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**Reeling in a Rogue Industry: Lethal E. Coli  
in California's Leafy Green Produce  
& The Regulatory Response**

by

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# REELING IN A ROGUE INDUSTRY: LETHAL E. COLI IN CALIFORNIA’S LEAFY GREEN PRODUCE & THE REGULATORY RESPONSE

*Matthew Kohnke\**

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*"The first duty of law is to keep sound the society it serves."*<sup>1</sup>

## I. INTRODUCTION

The U.S. fresh produce industry is a rapidly growing, multi-billion dollar empire that has firmly established itself as an integral part of this nation's food economy.<sup>2</sup> Its fiscal success over the last few decades, particularly in the fresh-cut sector,<sup>3</sup> can be primarily attributed to the increasingly health conscious and convenience-oriented attitude of today's modern consumer.<sup>4</sup> However, while these overlapping trends have been beneficial to both the fresh produce industry and the consuming public, new and difficult challenges have emerged in the wake of this changing societal landscape.<sup>5</sup> One of the most difficult obstacles presented has been how to protect the health of the nation's citizenry and economy from the growing threat of foodborne illness outbreaks linked to this vital food source.<sup>6</sup> The lethal and much publicized *E. coli* outbreaks in 2006 involving spinach and lettuce grown in California brought this important food safety issue to the forefront of public debate, causing the nation to focus its scrutiny on California's historically problematic leafy green produce industry.<sup>7</sup> As concerns and

1. President Woodrow Wilson, First Inaugural Address (Mar. 4, 1913), *reprinted in* THE AVALON PROJECT AT YALE LAW SCHOOL, <http://www.yale.edu/lawweb/avalon/presiden/inaug/wilson1.htm>.

2. See CTR. FOR FOOD SAFETY & APPLIED NUTRITION, U.S. FOOD & DRUG ADMIN., ANALYSIS AND EVALUATION OF PREVENTATIVE CONTROL MEASURES FOR THE CONTROL AND REDUCTION/ELIMINATION OF MICROBIAL HAZARDS ON FRESH AND FRESH-CUT PRODUCE, ch. I § 2.1 (2001), *available at* <http://www.cfsan.fda.gov/~comm/ift3-1.html> ("The total fresh produce market reached \$70.8 billion in retail and food service sales in 1997, up from \$34.6 billion in 1987." As of 2005, it totaled \$95 billion with steady growth expected to continue.).

3. See Notice of Hearing and Request for Comments on the Safety of Fresh Produce, 72 Fed. Reg. 8750, 8751 (Feb. 27, 2007), *available at* <http://www.fda.gov/OHRMS/DOCKETS/98fr/07-891.pdf> ("'Fresh cut produce' refers to minimally processed fruits and vegetables that have been altered in form by peeling, slicing, chopping, shredding, coring, or trimming . . . prior to being packaged."); CTR. FOR FOOD SAFETY, *supra* note 2, at ch. I, § 2.1 ("Estimated at \$11 billion in retail and foodservice sales in 2000, the fresh-cut produce market has grown exponentially since its infancy in the early 1980's.").

4. See MORTON SATIN, FOOD ALERT! THE ULTIMATE SOURCEBOOK FOR FOOD SAFETY 151-52 (1999).

5. See *id.* at 184.

6. See Colo. St. Univ., *Produce-Related Foodborne Illness*, SAFEFOOD NEWS, Winter 2004, *available at* <http://www.colostate.edu/Orgs/safefood/NEWSLTR/v8n2s05.html> (indicating that produce has become an important cause of food borne illness in the United States).

7. See Rong-Gong Lin II & Mary Engel, *Lettuce was Culprit in Latest Case*, L.A. TIMES, Jan. 13, 2007, at A1 ("It just adds more fuel to the fire of the need to address this . . . " (quoting FDA Chief Medical Officer, Dr. David Acheson)).

criticisms mounted, industry leaders and state government representatives separately set to work, formulating new regulatory programs with the common goal of improving the safety of leafy greens grown and handled in California.<sup>8</sup> However, as fundamental divergences in their proposals became more evident, debate erupted as to which approach would better protect the State's massive supply of leafy green produce against contamination.<sup>9</sup>

## II. CALIFORNIA'S LEAFY GREEN INDUSTRY & THE 2006 OUTBREAKS

As the most populous and diverse state,<sup>10</sup> California also succeeds at being the most agriculturally productive.<sup>11</sup> In 2004, California's cash receipts from its agriculture industry totaled \$31.8 billion, which was more than Texas and Iowa (the second and third leading states) combined.<sup>12</sup> It yields 350 different crops and is responsible for producing half of the nation's supply of fresh fruits and vegetables.<sup>13</sup> In regards to leafy green produce, the state of California accounts for more than seventy percent of the spinach and lettuce grown in the United States, totaling approximately \$1.6 billion in annual revenue.<sup>14</sup> With steady all-around growth expected to continue, California's agricultural community has firmly established itself as a dominant entity in this nation's economic marketplace.<sup>15</sup>

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8. See Press Release, Western Growers Ass'n, Western Growers Board Takes Action to Require Mandatory Food Safety Practices (Oct. 30, 2006), available at <http://www.wga.com/LinkClick.aspx?link=DocumentLibrary%2f103006.pdf&tabid=203&mid=9>; see also Frank D. Russo, *Package of Major Food Safety Bills Introduced by California State Senator Dean Florez*, CAL. PROGRESS REP., Feb. 1, 2007, [http://www.californiaprogressreport.com/2007/02/package\\_of\\_majo.html](http://www.californiaprogressreport.com/2007/02/package_of_majo.html).

9. See Video: Informational Hearing, Farming and the Environment: An Overview of 2006 E. Coli Outbreak, Assembly and Senate Committee on Agriculture, California State Legislature (Cal. Channel Broad. Feb. 27, 2007) [hereinafter Cal. Channel Broad.], available at <http://www.calchannel.com/MEDIA/0227E.aspx>; Senator Florez, Remarks on Introducing Bills on E. coli Outbreak and Food Safety, CAL. PROGRESS REP., Feb. 1, 2007, available at [http://www.californiaprogressreport.com/2007/02/remarks\\_of\\_cali.html](http://www.californiaprogressreport.com/2007/02/remarks_of_cali.html) [hereinafter Remarks].

10. Richard C. Atkinson, *The California Crucible: Demography, Excellence, and Access at the University of California*, Address Before the 2001 International Assembly of the Council for Advancement and Support of Education (July 2, 2001), available at [http://works.bepress.com/cgi/viewcontent.cgi?article=1030&context=richard\\_atkinson](http://works.bepress.com/cgi/viewcontent.cgi?article=1030&context=richard_atkinson).

11. CAL. DEP'T OF FOOD AND AGRIC., CALIFORNIA AGRICULTURAL RESOURCE DIRECTORY 2005.

12. *Id.*

13. *Id.*

14. Jerry Hirsch, *State OKs Certification Program for Leafy Crops*, L.A. TIMES, Feb. 8, 2007.

15. See, e.g., Univ. of Cal., *UC and the Economy-Growing California's Agriculture*, <http://www.universityofcalifornia.edu/economy/agriculture.html> (last visited Nov. 15, 2007).

Despite the enormous amounts of safe produce sent to market each year by the state of California, 2006 was a year that its leafy green industry will forever associate with failure. On September 14, 2006, the Centers for Disease Control and Prevention ("CDC") issued a nationwide health alert, informing consumers of a multi-state outbreak of *E. coli* O157:H7 infections linked to packages of fresh spinach.<sup>16</sup> Over the weeks that followed, this outbreak proved to be "one of the largest and deadliest outbreaks of foodborne illness in recent years, affecting 26 states and resulting in 204 cases of illness, 104 hospitalizations, 31 cases of HUS and three deaths."<sup>17</sup> A trace-back investigation launched by authorities found that the source of the *E. coli*-tainted spinach was a fifty-acre growing field located in California's fertile Salinas Valley.<sup>18</sup>

With California's supply of leafy greens under the media's spotlight, the industry endured an additional blow later when another *E. coli* O157:H7 outbreak struck the nation.<sup>19</sup> On December 6, 2006, the CDC announced that an outbreak of *E. coli* from an unknown food source served at Taco Bell and Taco John's restaurants in the northeastern United States had infected forty-three people across four different states.<sup>20</sup> As of December 14, 2006, that number rose to seventy-one infections and, among the ill, fifty-three were hospitalized, and eight developed HUS.<sup>21</sup> Again, an investigation was conducted, revealing that fresh pre-packaged lettuce, also grown in the Salinas Valley, was the culprit.<sup>22</sup>

As a result of the death, illness, and monetary loss caused by these two outbreaks,<sup>23</sup> California's leafy greens supply chain, and its susceptibility to *E. coli* in particular, became subjects of nationwide concern. As it turned out, these out-

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16. Press Release, Ctrs. for Disease Control and Prevention, Multiple States Investigating a Large Outbreak of *E. coli* O157:H7 Infections (Sept. 14, 2006), <http://www2a.cdc.gov/han/ArchiveSys/ViewMsgV.asp?AlertNum=00249>.

17. S.B. 200, 2007 Sess. (Cal. 2007).

18. See generally, *Regulators Wrestle Over How to Ensure Safe Salad*, ASSOC. PRESS, Sept. 12, 2007 (on file with the author). See Jesse McKinley et al., *Farmers Vow New Procedures: Bacteria Eyed in Boy's Death*, N.Y. TIMES, Sept. 22, 2006, at A15 (The Salinas Valley is a vast stretch of land in the State's heartland often dubbed "the salad bowl of the world.").

19. Press Release, Ctrs. for Disease Control & Prevention, Multistate Outbreak of *E. coli* O157 Infections, November-December 2006 (Dec. 14, 2006), <http://www2a.cdc.gov/HAN/ArchiveSys/ViewMsgV.asp?AlertNum=00256>.

20. *Id.*

21. *Id.*

22. See Lin & Engel, *supra* note 7; Ctrs. for Food Safety & Applied Nutrition, U.S. Food & Drug Admin., *Questions and Answers: Taco Bell E. coli O157:H7 Lettuce Outbreak*, Dec. 14, 2006, <http://www.cfsan.fda.gov/~dms/tacobqa.html>.

23. See Elisa Odabashian, *California Leafy Green Industry's Marketing Agreement Will not Ensure Nation's Salad Bowl is Safe*, CAL. PROGRESS REP., July 25, 2007, [http://www.californiaprogressreport.com/2007/07/california\\_leaf.html](http://www.californiaprogressreport.com/2007/07/california_leaf.html) (The spinach outbreak alone caused three deaths, 205 illnesses, and over \$100 million in industry losses.).

breaks, together, proved to be “a watershed event for the [the state’s leafy greens] industry.”<sup>24</sup>

### III. *E. COLI* O157:H7 – A FOODBORNE PATHOGEN

*Escherichia coli* O157:H7, although not discovered until 1982, has emerged as one of the most dangerous foodborne bacterial pathogens to ever plague the U.S. food supply.<sup>25</sup> Its exceptional virulence, coupled with its talent for avoiding detection, has made the battle against this dangerous pathogen an especially difficult one.<sup>26</sup> Over the past decades, numerous individuals, particularly young children and the elderly, have either died or become seriously ill as a direct result of consuming food products laced with this pathogen.<sup>27</sup> According to the CDC, 73,000 cases of *E. coli* O157:H7 occur annually in the United States.<sup>28</sup> Among these occurrences, 2,100 Americans are hospitalized and sixty-one people die as a result of complications.<sup>29</sup> With a steady rise in these numbers expected to continue, the need to educate the consuming public about this virulent strain of *E. coli* has become more pronounced than ever before.

#### A. *Its Effect on the Human Body*

Once a person is infected by *E. coli* O157:H7, the most common disease that arises is a type of gastroenteritis known as hemorrhagic colitis.<sup>30</sup> According to one food safety expert, this foodborne illness causes “severe abdominal cramps and diarrhea that is initially watery, sometimes becoming grossly bloody to the point that it consists of blood without fecal material.”<sup>31</sup> Such symptoms are due to the induced production of potent toxins within the body that attack the victim’s intestinal lining.<sup>32</sup> While they will normally subside within a week for

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24. *California Growers Launch Produce Safety Plan*, SUPERMARKET NEWS, April 9, 2007 (quoting Tom Nassif, president of the Western Growers Association).

25. SATIN, *supra* note 4, at 185.

26. REBECCA HOHLSTEIN, *FOOD FIGHT: THE PEOPLE’S GUIDE TO FOOD SAFETY IN A DANGEROUS WORLD* 108 (2003).

27. MARION NESTLE, *SAFE FOOD: BACTERIA, BIOTECHNOLOGY, AND BIOTERRORISM* 41, 43 (2003).

28. Marler Clark, *About E. coli O157:H7*, <http://www.about-ecoli.com/> (last visited Nov. 15, 2007).

29. *Id.*

30. HOHLSTEIN, *supra* note 26, at 111.

31. *Id.*

32. Chryssa V. Deliganis, *Death by Apple Juice: The Problem of Foodborne Illness, the Regulatory Response and Further Suggestions for Reform*, 53 *FOOD & DRUG L.J.* 681, 683 (1998).

otherwise healthy adults and resolve without medical attention, up to fifteen percent of those who contract this infectious disease develop severe complications.<sup>33</sup>

The most dreaded complication that often arises from hemorrhagic colitis is the development of "Hemolytic Uremic Syndrome" ("HUS"), a debilitating illness that has a mortality rate between three and five percent.<sup>34</sup> Although its initial symptoms resemble that of hemorrhagic colitis, the consequences are much more severe, often resulting in permanent damage to the victim's kidneys and red blood cells.<sup>35</sup> While HUS can occur in people of all ages, the most frightening aspect of this disease is its effect on the nation's more vulnerable populations.<sup>36</sup> Along with the elevated threat it poses to the elderly, HUS is also the principal cause of kidney failure among children in the United States, with a mortality rate between five and ten percent.<sup>37</sup> With no cure in sight and effective medical treatment lacking for those in need, the dangers posed by this foodborne pathogen to the health of the nation's citizenry will certainly endure for many years to come.

### B. *An Increase in Leafy Green and Other Produce-Related Outbreaks*

While outbreaks caused by foodborne pathogens are traditionally linked in the public's eye to beef and poultry products, a variety of other food sources, not typically perceived as "high-risk,"<sup>38</sup> are emerging as common vehicles for transmission.<sup>39</sup> For instance, *E. coli* O157:H7 outbreaks involving fresh produce have nearly doubled over the past decade, from forty-four outbreaks in 1998 to eighty-five in 2004.<sup>40</sup> Furthermore, in an analysis of 3,000 outbreaks from 1990

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33. HOHLSTEIN, *supra* note 26, at 112.

34. *Id.* See SATIN, *supra* note 4, at 111.

35. See CTR. FOR FOOD SAFETY & APPLIED NUTRITION, U.S. FOOD & DRUG ADMIN., *ESCHERICHIA COLI* O157:H7 <http://www.cfsan.fda.gov/~mow/chap15.html> (last visited Nov. 15, 2007).

36. SATIN, *supra* note 4, at 111.

37. HOHLSTEIN, *supra* note 26, at 112.

38. See Deliganis, *supra* note 32, at 688.

39. Ctrs. for Disease Control & Prevention, Questions and Answers About *E. coli* O157:H7: Outbreak from Fresh Spinach (Oct. 12, 2006), <http://www.cdc.gov/ecoli/2006/september/qa.htm> ("Transmission of *E. coli* was first associated with contaminated ground beef but has also been spread through unpasteurized fruit juices, lettuce, and contaminated drinking water . . .").

40. CTR. FOR FOOD SAFETY & APPLIED NUTRITION, U.S. FOOD & DRUG ADMIN., DRAFT GUIDANCE FOR INDUSTRY: GUIDE TO MINIMIZE MICROBIAL FOOD SAFETY HAZARDS OF FRESH-CUT FRUITS AND VEGETABLES (2006) (updated March 2007), available at <http://www.cfsan.fda.gov/~dms/prodguid.html>; Ctr. for Sci. in the Pub. Interest, *Behind CSPI's Outbreak Data: A Look at the Produce Outbreak Numbers*, [http://www.cspinet.org/foodsafety/produce\\_data.pdf](http://www.cspinet.org/foodsafety/produce_data.pdf) (last visited Nov. 15, 2007).

to 2003, it was determined that, unlike previous decades, contaminated fresh produce was “responsible for the greatest number of individual foodborne illnesses – more than were caused by eggs and beef combined.”<sup>41</sup> As a result of these disturbing trends, the consuming public has become increasingly concerned about the safety of this indispensable food source.<sup>42</sup>

Within the nation’s fresh produce industry, California’s leafy green sector has proven itself particularly susceptible to contamination.<sup>43</sup> Since 1995, there have been twenty-two documented outbreaks of *E. coli* O157:H7 linked to leafy greens grown on farms in California.<sup>44</sup> Among these incidents, the State’s fertile Salinas Valley has been implicated in nine confirmed outbreaks of *E. coli* in leafy greens.<sup>45</sup> According to government statistics, prior to these latest outbreaks, leafy green produce grown on this fertile stretch of land had caused more than 400 cases of individual foodborne illness.<sup>46</sup> With the incidence of produce-related outbreaks and illnesses on the rise, many began to wonder how *E. coli* O157:H7 and other foodborne pathogens came to be such a formidable presence in California’s leafy green industry.<sup>47</sup>

According to many food safety experts, the increase in these numbers can be attributed to changing patterns involving fresh produce consumption and production.<sup>48</sup> As of late, people are eating fresh produce in increasing amounts,<sup>49</sup> and their demands for readily available items that fit their busy lifestyles are growing stronger by the day.<sup>50</sup> In order to keep up with these evolving social trends, fresh produce operations (especially those associated with leafy green produce) have become increasingly dedicated to the manufacture of convenience-

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41. Daniel Akst, *Big Farms Will Keep Spinach on the Table*, N.Y. TIMES, Oct 15, 2006. See CTR. FOR SCI. IN THE PUB. INTEREST, OUTBREAK ALERT: CLOSING THE GAPS IN OUR FEDERAL FOOD-SAFETY NET 19 (2006), [http://www.cspinet.org/foodsafety/outbreak\\_alert.pdf](http://www.cspinet.org/foodsafety/outbreak_alert.pdf).

42. Marian Burros, *E. coli Fears Inspire a Call for Oversight*, N.Y. TIMES, Dec. 9, 2006, at B1.

43. See generally Linda Calvin, *Outbreak Linked to Spinach Forces Reassessment of Food Safety Practices*, AMBER WAVES (June 2007), available at <http://www.ers.usda.gov/AmberWaves/June07/Features/Spinach.htm>.

44. Remarks, *supra* note 9.

45. Lin & Engel, *supra* note 7.

46. See Ctrs. for Food Safety & Applied Nutrition, U.S. Food & Drug Admin., *Letter to California Firms that Grow, Pack, Process, or Ship Fresh and Fresh-cut Lettuce* (Nov. 4, 2005), available at <http://www.cfsan.fda.gov/~dms/prodlttr2.html>.

47. See Deliganis, *supra* note 32, at 688.

48. NESTLE, *supra* note 27, at 42.

49. See Deliganis, *supra* note 32, at 698-99 (stating that produce eaten daily rose from an average of 3.9 servings during 1989-91 to 4.4 servings between 1991-94).

50. See CTR. FOR FOOD SAFETY, *supra* note 2, at ch. I, § 2.1.



oriented products.<sup>51</sup> However, while this shift is typically perceived in a positive light, convenient fresh produce items are proving to be especially susceptible to contamination.<sup>52</sup> Aside from the added dangers of simply being fresh-cut,<sup>53</sup> the risk of contamination is higher in these raw food products because they are “often consumed without cooking or other treatments, [such as additional consumer washing,] that could eliminate pathogens if they are present.”<sup>54</sup> Furthermore, due to the increased centralization of the fresh produce industry, modern outbreaks linked to these products often affect many different states and yield high rates of infections.<sup>55</sup> In today’s marketplace, where the majority of distribution is conducted by a few large scale processing plants that mix products from numerous farms, all it takes is a single contaminated leaf to spoil a massive multi-state supply of leafy greens.<sup>56</sup>

In order to reduce the incidence of foodborne illness outbreaks caused by *E. coli* O157:H7, a great deal of money and effort have been expended studying the elusive path of this dangerous pathogen along the farm-to-fork continuum.<sup>57</sup>

### C. *Transmission of this Potentially Lethal Bacterium*

A good place to begin a discussion about the transmittability of *E. coli* O157:H7 is at its source. While this contaminant has been found in the intestines

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51. See Carol Radice, Grocery Headquarters, *Coming Up Green: Prepackaged Salads Area a \$2 Billion a Year Business*, Feb. 2003 (on file with the author).

52. Nina Planck, Op-Ed., *Leafy Green Sewage*, N.Y. TIMES, Sept. 21, 2006, at A31.

53. Press Release, U.S. Food & Drug Admin., FDA Issues Final Guidance For Safe Production of Fresh-Cut Fruits and Vegetables (Mar. 12, 2007), <http://www.fda.gov/bbs/topics/NEWS/2007/NEW01584.html> (“Processing produce into fresh-cut product increases the risk of bacterial contamination and growth by breaking the natural exterior barrier of the produce by peeling, slicing, coring, or trimming [processes] . . .”).

54. Robert E. Brackett, Dir., Ctr. for Food Safety & Applied Nutrition, Statement to the Committee on Health, Education, Labor and Pensions (Nov. 15, 2006), <http://www.fda.gov/ola/2006/foodsafety1115.html>.

55. See NESTLE, *supra* note 27, at 43.

56. See generally Deliganis, *supra* note 32, at 696 (“When a contamination problem occurs at one of these [large manufacturing] facilities, a product may be distributed to thousands, or hundreds of thousands, of people before the danger is discovered.”). See also Press Release, Ctrs. for Disease Control & Prevention, Update on Multi-State Outbreak of *E. coli* O157:H7 Infections from Fresh Spinach (Oct. 6, 2006), <http://www.cdc.gov/ecoli/2006/september/updates/100606.htm> (Spinach from Natural Selection Foods, a massive grower/processor of leafy greens, was implicated in the infection of 199 people from 26 different states.).

57. See EcoliBlog.com, \$5.5 Million to go Toward E. Coli Research, <http://www.ecoliblog.com/2007/08/articles/e-coli-watch/55-million-to-go-toward-e-coli-research/> (Aug. 22, 2007) (In August 2007, “the USDA announced that it has awarded \$5.5 million to researchers who are working to determine the risk factors and prevention measures for *E. coli* O157:H7 contamination in fresh produce.”).

of pigs, chickens, and sheep, studies show that beef and dairy cattle are its primary hosts.<sup>58</sup> After infection, the dangerous strain of *E. coli* remains lodged in the animal's gastrointestinal tract until it is shed by way of excretion.<sup>59</sup> Once this process has taken place, the future of the freed pathogen is as unpredictable as its new open-air environment.<sup>60</sup>

Although its chances of ever reaching the consuming public are relatively slim, the risk of *E. coli* O157:H7 contamination remains an ever-present and growing threat to the nation's food supply.<sup>61</sup> According to a top food safety official in the California Department of Health Services ("CDHS"), contamination of fresh produce typically occurs on the farm level through one or more of the following channels: (1) irrigation water, (2) fertilization with manure, (3) access to wildlife and (4) farm worker hygiene.<sup>62</sup> Moreover, along with these potential environmental risk factors, the elusive strain of *E. coli* can also reach growing fields through accidental water runoff from nearby cattle ranches.<sup>63</sup> With several opportunities for contamination present across the rest of the fresh produce supply chain as well, people were beginning to wonder whether leafy greens and other produce items grown outdoors "[could] ever be rendered safe – as pathogen-free as, say, a glass of pasteurized milk."<sup>64</sup>

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58. See Marler Clark, *supra* note 28 (stating that *E. coli* could be isolated to 13.8 percent of beef cattle and 5.9 percent of dairy cattle); see also Planck, *supra* note 52 (stating "[U]p to 80 percent of dairy cattle carry O157").

59. See Nat'l Ass'n of State Pub. Health Veterinarians, Ctr. for Disease Control & Prevention, *Compendium of Measures to Prevent Disease Associated with Animals in Public Settings* (Mar. 25, 2005), <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5404a1.htm>; see also Agric. Research Serv., U.S. Dep't of Agric., *Targeting E. coli Infections at Their Source*, <http://www.ars.usda.gov/is/AR/archive/aug04/ecoli0804.htm?pf=1> (last visited Nov. 15, 2007) (As explained by one reputable microbiologist, Evelyn Dean-Nystrum, "In cattle, these bacteria almost always have no easily discernible effect. . . . That's a major reason why *E. coli* O157:H7 is hard to detect in them." While the ability to track this pathogen from its source would be much easier if the infected livestock exhibited symptoms of illness, this unfortunately is not the case. As a result, efforts aimed at containing this pathogen to its animal source are largely unsuccessful.).

60. Brackett, *supra* note 54 (As explained by Dr. Brackett, "[r]eady-to-eat fresh vegetables, fruits, and prepared salads have a high potential risk of contamination because they are generally grown in a natural environment (for example, a field or orchard).").

61. See Remarks, *supra* note 9.

62. Cal. Channel Broad., *supra* note 9 (statement of Dr. Kevin Reilly, Deputy Director for Prevention Services of the California Department of Health Services) (minute 14:40).

63. See generally J.G. Davis & P. Kendall, Colo. State Univ. Extension, Food and Nutrition Series: Food Safety No. 9.369, *Preventing E. coli From Garden to Plate*, (June 25, 2007), <http://www.ext.colostate.edu/Pubs/foodnut/09369.pdf>.

64. EcoliBlog.com, Anniversary of an Outbreak, <http://www.ecoliblog.com/2007/08/articles/e-coli-outbreaks/anniversary-of-an-outbreak/> (Aug. 14, 2007) (Unlike fresh produce industry, milk operations have a "kill step" (pasteurization) which eliminates any remaining pathogens.).

Seeking to avoid the transmission of this dangerous bacteria to the consuming public, growers and handlers of fresh produce, over the course of the last decade, have worked to reduce the incidence of contamination through their own food safety frameworks.

#### IV. THE FRESH PRODUCE INDUSTRY'S FOOD SAFETY FRAMEWORK PRIOR TO THE 2006 OUTBREAKS

Following the 2006 *E. coli* O157:H7 outbreaks linked to fresh spinach and lettuce grown in California, it became widely publicized that, in regards to food safety, the U.S. fresh produce industry was an entirely self-regulated entity.<sup>65</sup> Unlike beef, poultry or seafood, which have been subject to firm mandatory federal government controls since the early 1990s,<sup>66</sup> growers, processors, and shippers of fresh produce have successfully avoided food safety regulations on both the state and federal levels.<sup>67</sup>

Over the course of the past decade, voluntary food safety guidance documents have been the primary tools that the public and private sectors have utilized to reduce the risk of microbial contamination along the fresh produce supply chain.<sup>68</sup> The Western Growers Association,<sup>69</sup> in conjunction with the International Fresh Produce Association (IFPA) in 1998, issued the first set of food safety guidelines for the fresh produce industry.<sup>70</sup> These quality-control standards, collectively known as Good Agricultural Practices (GAPs), provided "general food safety guidance on critical production steps where food safety might be comprised during the growing, harvesting, transportation, cooling,

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65. Burros, *supra* note 42. See Anil K. Gupta & Lawrence J. Lad, *Industry Self-Regulation: An Economic, Organizational, and Political Analysis*, 8 ACAD. OF MGMT. REV. 416-25 (1983) (defining "industry self-regulation" as "a regulatory process whereby an industry-level, as opposed to a governmental – or firm – level, organization . . . sets and enforces rules and standards relating to the conduct of firms in the industry"), available at <http://www.jstor.org/view/03637425/ap010031/01a00060/0>.

66. See Douglas C. Michael, *Self-Regulation for Safety and Security: Final Minutes or Finest Hour?*, 36 SETON HALL L. REV. 1075, 1106 (2006).

67. See Burros, *supra* note 42 (noting that industry leaders have historically shifted the blame to household sanitary conditions).

68. See Cal. Dep't of Health Servs., Food & Drug Branch, Voluntary Guidelines for Control of Microbial Hazards, <http://www.dhs.ca.gov/ps/fdb/HTML/food/microguide.htm> (last visited Nov. 15, 2007).

69. Cary Blake, *Mandatory Food Safety Marketing Sought by Western Growers*, W. FARM PRESS, Dec. 1, 2006, available at <http://www.westernfarmpress.com/news/120106-food-safety/index.html> ("Western Growers' 2,601 members grow, pack and ship 90 percent of the fresh fruits, nuts, and vegetables in California . . .").

70. Cal. Dept. of Health Servs., *supra* note 68.

packing and storage of fresh produce.”<sup>71</sup> Following their release, the United States Food and Drug Administration (“FDA”) adopted these practices as the foundation for its first fresh produce guidance document titled: “The Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables.”<sup>72</sup> In the years that followed, these GAPs were increasingly tailored to specific fresh and fresh-cut produce items, such as leafy greens, that have been repeatedly implicated in foodborne illness outbreaks.<sup>73</sup>

However, despite the progress that has been made, the effective regulation of leafy green produce under the industry’s existing food safety framework proved to be an especially difficult task. One of the most glaring flaws in the regulatory system was that it did not require mandatory compliance with the available food safety guidelines.<sup>74</sup> As explained by one leading food safety expert, “[w]hile a grower or processor may chose to use the guidance one week, they could choose not to use it the next, and there’s nothing the government can do if the grower or processor chooses not to use the standards.”<sup>75</sup> United in agreement on this matter, lawmakers and industry representatives, in a move that seemed to signal the beginning of regulatory reform for fresh produce operations as a whole, set to work formulating a new mandatory food safety framework for California’s outbreak-prone leafy greens industry.<sup>76</sup>

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71. INT’L FRESH-CUT PRODUCE ASS’N ET AL, COMMODITY SPECIFIC FOOD SAFETY GUIDELINES FOR THE LETTUCE AND LEAFY GREENS SUPPLY CHAIN 1 (2006), <http://www.cfsan.fda.gov/~acrobat/letsup.pdf>.

72. Notice of Draft Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables, 63 Fed. Reg. 70 (Apr. 13, 1998), *available at* <http://www.cfsan.fda.gov/~lrd/fr980413.html>.

73. Compare INT’L FRESH-CUT PRODUCE ASS’N ET AL, *supra* note 71 with 63 Fed. Reg. 70, *supra* note 72.

74. See e.g., Western Growers Ass’n, Leafy Green Marketing Agreement and Marketing Order Frequently Asked Questions (Jan. 2, 2007), *available at* <http://caff.org/policy/documents/FAQfromWesternGrowers.pdf>.

75. Assoc. Press, *New Produce-Safety Rules Called ‘Unenforceable,’* MSNBC.COM, Mar. 12, 2007, <http://www.msnbc.msn.com/id/17582295/print/1/displaymode/1098/> quoting Caroline Smith DeWaal, Director of Food Safety at the Center for Science in the Public Interest).

76. Cal. Channel Broad., *supra* note 9; Video: Hearing Before the California Senate Select Committee on Food-Borne Illness (Cal. Channel Broad. Feb. 28, 2007) [hereinafter *Hearing Before the California Senate*], <http://www.calchannel.com/MEDIA/0228B.asx>. Author’s Note: Although the FDA has jurisdiction over produce sold in interstate commerce, the 2006 outbreaks were nationwide epidemics, and the United Fresh Produce Association (“UFPA”) has recently called for mandated federal regulation of fresh produce and leafy greens, there has been extensive study on the ineptitude of the FDA when it comes to regulating food safety. These criticisms range from the FDA’s poor food safety budget and manpower (in comparison to the United States Department of Agriculture (“USDA”), which is responsible for regulating meat and poultry), to its reluctance to regulate in the first place. As a result, it is clear that a federally mandated solution in the produce industry is not likely (at least not in the near future). The 2006 *E. coli* O157:H7 out-

## V. THE REGULATORY RESPONSE: TWO CONTRASTING FOOD SAFETY PROGRAMS

Following the recent string of *E. coli* O157:H7 outbreaks linked to California-grown leafy greens, the nation's attention turned and focused on two separate groups: (1) those responsible for causing the outbreaks, and (2) those responsible for protecting public health in these types of matters. As leafy green industry leaders and government officials came under added pressure to remedy this growing problem, two contrasting food safety proposals emerged. One came from Western Growers Association, the nation's largest agricultural trade association whose members grow, pack, and ship ninety percent of the fresh fruits and vegetables grown in California. The other proposal was authored by California State Senator Florez (D-Shafter), who chairs the California Senate Select Committee on Foodborne Illness. While Senator Florez's approach differed in many significant respects from the regulatory program devised by Western Growers,<sup>77</sup> its primary distinguishing feature was that it ultimately called on the California government, as opposed to the industry, to remedy this growing food safety problem.<sup>78</sup> Confronted with such an irreconcilable conflict, debate erupted as to which regulatory approach would better protect California's large supply of leafy greens against future *E. coli* O157:H7 contaminations.

A. *Government's Role in Reducing Foodborne Risks & California Senator Florez's Legislative Solution*

Protecting the food supply against threats has been a core function of government officials for more than two-thousand years.<sup>79</sup> It became an obligation of the U.S. government in 1906, when Congress passed the Pure Food and Drugs Act ("PFDA") and the Meat Inspection Act ("MIA").<sup>80</sup> Shortly thereafter, the importance of governmental oversight in matters of food safety was solidified when President Woodrow Wilson, during his 1913 Inaugural Address, acknowledged that "[t]he first duty of law is to keep sound the society it serves. Sanitary laws [and] pure food laws . . . are intimate parts of the very business of justice and legal efficiency."<sup>81</sup>

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breaks, although invoking discussion about the FDA's role, have stirred a unique debate between those on the state and industry levels who are more intimately connected to this crisis and have been the frontrunner of food safety reform in regards to California's leafy green produce.

77. Russo, *supra* note 8.

78. *Id.*

79. Richard A. Merrill & Jeffrey K. Francer, *Organizing Federal Food Safety Regulation*, 31 SETON HALL L. REV. 61, 64 (2000).

80. *Id.*

81. Wilson, *supra* note 1.

Since then, the government's role in protecting the safety of food has become more important than ever before. Along with its control of the meat-packing industry, the U.S. government has come to regulate food safety within the growing poultry and seafood industries as well.<sup>82</sup> As explained by Dan Glickman, Secretary of Agriculture under the Clinton Administration, "[f]ood safety is one area where people want strong government. It's the same with airplane safety, bank solvency and national security; people look to government to protect them in ways they cannot protect themselves, and cannot rely exclusively on the private sector to do it either."<sup>83</sup> As a natural result of this demand, the popular notion emerged that "[f]ood safety really is part of the basic contract now between the consumers of our country and their Government."<sup>84</sup>

With this strong record of federal government involvement in the regulation of food safety, the lethal multi-state outbreaks of *E. coli* O157:H7 in 2006 linked to California-grown spinach and lettuce provided officials with yet another opportunity to flex their regulatory muscles. However, no such flexion ever occurred. In fact, the only serious legislative proposal to materialize in the aftermath of this crisis came from Senator Florez, who firmly believed that a government-regulated solution was the only appropriate response.<sup>85</sup> Although his state-based approach would naturally lack the far-reaching effects of a federal legislative solution, it was, arguably, a very sound option because its scope, if enacted, would cover roughly three-quarters of the nation's supply of leafy greens. Furthermore, the fact that twenty-two outbreaks were linked to California-grown leafy greens seemed to lend credence to the notion that this is a state problem that could be remedied by an effective state legislative scheme. As a result, it appeared that, despite the lack of traditional federal involvement, this piece of state legislation would be able to provide the consuming public with the high level of

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82. Food Safety & Inspection Serv., U.S. Dep't of Agric., Agency History, [http://www.fsis.usda.gov/About\\_FSI/Agency\\_History/index.asp](http://www.fsis.usda.gov/About_FSI/Agency_History/index.asp) ("Congress passed the Poultry Products Inspection Act (PPIA) in 1957 in response to the rapidly expanding market for dressed, ready-to-cook poultry and processed poultry products.") (last visited Nov. 16, 2007).

83. Dan Glickman, Sec'y, U.S. Dep't of Agric., Remarks at the Kennedy School of Government, (Feb. 11, 1998) (transcript available at USDA, National News Releases, <http://www.usda.gov/news/releases/1998/02/0071>).

84. President Bill Clinton, Remarks Supporting Food Safety Legislation (Mar. 4, 1998), <http://www.clintonpresidentialcenter.org/legacy/030498-speech-by-president-at-food-safety-event.htm>.

85. Frank D. Russo, *California Should Not Wait for More Deaths from E. Coli Before Policing Leafy Greens Industry*, CAL. PROGRESS REP., Sept. 19, 2007, [http://www.californiaprogressreport.com/2007/09/california\\_shou\\_4.html](http://www.californiaprogressreport.com/2007/09/california_shou_4.html) ("In the end, it is government which is ultimately responsible for protecting the health of the public and which has proven itself the last line of defense between industry and consumers," Senator Florez said.).

government oversight they have come to expect and rely upon in matters of food safety.

On February 1, 2007, Senator Florez introduced a package of major food safety bills, titled "The California Produce Safety Action Plan," in the hopes of achieving a traditional government-based regulatory framework in the State's struggling leafy greens industry.<sup>86</sup> According to Senator Florez, this is a "food safety program that we can all stand behind that will ensure that California farmers are producing the most reliably safe product as possible."<sup>87</sup> As part of the legislative strategy, three bills (S.B. 200, 201, and 202) were introduced which sought food safety reforms throughout California's struggling leafy greens industry, with particular emphasis on its growing operations.<sup>88</sup>

The Senator's first bill, S.B. 200, was significant in that it vested control of managing future outbreaks with the CDHS, the state agency charged with protecting public health, and outlined a new inspection program that would send CDHS inspectors onto farms to conduct extensive review of their testing of water, soil, and leafy green vegetables.<sup>89</sup> The second measure, S.B. 201, called on the same state public health agency to adopt regulations implementing Hazard Analysis Critical Control Point (HACCP) programs for processors, and minimum GAPs for the more vulnerable growing operations.<sup>90</sup> While these quality-assurance practices on the farm level would not stray far from those followed under the industry's approach, the GAPs under this bill had more restrictive provisions, such as additional pathogen testing by growers and a detailed record-keeping requirement to monitor their compliance.<sup>91</sup> The third bill in the package, S.B. 202, called for an improved traceback system which "would allow DHS to quickly trace contaminated greens to their precise source, preventing a repeat of September when all spinach was suspect and all growers took the hit because consumers did not immediately know which produce they could trust."<sup>92</sup> These were the key elements of Senator Florez's legislative proposal, and the civil penalty for violating any provision or regulation of this act ranged from \$10,000 to \$25,000 in fines, plus any private right of action.<sup>93</sup>

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86. Russo, *supra* note 8.

87. Remarks, *supra* note 9.

88. Russo, *supra* note 8.

89. S.B. 200, 2007 Sess. (Cal. 2007); Russo, *supra* note 8 (The Bill provides powers, "such as allowing DHS to recall, quarantine, or destroy tainted produce.").

90. See S.B. 201, 2007 Sess. (Cal. 2007) (A.K. Kakamura testifies that most incidents of contamination occur on the farm level.).

91. Russo, *supra* note 8.

92. *Id.* See S.B. 202, 2007 Sess. (Cal. 2007).

93. S.B. 201, 2007 Sess. (Cal. 2007).

Before we turn to the tenets of Western Grower's regulatory approach, it is important to note the immediate advantages of Senator Florez's food safety framework. Although subject to some debate, most agree that a government-based solution, such as the one he proposed, would better address the crisis of consumer confidence in the state's leafy greens industry. Statistics show that the industry suffered \$100 million in losses due to reduced consumer sales in the months that followed the lethal 2006 spinach outbreak.<sup>94</sup> As noted above, the consuming public generally has a strong desire for government control in matters of food safety and, as a corollary, feels more secure when they know this oversight exists.<sup>95</sup> Another, more important advantage of Senator Florez's proposal was its ability to improve the safety of California-grown leafy greens simply by virtue of its legislative nature. If enacted into state law, the carefully crafted regulatory program would require compliance with baseline food safety standards from every last grower, packer, and shipper of leafy greens that operates intra-state.<sup>96</sup> To replace the current system of voluntary guidelines with such a mandatory framework would undoubtedly result in a more controlled and, therefore, safer leafy greens supply chain.<sup>97</sup>

Despite these obvious benefits, State Senator Florez's proposal suffered a near fatal blow exactly one month to the day after it was officially introduced.<sup>98</sup> On March 1, 2007, the Los Angeles Times announced California Governor Ar-

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94. See Thomas Nassif, President & CEO, W. Growers Ass'n, Written Testimony to U.S. Food & Drug Admin. Public Hearing on Safety of Fresh Produce (April 13, 2007), available at <http://www.fda.gov/OHRMS/DOCKETS/DOCKETS/07n0051/07n-0051-ts00009-Nassif-vol1.pdf>; see also Elisa Odabashian, Editorial, *California Needs New Laws to Protect Against E. coli Contamination in Leafy Green Vegetables*, CAL. PROGRESS REP., May 10, 2007, [http://www.californiaprogressreport.com/2007/05/california\\_need\\_2.html](http://www.californiaprogressreport.com/2007/05/california_need_2.html) ("According to the Food Marketing Institute's 'U.S. Grocery Shopper Trends, 2007' report, the number of consumers 'completely confident' or 'somewhat confident' in the safety of supermarket food declined from 82 percent in 2006 to 66 percent in 2007 – the lowest point since 1989. Seventy-one percent of respondents said they stopped buying spinach after last September's E. coli outbreak from tainted spinach. The survey was conducted in January 2007.").

95. See ConsumersUnion.org, About Consumers Union, <http://www.consumersunion.org/about/> (last visited Nov. 16, 2007) (The concept of the consuming public wanting strong government oversight in food safety matters is supported by the fact that the Consumers Union, an independent, non-profit, organization, "whose mission is to work for a fair, just, and safe marketplace for all consumers," was the sole proponent of Senator Florez's legislative proposal.).

96. Leafy Green Vegetable Crop Safety: Hearing on S.B. 201 Before the Cal. Assem. Comm. on Agric., 2007-2008 Sess. (2007), available at [http://info.sen.ca.gov/pub/07-08/bill/sen/sb\\_0201-0250/sb\\_201\\_cfa\\_20070716\\_113203\\_asm\\_comm.html](http://info.sen.ca.gov/pub/07-08/bill/sen/sb_0201-0250/sb_201_cfa_20070716_113203_asm_comm.html).

97. This would also have a corollary benefit to the industry because a safer food supply means less outbreaks, and less outbreaks naturally boosts consumer confidence.

98. See S.B. 200, 2007 Sess. (Cal. 2007); See also Marla Cone, *Gov. 's Stance an Obstacle for Spinach Safety Bills*, L.A. TIMES, March 1, 2007, at 1.



nold Schwarzenegger's opposition to this piece of legislation and indicated that he instead, "prefer[ed] an industry-regulated solution."<sup>99</sup> His spokesperson was quoted as saying, "[The Governor] believes the industry can police itself, because they have a very vested interest in ensuring their product is safe."<sup>100</sup> However, while Governor Schwarzenegger put his faith in the strength of market forces and endorsed Western Growers' proposal, he did not affirmatively indicate whether he would veto Senator Florez's package of bills if given the opportunity.<sup>101</sup> With this veto hanging in the balance, it was up to Western Growers to prove that its industry-run program was better than a traditional, government-based food safety framework.<sup>102</sup>

#### B. *Western Growers' Regulatory Proposal: A Tiered, Industry-Driven Approach*

On October 30, 2006, Western Growers issued the following press release, outlining its new regulatory strategy for enhancing the safety of California-grown leafy greens and regaining consumer confidence:

Western Growers today announced that it will take action to initiate a California Marketing Agreement and a Marketing Order that establish mandatory Good Agriculture Practices (GAP) that strengthen spinach and leafy green food safety procedures. The action by the Western Growers Board of Directors would also include the initiation of a federal marketing order to develop comprehensive and mandatory national spinach and leafy green food safety standards.

The effect of these actions, when completed, will be to impose enhanced and mandatory food safety processes on all aspects of growing, packing, processing, and shipping of spinach and leafy greens. Enforcement and process verification will be overseen by state and federal government regulatory agencies.<sup>103</sup>

In sharp contrast to Senator Florez's legislative solution, this leafy greens safety program called for a tiered, regulatory approach that was primarily industry-driven.

As set forth in its comprehensive proposal, Western Growers' initial efforts focused on the creation of a voluntary device known as a "marketing

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99. Cone, *supra* note 98.

100. *Id.*

101. *Id.*

102. See generally Russo, *supra* note 85. The status of Florez's legislation as of September 19, 2007 was as follows: "Florez has a package of legislation that has already passed the California Senate but is bottled up in the Assembly Agriculture Committee, just a few votes from going to the Governor."

103. Western Growers Ass'n, *supra* note 8.

112. Jim Prevor, *Marketing Agreement Signatories Account for Nearly 100% of Product*, JIM PREVOR'S PERISHABLE PUNDIT, Apr. 4, 2007, <http://www.perishablepundit.com/dailypundit/2007/april/Pundit070404-1.htm>.

with such impressive statistics, concerns about the potential effectiveness of industry's marketing-based approach were sure to lessen considerably.

However, what was most surprising about Western Growers' initial approach was not that it adopted a marketing agreement, but that it used this type of regulatory tool to improve food safety. Touted by the industry as "the first of its kind in the nation,"<sup>113</sup> the Leafy Greens Marketing Agreement was also subject to heavy scrutiny on the grounds that public health is too important a matter to be left to such an experimental program. Ordinarily, monetary gain is the primary motivating factor underlying an agricultural industry's decision to employ a marketing agreement.<sup>114</sup> As explained by one expert on the matter, "marketing agreements and orders have one major purpose – to improve the market power of producers [or handlers]. In most cases the objective is to stabilize marketing conditions, which will improve [handler's] income."<sup>115</sup> Aware of the economic benefits that can flow from voluntarily binding together, a significant number of California marketing agreements have been entered into over the years for this limited purpose.<sup>116</sup>

However, due to the Leafy Greens Marketing Agreement's near-perfect rate of participation and its provision mandating compliance with improved food safety procedures from signatory handlers and their growers, the notion that cooperative marketing agreements could only be used to facilitate private ends, such as monetary growth, began to fade rapidly. Assuming a role normally reserved for the public sector, Western Growers argued that its tiered, marketing-based approach would actually exceed Senator Florez's proposed legislation in terms of promoting public health.

One advantage of the industry's proposal was the speed at which its initial Marketing Agreement could be implemented.<sup>117</sup> As explained by a government official in the CDHS, "[m]arketing . . . agreements are the fastest way of

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113. Press Release, Western Growers Ass'n, Western Growers Applauds State Certification of Landmark Food Safety Marketing Agreement (Feb. 8, 2007), available at <http://www.wga.com/Portals/0/DocumentLibrary/RELEASE%20-%201-08-07%20P20214F.pdf> ("The Leafy Greens Marketing Agreement for food safety is the first of its kind in the nation.").

114. Wood, *supra* note 104, at 70.

115. *Id.*

116. See e.g., *id.* ("1. California Lemons. A program was established under state enabling legislation to improve the market power of lemon producers . . . . The program was successful in raising returns to lemon producers."). See Agric. Mktg. Serv., U.S. Dep't of Agric., *Small Business Guide for Complying with Marketing Agreements and Orders for Fruits, Vegetables and Specialty Crops*, <http://www.ams.usda.gov/fv/sm-bus-c.htm> (last visited Nov. 16, 2007) (A few state marketing-based programs driven by economic, not food safety, gains include: "Program No./ Commodity: 916 California nectarines, 917 California peaches, 920 California kiwifruit, 925 California desert grapes . . .").

117. Western Growers Ass'n, *supra* note 74.

implementing standardized, good agricultural practices . . . . It's the fastest way to reduce [the] risk now."<sup>118</sup> Unlike legislation, "which . . . takes a year to pass into law and an additional six months to develop implementing regulations," the industry's Marketing Agreement would give California handlers the immediate opportunity to bind together under a uniform set of safety standards.<sup>119</sup> The need to move quickly was particularly strong given the high rate of contamination that existed under the industry's failed system of voluntary guidelines.<sup>120</sup>

Although the industry's Marketing Agreement was vulnerable to criticism on the grounds that it failed to cover 100 percent of leafy greens grown in California, Western Growers was quick to note that its Agreement was only the first step, and that its regulatory scheme contained "several expanding layers of protection."<sup>121</sup> The next phase of regulation would include the implementation of a separate program known as a "marketing order" at both the state and federal levels.<sup>122</sup> As explained by Western Growers' President, Tom Nassif, "[t]he state and federal marketing orders [would] . . . put teeth into food safety practices and guidelines by making them mandatory and by imposing sanctions on those who do not follow those guidelines."<sup>123</sup> Therefore, unlike the industry's initial marketing-based approach, the subsequent "California Leafy Greens Marketing Order"<sup>124</sup> would demand compliance with the newly developed GAPs from one hundred percent of leafy green growers in the state, thus closing any food safety gap left by its voluntary predecessor.<sup>125</sup> The industry group went on to emphasize that a state marketing order could be implemented much quicker than a mandato-

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118. Akkad, *supra* note 106.

119. Western Growers Ass'n, *supra* note 74.

120. Nassif, *supra* note 94.

121. Cal. Channel Broad., *supra* note 9 (minute 1:14:30).

122. Western Growers Ass'n, *supra* note 74 ("A marketing order is [a state regulation] typically used by growers, [that] requires a super majority vote of growers to implement and, once the requisite vote it is obtained, is mandatory to all growers.").

123. Western Growers Ass'n, *supra* note 8.

124. Cal. Channel Broad., *supra* note 9 (statement of Jasper Hempel, Western Growers Executive Vice President and General Counsel, "[B]y April 1, [2007] is our goal" to begin implementation of the Marketing Order) (minute 1:48:50).

125. E-mail from Community Alliance with Family Farmers, to Community Alliance with Family Farmers Members (Jan. 17, 2007), *available at* [http://www.caff.org/policy/ActionAlert\\_leafygreen.shtml](http://www.caff.org/policy/ActionAlert_leafygreen.shtml) (Under the marketing order, "all growers of leafy greens in California would be subject to the order."); Western Growers Ass'n, *supra* note 74 (Implementation requires a positive vote from fifty-one percent of California growers who represent sixty-five percent of leafy green volume.). Since more than sixty percent of leafy green growers, representing more than ninety percent of the state's volume, would already be subject to the industry's new GAPs under the Marketing Agreement, it is almost guaranteed that they will vote 'yes' on the Marketing Order when given the opportunity – this would not subject them to any further regulation – thus resulting in its implementation across the growing industry.

ry legislative program,<sup>126</sup> and that its future federal marketing order would extend beyond the reach of Senator Florez's state-based proposal to require nationwide compliance with industry GAPs on "every farm, every time."<sup>127</sup>

### C. *Quality Assessment: The Newly Developed GAPs & Their Enforcement*

Although Western Growers' implementation of a mandatory Marketing Order would alleviate some of the concerns that surrounded its voluntary predecessor, criticism of the industry's proposal persisted, and Senator Florez remained steadfast in his belief that legislation was the proper remedy.<sup>128</sup> In the wake of these critiques, debate ensued over the core issues of any food safety plan: (1) the quality of the food safety standards, and (2) the quality of their enforcement.

#### 1. *Should the Creation of the new GAPs be Left to the California Government or to the State's Leafy Greens Industry?*

One of the most glaring distinctions between Western Growers' approach and the one proposed by Senator Florez concerned the rulemaking process by which the new, uniform GAPs would be created.<sup>129</sup> While Western Growers called on the industry to control the creation of these farm-level safety standards, Senator Florez disagreed and insisted that they be promulgated through normal government rulemaking procedures.<sup>130</sup> Faced with two sharply contrasting approaches, debate erupted over which approach would result in better quality leafy green safety standards.

As Western Growers' regulatory proposal was the first to emerge in the wake of the 2006 outbreaks, it was also the first to be criticized. In terms of its general industry-driven framework, Senator Florez and others argued that it was

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126. Western Growers Ass'n, *supra* note 74 (noting that legislation takes one year to pass into law and another six months to develop regulations, whereas mandatory marketing orders take "6 to 8 months to complete.")

127. Cal. Channel Broad., *supra* note 9 (statement of Jasper Hempel, Western Growers Executive Vice President and General Counsel) (minute 1:29:00).

128. Remarks, *supra* note 9.

129. E.J. Schultz, *Bills Take Aim at E. Coli*, THE SACRAMENTO BEE, Feb. 2, 2007, at A1 (Under the WGA plan, there would be "industry-developed best practices"); Remarks, *supra* note 9 (Under Senator Florez' plan, DHS will act as the gatekeeper and will be charged with the GAPs in the form of regulations.).

130. Remarks, *supra* note 9. See CAL. DEP'T OF FOOD & AGRIC., *supra* note 105, at art. II (A)(3) (detailing the administrative rule-making process through which Leafy Green Best Practices would be passed); Western Growers Ass'n, *supra* note 74 (pointing out the lengthy rule-making process).

unacceptable for the creation of the GAPs to be left to the same industry that had caused twenty-two food-borne illness outbreaks since 1995.<sup>131</sup> Such a poor performance history served as circumstantial evidence of the industry's inability to effectively regulate itself both in the past and into the future.<sup>132</sup> Another criticism of Western Growers' approach focused on "the insular, exclusive way in which these [new GAPs] were developed."<sup>133</sup> Under such a "closed door" approach, the quality of the GAPs were thought to be in jeopardy because the traditional safeguards inherent in administrative rulemaking procedures, such as forced consideration of public input, would not apply.<sup>134</sup> As a result, Senator Florez doubted the effectiveness of Western Growers' self-regulatory approach and touted it as nothing more than "the fox [guarding] the henhouse."<sup>135</sup>

Another objection raised by Senator Florez and his supporters focused on the framework of the ruling body, known as the "Leafy Green Advisory Board,"<sup>136</sup> which would be responsible for adopting the new GAPs that were to be implemented under the Western Growers' marketing-based approach.<sup>137</sup> As set forth in its initial Marketing Agreement, "the Board shall consist of no less than seven (7) and no more than thirteen (13) Signatory Handler members . . . [and the CDFA] may appoint one (1) member . . . to the Board to represent the general public."<sup>138</sup> Many objected to such an industry-dominated panel,<sup>139</sup> demanding increased transparency and representation from independent parties who would

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131. *California Hearings on E. coli Outbreaks Begin with Strong Statement from Senator Florez*, CAL. PROGRESS REP. Mar. 1, 2007, [http://www.californiaprogressreport.com/2007/03/California\\_sena\\_4.html](http://www.californiaprogressreport.com/2007/03/California_sena_4.html), [hereinafter *California Hearings*] (hearing available on the California Channel archive for Feb. 28, 2007).

132. See Russo, *supra* note 8.

133. Odabashian, *supra* note 23 (CDFA says it will take the advice of the industry on the best practices.).

134. *Id.*

135. Frank D. Russo, *Key Senator Lands Inclusion of Food Safety Funds in California State Budget After Deadly E. coli Outbreak, But Says Proposed Marketing Order "Leaves Fox Guarding the Hen House,"* CAL. PROGRESS REP., Jan. 10, 2007 [http://www.californiaprogressreport.com/2007/01/key\\_senator\\_lau.html](http://www.californiaprogressreport.com/2007/01/key_senator_lau.html).

136. See Western Growers Ass'n, *supra* note 74 (There would be a similar Board for the Marketing Order, made up of industry members as well.).

137. CAL. DEP'T OF FOOD & AGRIC., *supra* note 105, at 4.

138. *Id.* at 3.

139. Jim Prevor, *WGA's Food Safety Plan Gets Attacked*, JIM PREVOR'S PERISHABLE PUNDIT, Dec. 19, 2006, <http://www.perishablepundit.com/dailypundit/2006/December/pundit061219-1.htm> ("The solution [Western Growers] proposes calls for those same growers to run the board that decides, in the end, what best practices it will adopt. Who could have [drafted] this document? It is designed to offend.").

not be pressured by profit considerations to relax standards.<sup>140</sup> As for the one public member, several of the proposal's critics doubted whether a single vote from someone heavily influenced by industry opinion would actually make a difference.<sup>141</sup> Furthermore, Senator Florez and others adamantly objected to the fact that certain members of the Board, including its chairman, had been at one point investigated for sending tainted fresh produce to market.<sup>142</sup> In light of these problems, many condemned the self-regulatory framework of this ruling body and reiterated the need for increased transparency, public input, and government oversight.<sup>143</sup>

Mindful of these concerns, Senator Florez proposed a legislative solution that called on the CDHS to establish new GAPs which growers of leafy greens in the state would be required to follow.<sup>144</sup> Under this traditional rulemaking approach, the leafy green safety standards would be set, not by an entity motivated by profits and losses, but by representatives of the people who have an elected duty to keep the public's best interests at heart.<sup>145</sup> Another perceived benefit of vesting this important responsibility in a state administrative agency was that the new GAPs would be put through "notice and comment rulemaking" before they became effective.<sup>146</sup> Along with transparency requirements, "[t]his process has the beneficial effect of getting input from a wide range of sources and experts, some of whom may have been previously unknown to the drafters of the standard."<sup>147</sup>

As set forth in Western Growers' initial Marketing Agreement, the industry's new GAPs, known as "Leafy Green Best Practices,"<sup>148</sup> would be "prepared by industry scientists, and reviewed by state and federal agencies, scientifically peer reviewed by a nationally renowned science panel and adopted and/or

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140. *Id.*; Remarks, *supra* note 9 ("[F]ood safety mandates that the final decisions be made in the public arena by government, not privately in the back room of industry.").

141. Elisa Odabashian, *Consumer's Union Blasts "Marketing Agreement" Approach in California Senate Hearing on E. coli Contamination of Vegetables*, CAL. PROGRESS. REP., March 2, 2007, [http://www.californiaprogressreport.com/2007/03/consumers\\_union.html](http://www.californiaprogressreport.com/2007/03/consumers_union.html); Prevor, *supra* note 139.

142. Cone, *supra* note 98 ("[S]ome members have been sued or investigated for tainted produce.").

143. Remarks, *supra* note 9.

144. Marla Cone, *Legislation Seeks to Ban Risky Practices in Growing Leafy Greens*, L.A. TIMES, Feb. 1, 2007, at B4.

145. See generally Remarks, *supra* note 9 (Senator Florez asks, "[S]hould we trust an industry that has a financial interest to develop its own regulations . . . ?").

146. Administrative Procedures Act, 5 U.S.C. § 553 (2006).

147. Odabashian, *supra* note 141.

148. CAL. DEP'T OF FOOD & AGRIC., *supra* note 105, at 2 (Best Practices are the Industry's version of GAPs under the Marketing Agreement and Marketing Order.).

amended by the Board.”<sup>149</sup> Western Growers championed this industry-driven rulemaking process and insisted that the quality of the GAPs would suffer if their creation was left to the California government.<sup>150</sup> According to the industry group, the government’s main impediment to drafting effective standards was the fact that it “doesn’t understand [the leafy greens] industry or its practices.”<sup>151</sup> Contrast that with the industry itself, which is intimately connected to its own operations and has a greater amount of expertise in such matters.<sup>152</sup> Western Growers went on to note that, unlike an inflexible piece of legislation, the quality of the GAPs could be constantly improved upon under an industry-driven approach.<sup>153</sup> “As we get more science . . . the marketing agreement can be amended,” stated an industry official, adding, “[i]t can reflect the latest science, the latest data and the latest trends . . . . A law is very difficult to change.”<sup>154</sup>

Furthermore, Western Growers argued that there were adequate safeguards built into its rulemaking process that would protect against any of the weaknesses associated with self-regulation.<sup>155</sup> One of these safeguards was that the “Leafy Green Best Practices” would be subject to extensive independent review before being sent to the Board for adoption.<sup>156</sup> As explained by Western Growers, “We have engaged outside scientists to assist with these efforts and have held countless discussions with growers, processors, academics, regulators and others as we assembled and refined a baseline draft.”<sup>157</sup> Furthermore, in regards to the critiques launched against the Board, Western Growers assured the public that the industry-laden make-up of the panel would not be problematic because its primary duty was not to create the Best Practices, but only to adopt them.<sup>158</sup> In this capacity, the Board’s discretion was limited to determining whether these standards were capable of being verified by CDFA inspectors.<sup>159</sup>

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149. *Id.* See Western Growers Ass’n, *supra* note 74 (The rulemaking process will be the same under the Marketing Order, except that a different industry-heavy Board will adopt the standards. So, the standards created under the Marketing Agreement will be “identical” to those governing all California growers under the Order.).

150. Western Growers Ass’n, *supra* note 74.

151. *Id.*

152. *See id.*

153. *Id.* (stating that best practice metrics are “living, breathing, and ever changing”).

154. Akkad, *supra* note 106.

155. *See generally* Western Growers Ass’n, Good Agricultural Practices (GAPs), <http://www.wga.com/Home/ScienceTech/FoodSafety/DRAFTBestPracticesforLeafyGreen/tabid/250/Default.aspx> (last visited Nov. 17, 2007).

156. *Id.*

157. *Id.*

158. Cal. Channel Broad., *Hearing before the California Senate*, *supra* note 76 (minute 1:30:00-1:35:00).

159. *Id.*



For such a “ministerial task,” the industry insisted that independent parties need not be involved.<sup>160</sup> Thus, with such safeguards in place, Western Growers reiterated that it would not be hindered in its goal of creating the best quality GAPs possible.

## 2. *The Quality of the GAPs’ Enforcement*

Although Western Growers stated on numerous occasions that its newly developed GAPs were “mandatory”<sup>161</sup> for all California leafy green growers, Senator Florez and others criticized the industry’s use of this label and insisted that its approach remained largely self-regulatory, amounting to nothing more than “the fox [guarding] the henhouse.”<sup>162</sup> Unlike the legislative solution, which imposed civil penalties on growers for their violations, the industry’s approach was mandatory in the sense that handlers would only lose the use of the state certified seal-of-approval if their growers violated the new GAPs.<sup>163</sup> Senator Florez and his supporters argued that this penalty was not a strong enough deterrent, and that based on traditional definitions, Western Grower’s marketing-based approach was essentially just another voluntary scheme.<sup>164</sup> As explained by one notable consumer advocate, “[i]ndustry self-regulation seldom protects consumers and often provides industry with cover when contamination occurs.”<sup>165</sup> Although not a purely private self-regulatory effort, the industry’s approach, at the most, can be classified as “audited self-regulation.”<sup>166</sup>

Another concern with Western Growers’ food safety framework was that the newly developed GAPs would not be enforced on 100 percent of leafy greens grown in California.<sup>167</sup> Although more than ninety-nine percent of the state’s leafy greens volume would be covered by the Marketing Agreement, the fact that a handful of growers would evade regulation meant that the system of full-blown voluntary self-regulation, under which twenty-two outbreaks occurred, would

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160. *Id.*

161. Western Growers Ass’n, *supra* note 8.

162. Russo, *supra* note 135.

163. Editorial, *Growers Better than Feds for Safe Greens*, MONTEREY COUNTY HERALD, June 30, 2007, at A1.

164. Douglas C. Michael, *Federal Agency Use of Audited Self-Regulation as a Regulatory Technique*, 47 ADMIN. L. REV. 171, 173-74 (1995) (As opposed to “self-regulation,” “regulation” is defined as essentially “the altering of people’s behavior by the . . . government . . . accomplished by ‘the imposition of rules backed by the use of penalties.’”).

165. Odabashian, *supra* note 141.

166. Michael, *supra* note 164, at 173-74 (“‘Audited’ self-regulation” is defined as “the exercise of . . . delegated power, subject to review by a [government] agency.”).

167. Odabashian, *supra* note 23.

still apply to these sectors of the industry.<sup>168</sup> In an industry that is only as strong as its weakest link, and where a single error can destroy public desire for an entire food product,<sup>169</sup> it was feared that the voluntary agreement would leave “the door open for contaminated produce to reach consumers.”<sup>170</sup> As a result, Senator Florez introduced a legislative solution that called for mandatory, across-the-board enforcement at the very start of regulation.<sup>171</sup> Furthermore, critics of the industry’s proposal also expressed concern over the provision in the Marketing Agreement that stated that signatories may withdraw from the regulations at any time they please.<sup>172</sup> Thus, although the Agreement currently covers ninety-nine percent of California-grown leafy greens, that number may go down in the future as handlers decide their financial interests would be better served through non-compliance.

In response to these criticisms, Western Growers reiterated that the Marketing Agreement was only the first step in a multi-pronged scheme and that 100 percent of California leafy green growers would be covered by the forthcoming Marketing Order.<sup>173</sup> It noted that a solution that demanded 100 percent compliance from all leafy green growers and was unwilling to compromise would be unable to provide the “quick, decisive action” needed to begin remedying this serious food safety problem.<sup>174</sup> Also, in regards to the industry’s certification method, the industry argued that the potential loss of the seal-of-approval or “mark” for signatory handlers would be just as effective a deterrent as the threat of being imposed a civil penalty by the government.<sup>175</sup> According to Western Growers, as the consuming public became better educated about the meaning of the seal and began selecting their produce based on this quality-assurance stamp, handlers would be forced to participate in the Agreement (and thereby earn the right to use the seal) to avoid being put out of business.<sup>176</sup>

Another significant difference between Western Growers plan and the one proposed by Senator Florez was the specific state administrative agency in which the responsibility of enforcement was vested. While the latter vested enforcement of the Best Practices in the CDFA, Senator Florez’s legislative solu-

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168. *See id.*

169. *See generally* Michael, *supra* note 66, at 1075-76.

170. Odabashian, *supra* note 141.

171. *See* Russo, *supra* note 8; S.B. 200, 2007 Sess. (Cal. 2007) (This was his first bill, which called for an inspection program to make sure that GAPs were being enforced by the state on all leafy green growers.).

172. CAL. DEP’T OF FOOD & AGRIC., *supra* note 105, at art. XII, § B.

173. Western Growers Ass’n, *supra* note 74.

174. *Id.*

175. CAL. DEP’T OF FOOD & AGRIC., *supra* note 105.

176. Burros, *supra* note 42.

tion called on the CDHS to enforce its newly created GAPs.<sup>177</sup> Although this contrasting allocation of authority may appear to be a minor issue, in that they are both state government agencies, the Senator's action to allocate this authority in the CDHS was, in fact, an important strategic decision.

According to Senator Florez, his legislative proposal put enforcement power into the hands of the CDHS because it was his contention that the CDFA is "a tool of the [leafy green] industry."<sup>178</sup> Others agreed with this assessment and preferred an enforcer whose primary mission statement was not the "protection and promotion of the agriculture industry."<sup>179</sup> Consumer advocates were particularly concerned about government oversight (or the lack thereof) under Western Growers' plan, and insisted that it would amount to simple "rubber stamping" by the CDFA.<sup>180</sup> To substantiate her claim, the advocate cited the following statement by a CDFA official: "The roles of the marketing agreement/marketing order/CDFA inspection services division are verification and education, not environmental or health safety regulation (of leafy greens)."<sup>181</sup> This admission of the CDFA's true role was considered a "serious abdication of government's duty to safeguard the food supply and protect the public."<sup>182</sup> Senator Florez shared this concern and, as a result, preferred a government enforcer, the CDHS, whose primary mission was the protection of people.<sup>183</sup> In support of this decision, the Senator explained that CDHS, aside from being more motivated to protect public health, would also be given enforcement authority that would go above and beyond that granted to CDFA inspectors under the industry's approach.<sup>184</sup> For instance, while CDHS inspectors would be placed on the farms of California leafy green growers to monitor their compliance with all laws and regulations,

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177. See CAL. DEP'T OF FOOD & AGRIC., *supra* note 105, at art. III, § D.

178. Akkad, *supra* note 106.

179. Cal. Channel Broad., *Hearing Before the California Senate*, *supra* note 76 (statement from Senator Florez, Chairman, reading from a CDFA letterhead with this mission statement at the top) (minute 1:00:00 – 1:10:00).

180. Elisa Odabashian, Comments to California Senate Select Committee on Food-Borne Illness Public Informational Hearing on the California Department of Food and Agriculture's California Leafy Green Marketing Agreement (Feb. 28, 2007), available at [http://www.consumerunion.org/pub/core\\_food\\_safety/004283.html](http://www.consumerunion.org/pub/core_food_safety/004283.html).

181. *Id.*

182. *Id.*

183. Cal. Channel Broad., *Hearing Before the California Senate*, *supra* note 76 (statement from Senator Florez, Chairman, referring to DHS's health-focused mission statement) (minute 1:05:00 – 1:10:00); Cal. Dep't of Health Serv. Homepage, <http://www.dhs.ca.gov/> (last visited Nov. 17, 2007) (mission statement: "To Protect and Improve the Health of All Californians.").

184. See CAL. DEP'T OF FOOD & AGRIC., *supra* note 105, at art. V, § C (Signatory handlers and the leafy green farmers they buy from are "subject to periodic inspection" by the CDFA.).

they would also have the discretion "to conduct independent on-farm investigations, including testing of water, soil and produce as they deem necessary."<sup>185</sup> In the end, Senator Florez and others believed that his food safety plan would result in better government oversight and, therefore, a safer leafy green food supply.<sup>186</sup>

However, in the wake of these criticisms, representatives of the CDFA came forth to defend their reputation and rebut the allegations made by Senator Florez and his supporters.<sup>187</sup> Upon notifying the Senator during a public hearing that the California Marketing Act<sup>188</sup> would prevent the CDHS from acting as the enforcer in these types of marketing programs, the Secretary of the CDFA, A.G. Kawamura, went on to assure the committee that the CDFA's primary concern is the health and well-being of the consuming public.<sup>189</sup> He clarified the Senator's interpretation of the CDFA's mission statement, insisting that the "protection" aspect was in reference to "the consumer and the food supply they rely on."<sup>190</sup> Furthermore, at that same public hearing, CDFA Chief Counsel John Dyer, stated that while DHS would not be in charge of oversight, it would contribute to the effectiveness of the industry's food safety plan in other ways.<sup>191</sup> Apart from helping with the creation of the safety standards, Dyer explained that DHS would have a representative on a forthcoming "advisory board"<sup>192</sup> to help provide the industry with the "latest and best information and inspection standards."<sup>193</sup> Thus, the CDFA was confident that it would be able to provide the quality government oversight and enforcement needed to protect California's vulnerable supply of leafy greens.<sup>194</sup>

## VI. CONCLUSION

Whether it is the regulatory proposal adopted by Western Growers or the one set forth by Senator Florez that one believes is the better approach, one thing

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185. S.B. 200, 2007 Sess. (Cal. 2007).

186. *See id.*

187. Cal. Channel Broad., *Hearing Before the California Senate*, *supra* note 76 (minute 1:05:00 – 1:10:00).

188. *See* CAL. FOOD & AGRIC. CODE § 58745 (West 2007) (indicating that only "the Department" (CDFA) can enter into marketing programs with entities).

189. Cal. Channel Broad., *Hearing Before the California Senate*, *supra* note 76 (statement by A.G. Kawamura, "protection of the food supply . . . is one of our core competencies.") (minute 1:07:00 – 1:08:00).

190. Cal. Channel Broad., *Hearing Before the California Senate*, *supra* note 76.

191. *Id.* (statement of John Dyer, Chief Counsel, Cal. Dep't of Food & Agric.) (minute 1:05:00 – 1:10:00).

192. *Id.*

193. *Id.*

194. *Id.*

is certain: the ongoing debate between the Senator and the State's leafy green industry is certainly an interesting and necessary one. While it is true that Americans enjoy the safest food supply in the world,<sup>195</sup> *E. coli* O157:H7 is a foodborne pathogen that continues to haunt the consuming public on an all too often basis. Western Growers and Senator Florez both recognize this bleak reality and, in response, have designed new food safety proposals to better protect California's supply of leafy greens against such contamination. I encourage these industry leaders and government representatives to continue in their efforts to create an effective food safety system so that we can maybe, one day, have a leafy green and produce supply where contamination by *E. coli* O157:H7 and other foodborne pathogens is a thing of the past.

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195. MarlerBlog.com, *E. coli* Outbreaks Prompt Push for Stricter Regulation, (Jan. 21, 2007) <http://www.marlerblog.com/2007/01/articles/case-news/e-coli-outbreaks-prompt-push-for-stricter-regulation/>.