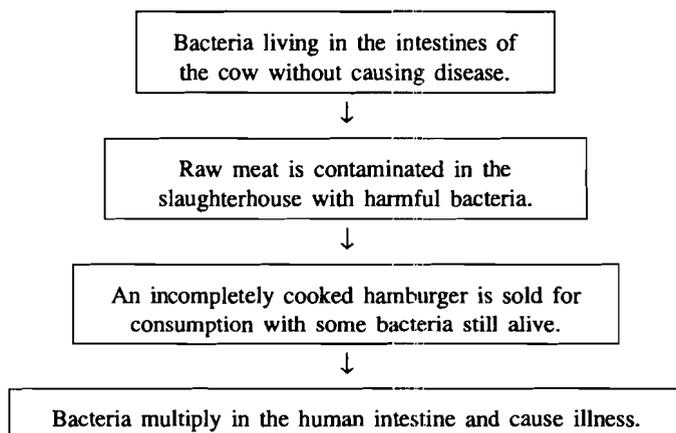
<sup>42</sup> Scientists consider 44 degrees to be within the safe zone for food stored in refrigerators.

<sup>43</sup> FSIS BACKGROUNDER, *supra* note 33.

erly, or the immune-compromised.<sup>44</sup> The distinctive trait of this strain is the toxin it produces. This poisonous substance, called “shiga-toxin” or “shiga-like toxin,” resembles the potent toxin produced by *Shigella dysenteriae*.<sup>45</sup> Following ingestion by the host and reproduction in the large intestine, *E. coli* O157:H7 produces the toxin, which damages the intestines and, if absorbed, exerts toxic effects on other tissues as well.<sup>46</sup> The spectrum of illnesses includes mild diarrhea, severe bloody diarrhea (hemorrhagic colitis), Hemolytic Uremic Syndrome (HUS)<sup>47</sup> and death.<sup>48</sup> *E. coli* O157:H7 has become a serious concern.

The transmission of *E. coli* O157:H7 is not complex. It occurs through contact with fecal matter during slaughter, through unsafe food handling, and can even be transmitted from person to person.<sup>49</sup> However, the most probable chain of transmission of *E. coli* O157:H7 is demonstrated below:

#### Anatomy of a Disease Outbreak<sup>50</sup>



<sup>44</sup> *Id.*

<sup>45</sup> David Brown, *From Herd to Hamburgers: The Mysterious Patterns of E. coli*, WASH. POST, Feb. 8, 1993, at A3.

<sup>46</sup> *E. coli Spread is Worrying Officials*, *supra* note 39.

<sup>47</sup> A disorder marked by renal failure, the gradual loss of the ability of the kidneys to excrete wastes. HUS is a serious and complicated illness often requiring kidney dialysis. *Hemolytic Uremic Syndrome (HUS)* (visited Jan. 4, 1997) <<http://www.housecall.com/databases/ami/convert/000510.htm>>.

<sup>48</sup> CDC Editorial Note, *Preliminary Report: Foodborne Outbreak of Escherichia coli O157:H7 Infections From Hamburgers-Western United States, 1993*, 269 JAMA 1089 (1993).

<sup>49</sup> FSIS BACKGROUNDER, *supra* note 33, at 2.

<sup>50</sup> Brown, *supra* note 45.

B. *E. coli* the "Adulterant"

In 1994, in *Texas Food v. Espy*,<sup>51</sup> *E. coli*<sup>52</sup> was defined as an "adulterant." The USDA had recently labeled *E. coli* as an "adulterant," which created a physical (i.e., more inspection procedures, etc.) and financial burden on the Texas meat industry. The meat industry filed suit contesting the USDA's authority to consider *E. coli* as an "adulterant" under the Federal Meat Inspection Act (FMIA).<sup>53</sup> The court looked to the language of FMIA to determine whether *E. coli* was an "adulterant." Under FMIA, a product is "adulterated" if:

it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance, such article shall not be considered adulterated under this clause if the quantity of such substance in or on such article does not ordinarily render it injurious to health.<sup>54</sup>

Plaintiff's primary argument was that ground beef contaminated with *E. coli* is not adulterated because it is only injurious to health if the meat is improperly cooked.<sup>55</sup> The court stated that unlike other pathogens, it is not "proper" cooking but "thorough" cooking that is necessary to protect consumers from *E. coli*. The court pointed out that Americans consider ground beef to be properly cooked rare, medium rare, or medium. Beef cooked in such a manner may cause serious physical problems, including death. Based on the evidence, the court held *E. coli* fits the definition of an adulterant under the FMIA.<sup>56</sup>

Generally if meat products are found to be adulterated, the processor or packer is required to either remove the contaminant or destroy

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<sup>51</sup> *Texas Food Industry Association v. Espy*, 870 F. Supp. 143, 148 (W.D. Tex. 1994).

<sup>52</sup> All *E. coli* can potentially cause spoilage of meat. However, some strains, if ingested, are more likely to cause serious disease in humans than others. *E. coli* O157:H7 is of particular concern because of its extremely devastating potential. *E. coli* does not normally live in the muscle tissues of healthy animals. Therefore, any strain of *E. coli* found in or on meat typically indicates the meat has been contaminated. This occurs either at the time the animal is slaughtered or sometime later in the processing of the meat. Any strain of *E. coli* in or on meat products should therefore be considered an "adulterant." Telephone Interview with Dr. Fred Aquino, Veterinarian and Acting Area Supervisor for USDA Meat Inspection Operations (Apr. 9, 1997).

<sup>53</sup> *Texas Food*, 870 F. Supp. at 148.

<sup>54</sup> Federal Meat Inspection Act 21 U.S.C. § 601(m)(1) (1996) (originally enacted as Act of Mar. 4, 1907, ch. 2907, 34 Stat. 1258).

<sup>55</sup> *Texas Food*, 870 F. Supp. at 149.

<sup>56</sup> *Id.*

the carrier.<sup>57</sup> If *E. coli* (or, for that matter, any other pathogen) is not considered an adulterant, a danger arises. Meat products containing these disease-causing contaminants would be considered unadulterated, "Wholesome" or "Inspected" and issued by the government into commerce.<sup>58</sup> For example, *Salmonella*,<sup>59</sup> another bacterial contaminant of meat and poultry, can cause nausea, abdominal cramps, vomiting, high fever, dizziness, headaches, dehydration, or diarrhea in humans.<sup>60</sup> In 1993, between 348 and 2,610 deaths were attributed to *Salmonella*.<sup>61</sup> In spite of its potentially lethal effects, *Salmonella* contamination is still not considered to constitute adulteration.<sup>62</sup> It is due to these circumstances, in which deadly pathogens are not considered to be adulterants, that HACCP's preventive and elimination system becomes so crucial.

Often, the consumer believes that a meat or poultry product approved by the government is safe and harmless. The consumer, therefore, relies on the meat industry and the government to ensure safe products. On the other hand, the industry and the government rely on the consumer to render the products safe by cooking the problem away.<sup>63</sup> This wishful system, however, has not proven effective. According to the Federal Centers for Disease Control and Prevention, *E. coli* causes approximately 20,000 illnesses in the United States each year, and 250 to 500 deaths.<sup>64</sup> Illnesses from all food-borne pathogens range from 33 to 81 million cases each year, with economic costs ranging from \$5.6 billion to \$9.4 billion per year.<sup>65</sup>

#### IV. THE 1993 JACK-IN-THE-BOX *E. COLI* OUTBREAK

Although *E. coli* O157:H7 was first identified as a problem in 1982, it was the 1993 outbreak that galvanized reformation.<sup>66</sup> In the 1993 outbreak, caused by undercooked hamburgers at Jack-in-the-Box restaurants, four people died and 700 became ill in the northwestern

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<sup>57</sup> *Kenney v. Glickman*, 96 F.3d 1118, 1121 (8th Cir. 1996).

<sup>58</sup> *American Public Health Ass'n v. Butz*, 511 F.2d 331, 332 (D.C. Cir. 1974).

<sup>59</sup> A common contaminant of poultry products. BLACK, *supra* note 16, at 752.

<sup>60</sup> *American Public Health*, 511 F.2d at 332.

<sup>61</sup> CAROLINE SMITH DEWAAL, CENTER FOR SCIENCE IN THE PUBLIC INTEREST, PLAYING CHICKEN 4 (1996).

<sup>62</sup> *American Public Health*, 511 F.2d at 333.

<sup>63</sup> DEWAAL, *supra* note 61, at 5.

<sup>64</sup> Philip J. Hilts, *Fierce Microbe is Rising Worldwide Problem*, N.Y. TIMES, July 25, 1996, at A9.

<sup>65</sup> *Bad meat. Don't Just Prod it*, THE ECONOMIST NEWSPAPER, July 13, 1996, at 29.

<sup>66</sup> Hilts, *supra* note 64.

United States.<sup>67</sup> As a result, the parent company of Jack-in-the-Box, Foodmaker Inc. of San Diego, California, spent millions of dollars to cover the medical bills of poisoned victims and to pay out-of-court settlements. The parents of Michael James Nole received \$1.3 million. Two-year-old Michael died twelve days after eating a hamburger.<sup>68</sup> Cheray Jefferson, age 4, who now suffers severe kidney damage and may require a kidney transplant, received \$5 million.<sup>69</sup> Brianne Kiner, 12, who spent 42 days in a coma, received the largest personal injury award in Washington State's history, \$15.6 million.<sup>70</sup> The Jack-in-the-Box outbreak focused attention on the current meat-inspection system. Parents, consumer groups, even members of the industry pushed for reform. The government initially responded with promises of more inspectors.<sup>71</sup> Ultimately, the government, with the help of others, developed and finalized HACCP.

## V. THE NEW RULE

### A. *The History of "HACCP"*

The concept and development of HACCP began with the Pillsbury Company. Pillsbury was involved in food production and research projects for the space program.<sup>72</sup> The Pillsbury Company developed the basics of HACCP with the cooperation and participation of the National Aeronautics and Space Agency (NASA), the Natick Laboratories of the U.S. Army, and the U.S. Air Force Space Laboratory Project Group.<sup>73</sup> In 1959, Pillsbury was asked to produce a food usable under zero-gravity conditions in the space capsules. Scientists attempted to produce 100 percent contaminant-free food. They found the objective extremely difficult to attain.<sup>74</sup> The scientists quickly determined that use of existing quality-control techniques gave no assurance that con-

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<sup>67</sup> *Id.*

<sup>68</sup> Dave Birkland, *\$1.3 Million Settlement in Boy's E. coli Death*, SEATTLE TIMES, Feb. 17, 1994, at B3.

<sup>69</sup> Dave Birkland, *Girl, 4, Gets \$5 Million in E. coli Case—Victim Faces Lifetime of Treatment*, SEATTLE TIMES, Apr. 27, 1995, at B3.

<sup>70</sup> Tyrone Beason, *\$15.6 Million E. coli-Case Settlement—Redmond Girl, 12, Survived Poisoning*, SEATTLE TIMES, Feb. 26, 1995, at B1.

<sup>71</sup> Terry McDermott & Robert T. Nelson, *E. coli Poisonings/One Year Later—Little Progress Made in Improving Detection*, SEATTLE TIMES, Jan. 16, 1994, at A1.

<sup>72</sup> Howard E. Bauman, *Introduction to HACCP PRINCIPLES AND APPLICATIONS 1* (Merle D. Pierson & Donald A. Corlett, Jr. eds. 1992).

<sup>73</sup> *Id.*

<sup>74</sup> *Id.*

tamination would not occur from bacterial or viral pathogens, toxins, chemicals, or physical hazards that could cause illness or injury.<sup>75</sup> They found the only successful method of assurance was to develop a “preventive system.”<sup>76</sup> Hence, HACCP was born. The primary objectives of a HACCP program for the food grower or processor with regard to biological hazards are: (1) destroy, eliminate, or reduce the hazard; (2) prevent recontamination; and (3) inhibit growth and toxin production.<sup>77</sup> Although the HACCP system has received broad support as a tool for improving the current system, the effectiveness of a HACCP system to prevent contamination of raw foods “remains more theoretical than proven.”<sup>78</sup> Thus, the impact and effectiveness of HACCP in meat and poultry slaughter and processing establishments are uncertain.

### B. The Rule

The Food Safety and Inspection Service’s (FSIS) Pathogen Reduction and HACCP System final rule mandates new measures to target and reduce the presence of pathogenic organisms in meat and poultry products.<sup>79</sup> These measures include:

- 1) Laboratory microbial testing, as follows:
  - a) testing for *Salmonella* by FSIS to verify pathogen-reduction performance standards are being met;<sup>80</sup> and
  - b) testing for generic *E. coli* by each establishment<sup>81</sup> to verify process control for fecal contamination.<sup>82</sup>
- 2) Mandatory Hazard Analysis and Critical Control Points (HACCP) systems in all meat and poultry plants.<sup>83</sup>

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<sup>75</sup> *Id.*

<sup>76</sup> *Id.* at 2.

<sup>77</sup> *Id.* at 10.

<sup>78</sup> CENTER FOR SCIENCE IN THE PUBLIC INTEREST, COMMENTS ON THE PROPOSED RULE ON PATHOGEN REDUCTION; HACCP SYSTEMS 3 (1995) (writing on behalf of American Public Health Association, Consumer Federation of America, Government Accountability Project, National Consumers League, Public Citizen, Public Voice for Food and Health Policy, United Food and Commercial Workers International Union).

<sup>79</sup> *FSIS Key facts: Microbial Testing Programs—FSIS Testing for Salmonella and Plant Testing for E. coli* (visited Aug. 26, 1996) <[http://www.usda.gov . . . y/fsis/keymicro.htm](http://www.usda.gov...y/fsis/keymicro.htm)> [hereinafter *FSIS Key facts: Microbial Testing*].

<sup>80</sup> *Id.*

<sup>81</sup> According to the rule, “establishment” includes all meat and poultry slaughter and processing establishments. Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems, 61 Fed. Reg. at 38,807.

<sup>82</sup> *FSIS Key facts: Microbial Testing*, *supra* note 79.

<sup>83</sup> *FSIS Key facts: Hazard Analysis and Critical Control Point (HACCP) Systems*

3) Written sanitation standard operating procedures (SOPs).<sup>84</sup>

FSIS's objective with the new rule is to ensure that meat, poultry, and egg products are safe, wholesome, and properly marked, labeled, and packaged. FSIS hopes this will reduce the risk of food-borne illness associated with the consumption of meat and poultry products to the maximum extent possible.<sup>85</sup> HACCP requires examination of every step in the food-production process. Each step at which a hazard can enter will be identified. Appropriate and feasible measures to prevent or reduce the potential hazard will be implemented at those pinpointed steps.<sup>86</sup>

1. Pathogen Reduction Standards and Microbial Testing

The current system does not require testing for microorganisms. However, a crucial provision of the new food-safety system involves microbiological testing. Sample testing for *Salmonella* on raw meat and poultry products will be conducted by FSIS.<sup>87</sup> This would act as an indicator of the slaughterhouse's compliance with performance and standards established under HACCP.<sup>88</sup> Further, testing for generic *E. coli* will be conducted on carcasses by the slaughter establishments. This testing will serve as an in-house assessment, enabling each establishment to evaluate its system's effectiveness for preventing and removing fecal contamination.<sup>89</sup>

As discussed earlier, *E. coli* is one of a number of microorganisms that are normal inhabitants of the colons of virtually all warm-blooded mammals. Under normal circumstances, these bacteria are harmless.<sup>90</sup> When an animal is slaughtered, the spilled intestinal contents (i.e., feces and ingesta and the associated bacteria) can contaminate the muscle tissue of the animal. The presence of some microorganisms on raw meat and poultry is unavoidable and highly variable. Therefore, microbial testing is desirable for determining the degree to which meat is

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(visited on Aug. 26, 1996) <[http://www.usda.gov . . . y/fsis/keymicro.htm](http://www.usda.gov...y/fsis/keymicro.htm)> [hereinafter *FSIS Key facts: HACCP Systems*].

<sup>84</sup> *FSIS Key facts: How USDA's New Food Safety System Will Fight Bacteria That Cause Foodborne Illness* (visited Aug. 26, 1996) <[http://www.usda.gov . . . y/fsis/keyfight.htm](http://www.usda.gov...y/fsis/keyfight.htm)>.

<sup>85</sup> Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems, 61 Fed. Reg. at 38,807.

<sup>86</sup> *Id.*

<sup>87</sup> *FSIS Key facts: Microbial Testing*, *supra* note 79.

<sup>88</sup> *Id.*

<sup>89</sup> *Id.*

<sup>90</sup> See *supra* text accompanying notes 33-35.

contaminated.<sup>91</sup>

There is a strong association of *E. coli* with the presence of enteric or intestinal pathogens and, in the case of slaughtering, the presence of fecal contamination.<sup>92</sup> There is wide acceptance in the international scientific community of the use of generic *E. coli* testing (i.e., for bio-type I, nonspecific as to species) as an indicator of the potential presence of enteric pathogens.<sup>93</sup> Generic *E. coli* occurs at a higher frequency than *Salmonella*, and quantitative *E. coli* testing permits more rapid and more frequent adjustment of process control. Analysis for *E. coli* poses fewer laboratory safety issues, and testing at the establishment site is more feasible than such testing for *Salmonella*.<sup>94</sup> For these reasons, experts concluded that microbial testing for generic *E. coli* would be the single most effective indicator for the purpose of demonstrating process control with respect to fecal contamination.<sup>95</sup>

## 2. HACCP System

Each meat-processing establishment must implement an effective HACCP system. The required HACCP system includes seven principles: (1) hazard analysis, (2) critical control point identification, (3) establishment of critical limits, (4) monitoring procedures, (5) corrective actions, (6) record keeping, and (7) verification procedures.<sup>96</sup>

Principle one requires the establishments to conduct an analysis to determine possible food-safety hazards. A food-safety hazard can be any biological, chemical, or physical property that may cause a food to be unsafe for human consumption. If potential hazards are identified, the necessary preventive measures to control these hazards must be established.<sup>97</sup>

Principle two requires the identification of critical control points (CCP). A CCP is a point, a step, or a procedure in the food process at which control can be applied to prevent, eliminate, or reduce to an acceptable level, the occurrence of a food-safety hazard.<sup>98</sup>

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<sup>91</sup> Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems, 61 Fed. Reg. at 38,839.

<sup>92</sup> *Id.*

<sup>93</sup> *Id.* at 38,837.

<sup>94</sup> *Id.* at 38,839.

<sup>95</sup> *Id.*

<sup>96</sup> *FSIS Key facts: HACCP Systems*, *supra* note 83.

<sup>97</sup> *Id.*

<sup>98</sup> *Id.*

Principle three requires the establishment to set a critical limit for each CCP. A critical limit is the maximum or minimum value to which a food-safety hazard must be controlled to prevent, eliminate, or at least reduce to an acceptable level, the occurrence of that identified food-safety hazard.<sup>99</sup>

Principle four is to establish CCP monitoring requirements. A monitoring system ensures the HACCP process is under control at each CCP.<sup>100</sup>

Principle five is to establish corrective actions. The final rule requires a plant's HACCP plan to identify the corrective actions to be taken when the monitoring system signals a deviation from an established critical limit. Corrective actions are intended to prevent products from entering commerce that might be injurious to health or which might be otherwise contaminated as a result of the deviation.<sup>101</sup>

Principle six requires the establishment to maintain record-keeping procedures. HACCP requires all plants to maintain certain documents, including its hazard analysis and written HACCP plan. Records documenting the monitoring of CCP, critical limits, verification activities, and the handling of processing deviations must also be maintained.<sup>102</sup>

Principle seven mandates validation and verification procedures that will confirm the HACCP system's effectiveness. Each establishment is required to validate its own HACCP plan; it will not be pre-approved by FSIS. Validation ensures the establishment's system does what it was designed to do, that is, successfully produce safe foods. Verification may include review of HACCP plans, CCP records, critical limits, and microbial sampling and analysis. This procedure will be conducted by both establishment personnel and FSIS inspectors. Verification confirms that HACCP plans are adequate and are functioning as intended.<sup>103</sup>

### 3. Sanitation Standard Operating Procedures (SOPs)

Another vital provision of the rule requires all meat and poultry establishments to develop, maintain, and adhere to written sanitation SOPs.<sup>104</sup> The concept is based on FSIS's belief that effective establish-

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<sup>99</sup> *Id.*

<sup>100</sup> *Id.*

<sup>101</sup> *Id.*

<sup>102</sup> *Id.*

<sup>103</sup> *Id.*

<sup>104</sup> Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems, 61 Fed. Reg. at 38,829.

ment sanitation is essential for food safety and for successful implementation of HACCP.<sup>105</sup> There are direct and substantial links between inadequate sanitation and the contamination of meat and poultry products by pathogenic bacteria.<sup>106</sup> The sanitation SOPs must delineate all daily procedures an establishment will conduct before and during operations to prevent direct product contamination.<sup>107</sup> The SOPs shall also specify the frequency with which each preventive procedure is to be conducted, and identify an employee responsible for the implementation and maintenance of such procedures.<sup>108</sup> This is a tremendous change from previous sanitation procedures, in which FSIS inspectors were the only ones who took responsibility for checking sanitation in slaughter establishments. In extreme cases of poor sanitation, government inspectors organized and supervised daily "bucket brigades" to clear out filth at slaughter establishments.<sup>109</sup> With the new SOPs, the responsibility for identifying and conducting procedures needed to maintain sanitary conditions or to rectify problem areas rests with the establishment rather than with FSIS.<sup>110</sup>

## VI. THE NEW ROLE OF THE GOVERNMENT

Under the current (Pre-HACCP) system, there is a heavy reliance on government inspectors.<sup>111</sup> This reliance on the government derived from the prescriptive nature of the current system. Establishments rely on FSIS inspectors to do what is necessary to direct the correction of deficiencies and to ensure that outgoing products are safe, unadulterated and properly labeled.<sup>112</sup> Some establishments operate on the assumption that if the inspector identifies no problem, their meat or poultry products may safely enter into commerce. The lines of responsibility are blurred.<sup>113</sup>

The new HACCP program will wean the industry from relying on government inspectors. HACCP clearly identifies the industry, not the government, as responsible for producing and marketing foods that are

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<sup>105</sup> *Id.*

<sup>106</sup> *Id.*

<sup>107</sup> FOOD SAFETY AND INSPECTION SERVICE, SANITATION STANDARD OPERATING PROCEDURES (SSOP) REFERENCE GUIDE 6 (1996).

<sup>108</sup> *Id.*

<sup>109</sup> *Id.* at 2.

<sup>110</sup> *Id.*

<sup>111</sup> Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems, 61 Fed. Reg. at 38,817.

<sup>112</sup> *Id.*

<sup>113</sup> *Id.*

safe, unadulterated, and properly labeled and packaged.<sup>114</sup> FSIS will be responsible only for inspecting products and facilities to verify that the new statutory requirements are met.<sup>115</sup> If not, FSIS will pursue "appropriate enforcement action."<sup>116</sup> The final rule does not specify what the "appropriate enforcement action" will be. However, it explains that the nature of the enforcement action taken will vary according to the severity of the alleged violation.<sup>117</sup> Hopefully, this will eliminate confusion and clarify the respective responsibilities of FSIS and the industry.

## VII. HACCP: THE GREAT COMPROMISES

### A. Consumer Compromises

#### 1. The Timetable

FSIS generated substantial debate concerning the implementation schedule. Consumer groups wanted immediate implementation. They believed the proposed timetable was too slow.<sup>118</sup> Their main concern was the seriousness of the food-safety issues involved. They felt it was crucial to implement the rule as soon as possible to prevent further food-borne illnesses.<sup>119</sup> Noting that many in the industry are already familiar with the HACCP system, consumer groups argued that little time is needed to adjust to the new system. In fact, they pointed out that many larger establishments have already adopted a HACCP system.<sup>120</sup>

On the other hand, the HACCP rule will place excessive burdens on smaller establishments that are less prepared technically and financially to carry out HACCP.<sup>121</sup> The final rule attempts to resolve the implementation debate. Although FSIS believes in the importance of rapid implementation, it did not require every establishment to imple-

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<sup>114</sup> *Id.*

<sup>115</sup> *Id.*

<sup>116</sup> *Id.* at 38,822.

<sup>117</sup> *Id.*

<sup>118</sup> *Id.* at 38,813.

<sup>119</sup> *Id.*

<sup>120</sup> *Id.* See generally H. R. CROSS & T.C. JACKSON INSTITUTE OF FOOD SCIENCE AND ENGINEERING, THE CURRENT STATUS OF HACCP IMPLEMENTATION (1995) (examining the results of an informal survey that received 151 responses from companies asked whether they had HACCP plans in place for one or more of their operations; 49.7 percent of respondents currently had HACCP plans while 47 percent did not).

<sup>121</sup> Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems, 61 Fed. Reg. at 38,813.

ment every aspect of the rule immediately nor at any one set time. Instead, FSIS developed a timetable in a stepped approach.<sup>122</sup> FSIS believed this would be more realistic for the implementation of this fundamental transformation.

The timetable was based primarily on establishment size.<sup>123</sup> The implementation schedule is as follows:

**IMPLEMENTATION SCHEDULE<sup>124</sup> FOR SANITATION SOP'S**

January 27, 1997 — All establishments

**FOR PROCESS CONTROL TESTING**

January 27, 1997 — All slaughter establishments

**FOR THE HACCP REGULATIONS**

January 26, 1998 — In large establishments, defined as all establishments with 500 or more employees

January 25, 1999 — In smaller establishments, defined as all establishments with 10 or more but fewer than 500 employees

January 25, 2000 — In very small establishments, defined as all establishments with fewer than 10 employees or annual sales of less than \$2.5 million

**FOR SALMONELLA PATHOGEN REDUCTION PERFORMANCE STANDARDS—**  
Applicable simultaneously with applicability dates listed above for implementation of HACCP.

## 2. FSIS Pre-Approval of HACCP Plans

Consumers were solicited for validation of HACCP plans. Of particular concern was the role FSIS plays in the development and approval of each establishment's HACCP plan. Consumers felt FSIS should assume at least some responsibility in these areas.<sup>125</sup> One idea was to implement a pre-approval system.<sup>126</sup> In this way, consumers argued, FSIS could verify and maintain oversight over the development and approval of HACCP plans rather than allowing the industry to "self-police."<sup>127</sup> Prior approval would assure consumers the greatest degree of protection and ensure that each plan is sufficient before it is implemented.<sup>128</sup> Others argued that neither formal acceptance nor prior ap-

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<sup>122</sup> *Id.* at 38,806.

<sup>123</sup> *Id.* at 38,813.

<sup>124</sup> *Id.* at 38,806.

<sup>125</sup> *Id.* at 38,825.

<sup>126</sup> CENTER FOR SCIENCE IN THE PUBLIC INTEREST, *supra* note 78, at 45.

<sup>127</sup> *Id.* at 45-46.

<sup>128</sup> *Id.*

proval of plans by FSIS should be required.<sup>129</sup> The final rule concludes that because prior approval of HACCP plans by FSIS would be contrary to redefined roles and responsibilities inherent in the HACCP philosophy, FSIS will neither approve nor validate HACCP plans prior to implementation. Each establishment will be responsible for developing its own HACCP plan and ensuring its adequacy.<sup>130</sup> FSIS does not prescribe any particular validation method, but does encourage establishments to use services of laboratories or processing authorities to validate their CCPs.<sup>131</sup> Thus, whether an establishment creates its own plan or has one created by an outside source, the establishment will validate its own HACCP plan.

### 3. Whistle-blower Protection

Consumers also urged FSIS to include whistle-blower protection in the new rule.<sup>132</sup> They argued that since HACCP is fundamentally a "self-policing" system, it will not work effectively without protection for establishment employees who alert authorities to potential violations.<sup>133</sup> Although the final rule does not incorporate whistle-blower protection, FSIS believes it will be alerted to possible wrongdoing by employees nonetheless.<sup>134</sup> FSIS stated that it has relied on information provided by employees for many years with an understanding that the identity of the informant would be kept confidential. FSIS believes this to be an effective policy that will remain.<sup>135</sup> Additionally, FSIS claims to have no statutory authority under the Federal Meat Inspection Act (FMIA)<sup>136</sup> nor the Poultry Products Inspection Act (PPIA)<sup>137</sup> to build explicit whistle-blower protection into the final rule. Neither FMIA nor the PPIA provides whistle-blower protection for industry employees.<sup>138</sup> However, consumers contend that the USDA not only could but should adopt these protections without a specific statutory

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<sup>129</sup> Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems, 61 Fed. Reg. at 38,825.

<sup>130</sup> *Id.* at 38,826.

<sup>131</sup> *Id.*

<sup>132</sup> *Id.* at 38,822.

<sup>133</sup> CENTER FOR SCIENCE IN THE PUBLIC INTEREST, *supra* note 78, at 59.

<sup>134</sup> Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems, 61 Fed. Reg. at 38,822.

<sup>135</sup> *Id.*

<sup>136</sup> 21 U.S.C. § 601 (1997).

<sup>137</sup> Poultry Products Inspection Act, 21 U.S.C. § 451 (1996).

<sup>138</sup> Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems, 61 Fed. Reg. at 38,822.

mandate, as these protections are essential for the proper functioning of HACCP.<sup>139</sup>

#### 4. Freedom of Information Act (FOIA) Concerns

Many consumers stated that records required to be maintained should not be available to requestors through FOIA.<sup>140</sup> Some argued that HACCP records should be used for verification only and should not be included in government files.<sup>141</sup> Others suggested that access to records by FSIS inspection personnel be restricted to records necessary for HACCP compliance monitoring, while others wanted to prohibit FSIS personnel from copying or removing any records from the establishment.<sup>142</sup> Of course, there were many who requested that HACCP records be available to the general public, based on the premise that consumers have a right to know about the safety of the food products they purchase.<sup>143</sup> The consumer's right to have access to such information is already recognized in the drug and device area. The Federal Department of Agriculture permits consumers to have access to essential information regarding the safety of these products.<sup>144</sup> Consumers asserted that broad public access to establishments' HACCP records enables the public to perform an important monitoring function.<sup>145</sup> However, FSIS believes there are some elements of HACCP plans and monitoring records that can be classified as trade secrets or commercial confidential information. Thus, under FOIA exemptions,<sup>146</sup> they may be protected from public disclosure. Nevertheless, FSIS believes record keeping is critical to the successful functioning of HACCP sys-

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<sup>139</sup> CENTER FOR SCIENCE IN THE PUBLIC INTEREST, *supra* note 78, at 60.

<sup>140</sup> Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems, 61 Fed. Reg. at 38,821.

<sup>141</sup> *Id.*

<sup>142</sup> *Id.*

<sup>143</sup> CENTER FOR SCIENCE IN THE PUBLIC INTEREST, *supra* note 78, at 54.

<sup>144</sup> *Id.* See 21 C.F.R. § 314.430 (drugs) and § 814.5 (devices).

<sup>145</sup> *Id.*

<sup>146</sup> Freedom of Information Act 5 U.S.C. § 552 (b) (1)-(9) (1996). The release by FSIS of information about establishments and their operations is governed by FOIA. This statute requires federal agencies to make available to the public agency rules, opinions, orders, records, proceedings, and information concerning agency organizations and operations. FOIA provides exemptions from public disclosure for various kinds of information, including information concerning trade secrets and confidential commercial or financial information, and information compiled for law enforcement purposes, the release of which would be prejudicial or harmful to law enforcement or to the privacy rights or safety of individuals.

tems in meat and poultry establishments.<sup>147</sup> Therefore, only FSIS will have access to HACCP records and other records that FSIS regulations require.<sup>148</sup> While the records required by this final rule are clearly within the establishment's domain and ownership, FSIS will be able to review them because they are necessary to effectuate a mandatory system of preventive controls to achieve food safety.<sup>149</sup>

### B. Industry Compromises

#### 1. Frequency and Cost of Testing

Initially it was proposed that the new rule would require daily microbial testing for each species and for raw, ground products.<sup>150</sup> Those who objected to the daily testing requirement argued that it would place an unfair cost burden and have a negative economic impact on some establishments. Meat processors hardest hit would be those producing multiple species and/or multiple ground products. For these meat producers, multiple tests would be required.<sup>151</sup> Consequently, a small establishment could conceivably conduct more tests per day than a much larger, higher-production establishment. Furthermore, many small establishments do not have on-site testing facilities and would have the additional cost of shipping samples for testing.<sup>152</sup>

On the other hand, there were many who supported the one-sample-per-day testing requirement, arguing it is a more efficient means of verifying process control. Still others recommended testing even more frequently than once per day.<sup>153</sup> Their main concern was that if sampling frequency were not conducted at this proposed frequency, it would result in an inadequate process control, resulting in large quantities of suspect meats being produced.<sup>154</sup> FSIS has explained that in the new rule, testing requirements will be based on production volume.<sup>155</sup> Whether sampling should be based on production volume or based on

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<sup>147</sup> Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems, 61 Fed. Reg. at 38,821.

<sup>148</sup> *Id.*

<sup>149</sup> *Id.*

<sup>150</sup> Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems, 61 Fed. Reg. at 38,839.

<sup>151</sup> *Id.*

<sup>152</sup> *Id.*

<sup>153</sup> *Id.*

<sup>154</sup> *Id.*

<sup>155</sup> *Id.*

a minimum number of daily tests, neither FSIS nor the industry can foresee which will be most effective.

## 2. Small Business

Members of the industry focused on the increased costs small businesses may face with the implementation of HACCP and urged that small businesses be exempt from HACCP.<sup>156</sup> As stated earlier, microbial analysis for *E. coli* will be conducted by the establishment.<sup>157</sup> The industry fears these costs may be higher for smaller establishments than for larger companies, given the number of daily tests required for the various species slaughtered or ground on a given day.<sup>158</sup> Further, establishments will be required to bear the cost of preparing a HACCP program. Small establishments may have to turn to outside (expensive) consultants for assistance in developing a HACCP program. These expenses, as well as others, would be significant to a company with less than \$250,000 in gross sales per year.<sup>159</sup> In response, FSIS has attempted to reduce some of the small business costs by providing some assistance in the development of a HACCP program. FSIS developed 13 generic HACCP models to assist "small" and "very small" establishments in preparing their HACCP plans.<sup>160</sup> The generic models will serve only as illustrations, rather than as prescriptive blueprints for a specific HACCP plan. FSIS believes this will remove much of the guesswork and reduce the costs associated with developing HACCP plans.<sup>161</sup> FSIS will also conduct HACCP demonstration projects and provide various HACCP materials that should assist these establishments in conducting their HACCP plans.<sup>162</sup> This is the only form of assistance FSIS has provided the smaller establishments. HACCP's true economic impact on smaller businesses will not be known until implementation is complete and the new system is in place and functioning properly.

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<sup>156</sup> *Id.* at 38,819.

<sup>157</sup> *See supra* text accompanying note 82.

<sup>158</sup> Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems, 61 Fed. Reg. at 38,819.

<sup>159</sup> Memorandum from Olson, Frank and Weeda, P.C. on "Mega-Reg" Update to Rosemary Mucklow, Executive Director, National Meat Institute (June 2, 1995) (on file with *San Joaquin Agricultural Law Review*).

<sup>160</sup> Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems, 61 Fed. Reg. at 38,819.

<sup>161</sup> *Id.*

<sup>162</sup> *Id.*

### 3. Layering

Another major concern of the industry was the concept of "layering." The industry fears that HACCP is layering new requirements on top of existing requirements.<sup>163</sup> Written SOP requirements for sanitation will be required under the new rule, but all current sanitation regulations will also remain in effect.<sup>164</sup> The industry believes, therefore, that HACCP should replace rather than complement the current carcass-by-carcass inspections.<sup>165</sup> The concern is that inspectors will not know which standards to enforce.<sup>166</sup> Consumers, on the other hand, believe this is not a matter of layering but rather a strengthening of the current system.<sup>167</sup> They insist that the implementation of a HACCP program is not an adequate substitute for the current inspection system. Instead, it will fill food-safety gaps in the current system without significantly increasing government costs.<sup>168</sup> Carcass-by-carcass inspection is a legal requirement that binds both FSIS and the industry. Thus, HACCP cannot supplant this method of inspection.<sup>169</sup> The final rule states that regulations, directives, and guidelines should be consistent with HACCP, and any that are inconsistent or incompatible with HACCP principles and procedures will be amended or revoked.<sup>170</sup>

## VIII. EFFECTS OF THE NEW RULE ON INDUSTRY LIABILITY

### A. HACCP as Proof of Compliance or Negligence

The effect of HACCP on an establishment's liability in civil lawsuits is uncertain. FSIS claims it will not be affected.<sup>171</sup> However, under the new HACCP program, the system may provide a stricter legal framework for assessing blame when consumers become ill. That is, a violation of the HACCP system can be used as proof of negligence.<sup>172</sup> On the other hand, the same system can work in favor of an

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<sup>163</sup> *Id.* at 38,818.

<sup>164</sup> Memorandum from Olson, Frank & Weeda, P.C., *supra* note 159.

<sup>165</sup> CENTER FOR SCIENCE IN THE PUBLIC INTEREST, *supra* note 78, at 4.

<sup>166</sup> Memorandum from Olson, Frank & Weeda, P.C., *supra* note 159.

<sup>167</sup> *Id.*

<sup>168</sup> CENTER FOR SCIENCE IN THE PUBLIC INTEREST, *supra* note 78, at 5.

<sup>169</sup> Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems, 61 Fed. Reg. at 38,818.

<sup>170</sup> *Id.*

<sup>171</sup> *Id.* at 38,839.

<sup>172</sup> *Seafood HACCP Will Expose, Protect Industry from Product Liability Lawsuits*, Food Chemical News, Aug. 5, 1996, available in LEXIS, Nexis Library, Newsl. File.

establishment and protect the food industry from product liability lawsuits. Since establishments are required to maintain records, the mandatory HACCP plan can provide evidence beneficial to the establishment in liability suits. These records may be reviewed and presented as evidence to show how the food in question was handled and at what points it was tested.<sup>173</sup> Under current product-liability laws, U.S. courts may hold an establishment responsible for damages to consumers that result from hazards present in food.<sup>174</sup> Claims may include personal injury, medical expenses, lost earnings, pain and suffering, property damage and impaired future earnings. Cases are evaluated as to whether the food producer measures up to current industry standards.<sup>175</sup> Prior to the mandating of HACCP, some in the industry voluntarily implemented HACCP. Establishments that had not implemented a HACCP plan were compared with their competitors that had.<sup>176</sup> This created a disparity in the industry. Now that HACCP is mandatory for all, establishments from large to small will have comparable programs and standards.

### B. *Whose Duty Is It?*

Under the current system, even though a government seal, "U.S. Passed and Inspected" or "U.S. Inspected for Wholesomeness," certifies a product has been inspected and approved for commerce by a government official, the establishment is still not relieved from liability.<sup>177</sup> In *Catani v. Swift & Company*,<sup>178</sup> the court held government inspection of meat does not relieve the packer from liability for damages. This is especially true when the packer has made no inspection nor taken any steps to ascertain for himself whether the meat sold was fit for consumption.<sup>179</sup> The duty to sell wholesome food remains the burden of the industry. The burden of discharging this duty has not been shifted to the government inspectors.<sup>180</sup> Historically, this is where the problem rested. Because of such a heavy reliance on government inspectors to assure the product was safe, the industry rarely inspected its own products. Under the HACCP system, however, the industry

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<sup>173</sup> *Id.*

<sup>174</sup> *Id.*

<sup>175</sup> *Id.*

<sup>176</sup> *Id.*

<sup>177</sup> *Ketterer v. Armour & Co.*, 247 F. 921, 927 (2nd Cir. 1917).

<sup>178</sup> *Catani v. Swift & Co.*, 95 A. 931, 933 (Pa. 1915).

<sup>179</sup> *Id.*

<sup>180</sup> *Id.*

will now be required to conduct numerous inspections on its own products. The HACCP plan thereby gives each establishment the tools necessary to ensure the production of safe foods. The net effect is that by protecting the consumers from illness, each establishment will have a greater opportunity to protect itself from lawsuits. However, this now means that under HACCP, the duty of and liability for inspection of meat products and ensuring their safety falls clearly and squarely on the producer, not on the government.

### *C. Accountability*

Consumers often cannot trace an illness to any particular food, nor can they even be certain that an illness was caused by food.<sup>181</sup> As a result, food retailers and restaurants are generally not held accountable by either their customers or by the courts for selling pathogen-contaminated products. Retailers, in turn, do not hold their wholesale suppliers accountable. This lack of marketplace accountability for food-borne illness has resulted in few establishments implementing extra measures and incurring extra costs to incorporate more than minimal pathogen controls.<sup>182</sup> The industry at every level, from the farm to the final retail sale, may distribute into commerce an unsafe product and never suffer adverse legal consequences nor experience a reduced demand for its product.<sup>183</sup> Furthermore, when food-borne illness occurred under the current system, few were willing to accept responsibility. Instead a considerable amount of finger pointing occurred. All involved—the slaughterhouse, the retailer, the inspector, even the consumer for undercooking the meat—were blamed and each blamed the other.

HACCP, by incorporating the use of science and technology into meat inspection, should reduce meat and poultry pathogens. All hope the HACCP program will culminate in substantial benefits for the industry, such as: (1) reduced premiums for product-liability insurance, (2) improved customer confidence, which has a positive influence on demand, (3) reduced operating costs such as the cost of product recalls or of settling product liability claims, and (4) reduced likelihood of loss of product reputation and loss of sales when a food-borne illness outbreak is publicized, identifying a product or company.<sup>184</sup>

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<sup>181</sup> Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems, 61 Fed. Reg. at 38,860.

<sup>182</sup> *Id.*

<sup>183</sup> *Id.*

<sup>184</sup> *Id.*

## IX. WHAT HACCP LEFT OUT

In April 1995, the Family Food Protection Act (FFPA) was introduced in both the House and the Senate. It never made it past the committee hearings.<sup>185</sup> FFPA sought to establish a "farm to table" food-safety system. Some believed the combination of regulatory and statutory changes included in the FFPA were "the one-two punch needed to restore Americans' confidence in the meat and poultry stamped 'Wholesome' by the government."<sup>186</sup> FFPA included several of the same provisions found in HACCP. Additionally, FFPA proposed several provisions that HACCP did not. The provisions are very consumer-conscious, and seek to impose more stringent laws on the industry. The provisions that consumers continue to pursue<sup>187</sup> include: (1) handling, processing and storing standards that would be voluntarily implemented by retail establishments. These standards would become mandatory if retailers were found not to be in substantial compliance;<sup>188</sup> (2) mandatory animal identification and recordkeeping for the purposes of trace back of carcasses. If harmful pathogens were found in animals, the Secretary of the USDA could take appropriate action to determine the source of the hazard, and could prohibit the movement of animals or products containing the human pathogens or other harmful substances;<sup>189</sup> (3) USDA mandatory recall authority for foods that the Secretary deems are unsafe for human consumption, adulterated or misbranded. District courts would have similar authority; (4) civil penalties of up to \$100,000 per day of violation for those establishments not in compliance.<sup>190</sup>

## CONCLUSION

HACCP's emphasis on controlling bacteria in meat and poultry products is a tremendous step forward from the 90-year-old meat-inspection system. Only time will determine whether HACCP produces the efficient system needed to prevent or reduce contaminated meat

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<sup>185</sup> H.R. 1423, 104th Cong. (1995); S. 515, 104th Cong. (1995).

<sup>186</sup> *Family Food Protection Act Will Hit The Hopper Next Week*, Food and Drink Daily, Feb. 3, 1995, available in LEXIS, Nexis Library, Newsl. File.

<sup>187</sup> These provisions are very important to consumers and will be re-introduced this congressional session in another form. Telephone interview with Caroline Smith DeWaal, Director of Food Safety, Center for Science in the Public Interest (Feb. 14, 1997).

<sup>188</sup> *Family Food Protection Act Will Hit The Hopper*, *supra* note 186.

<sup>189</sup> *Id.*

<sup>190</sup> *Id.*

products. From the consumer perspective, this is just the beginning in meat-inspection reformation.<sup>191</sup> The future may require the industry to implement and conform to additional mandatory inspection requirements. Unfortunately, *E. coli* is not an isolated problem within the meat industry. Recently, it has become a problem in the fresh fruit and vegetable industry.<sup>192</sup> With the recent emergence of *E. coli* O157:H7 contamination in unpasteurized apple juice, the government will again have to respond and take the necessary steps to effectuate the removal of *E. coli*.<sup>193</sup> It is unknown where the next outbreak of *E. coli*, or other food-borne pathogens, may occur. Thus, it is apparent that the introduction of new laws concerning food-safety issues is likely to escalate in number and in breadth.

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<sup>191</sup> See *supra* text accompanying note 186.

<sup>192</sup> Karen Houppert, *Food Poisoning: Why This Fruit Could Kill You*, REDBOOK, June 1996, at 116.

<sup>193</sup> *Id.*