Bacteria and Bagged Salads:

Better Standards and Enforcement Needed

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Summary

A Consumers Union test of 208 packages of salad greens, funded by the Pew Health Group, found no evidence of three pathogenic bacteria (*E. coli* O157:H7, *Salmonella*, *and Listeria)* that, when present in food, have made people sick and, in some cases, killed them. However, Consumers Union did find other bacteria, called "indicator organisms" (generic *E. coli, Enterococcus*, total and fecal coliforms), that are found in the digestive tract of humans, other animals, and the environment, and that public health officials say indicate inadequate sanitation, fecal contamination, and the potential for the presence of pathogenic bacteria.

Although there are U.S. government standards for indicator organisms in milk, meat, drinking water, and even swimming water, there are no federal standards for these bacteria in salad greens. However, some 23 percent of the samples tested exhibited levels of *Enterococcus*, and 39 percent showed levels of total coliforms, that several industry experts deem unacceptable in bagged salad.

Consumers Union found that bagged salads that were closer to their "use-by" date tended to have somewhat higher levels of these bacteria. The tests found no significant differences between organic and non-organic greens. Bacteria levels varied enormously within the same brands, in some cases ranging from non-detectable to more than one million Colony Forming Units (CFU) or Most Probable Number (MPN) per gram (roughly comparable measures), suggesting more research and effort is needed within the industry to achieve consistently lower levels of contamination.

The U.S. Food and Drug Administration (FDA) should establish performance standards for these bacterial indicator organisms in all leafy greens as part of its on-going effort to propose regulations on produce safety by October 2010. FDA should also formally declare that the pathogenic bacteria—such as *E. coli* O157:H7 and *Salmonella*—will be considered adulterants when found in salad greens. Congress should immediately pass pending FDA food safety reform legislation that requires FDA to set performance standards for levels of bacteria in finished products, develop on-farm standards for growing of fresh produce, and inspect processors of high risk foods at least once a year.

Background

The bagged salad[1] industry has grown rapidly in the last 20 years. Earthbound Farms started selling ready-to-eat packaged organic salads in the San Francisco area in1986. In 1989, Fresh Express created the first mass-produced, ready-to-eat, bagged salad. From that point on, the fresh-cut, bagged salad industry took off, with sales currently close to $3 billion a year, according to industry experts, and with demand still increasing.[2] Two companies, Fresh Express (owned by Chiquita Brands) and Dole dominate the market, together accounting for close to three quarters of all sales. [3] Earthbound Farm, Ready Pac, and store brands account for the rest.

Consumers love the convenience of making salad simply by dumping a pre-washed bag of greens into a bowl. However, for more than a decade, experts and regulators have raised concerns about bacterial contamination of these bagged salads. Leafy greens can become contaminated at multiple points in the production-processing chain. Initially, the greens can become contaminated on the farm through contact with wild animals, manure, contaminated water, or unsanitary handling practices during harvest. Chlorine washes and other post-harvest treatments can help reduce surface contamination but they don't necessarily make contaminated products safe to eat, as foodborne pathogens can be internalized in plant tissue, thereby allowing contamination to remain even after thorough washing.[4]

In addition, bacteria can remain in the washing systems used to make "pre-washed" bagged salad, transferring dangerous bacteria from one contaminated lot to the next and potentially affecting a full day's production, or more. A 2007 study by university scientists in the U.S. and Canada that looked at 1,356 spinach samples from two packing

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[1] When we use the term "bagged salad" in this report, we are referring to some combination of "leafy greens" -- iceberg lettuce, romaine lettuce, leaf lettuce, butter lettuce, baby leaf lettuce (immature lettuce or leafy greens), escarole, endive, spring mix, spinach, cabbage, kale, arugula or chard — usually prewashed, either cut or un-cut, and sold in either a plastic bag or plastic container (called a "clamshell") or plastic bag packaged in a plastic container.

[2] ARS. 2008. Safe leafy greens—before and after bagging. *Agricultural Research*, July, 2008. At: http://www.ars.usda.gov/is/AR/archive/jul08/greens0708.htm

[3] Anon. 2005. State of the industry: mixed bag; Maturing fresh-cut salad sector growing, shifting. *Refrigerated and Frozen Foods.* At: http://www.allbusiness.com/wholesale-trade/merchant-wholesalers-nondurable/490721-1.html

[4] Foodborne pathogens can be internalized in the plant tissue of leafy greens in the pre-harvest stages, through plant roots, stomata, and bruises or cuts. See, e.g. Wachtel, M. R., L. C. Whitehand, , and R. E. Mandrell. 2002. Association of *Escherichia coli* O157:H7 with preharvest leaf lettuce upon exposure to contaminated irrigation water. J. Food Prot. 65:18-25. Of the pathogens studied, *E. coli* O157:H7 has exhibited greatest survival when internalized. *E. coli* O157:H7 may be transferred to the spinach (and by implication lettuce) leaf from the soil/root system during harvest, after which it is subjected to internalization at the cut, stomata, or bruises. See Warriner K, F.Ibrahim, M. Dickinson, C. Wright, and W. M. Waites. 2003. Interaction of *Escherichia coli* with growing salad spinach plants. J. Food Prot. 66:1790-1797.

plants found that the proportion of samples positive for total coliforms increased from 53 percent before the chlorine wash to 79 percent after the wash.[5]

The FDA, which is responsible for the safety of all fruits and vegetables, has been aware of the problems for many years. In November 2005, FDA sent a letter to California firms that grow, pack, process or ship leafy greens stating, "(FDA's) serious concern with the continuing outbreaks of foodborne illness," noting that since 1995, there had been 19 outbreaks of *E. coli* O157:H7 that implicated fresh or fresh-cut lettuce or spinach.[6] The Center for Science in the Public Interest, using data from the Center for Disease Control and Prevention (CDC) and other sources, recently published a report showing that, between 1990 and 2009, leafy greens were linked to 363 outbreaks involving 13,569 reported cases of illness[7].

A particularly serious outbreak of deadly *E. coli* O157:H7 in bagged spinach in 2006 led to hundreds of illnesses, 103 hospitalizations and 3 deaths,[8] and shut down the industry for weeks, leading to hundreds of millions of dollars of losses. The 2006 outbreak was ultimately traced to Dole brand Baby Spinach, bagged at a processing facility operated by National Selection Foods LLC, doing business as Earthbound Farm. The implicated greens were harvested from four different fields in the Salinas Valley (Monterey and San Benito counties), which is called "America's salad bowl" because some 80percent of the nation's lettuce is grown there.[9] Investigators found the same outbreak strain identified in the bagged spinach in river water, cattle feces, and wild pig feces on a neighboring ranch, which was slightly less than one mile from one of the spinach fields. However, the source of the pathogens will never be known with certainty.[10]

In the aftermath of this outbreak, the industry sought to address the problem of *Salmonella* and *E. coli O157:H7* through the California Leafy Greens Marketing Agreement (LGMA),[11] a voluntary self-regulatory program. In addition, individual processors have in some cases even gone beyond the LGMA provisions to require on-farm measures (called "super-metrics") that some sustainable agriculture advocates

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[5] Sanja, I, Odomeru, J and JT LeJeune. 2008. Coliforms and prevalence of *Escherichia coli* and foodborne pathogens on minimally processed spinach in two packing plants. *Journal of Food Protection*, 71(12): 2398-2403(6).

[6] http://www.fda.gov/Food/FoodSafety/Product-SpecificInformation/FruitsVegetablesJuices/GuidanceComplianceRegulatoryInformation/ucm118911.htm

[7] Klein, S, Witmer, J, Tian, A and CS DeWaal. 2009. *The Riskiest Foods Regulated by the US Food and Drug Administration.* Center for Science in the Public Interest. At: http://www.cspinet.org/new/pdf/cspi_top_10_fda.pdf

[8] California Food Emergency Response Team (CalFERT). 2007. Investigation of an *Escherichia coli* O157:H7 outbreak associated with Dole pre-packaged spinach. March 21, 2007. At: http://www.dhs.ca.gov/fdb/local/PDF/2006%20Spinach%20Report%20Final%20redacted%20no%20photosfigures.PDF

[9] 2008 statistic. See: http://www.salinaschamber.com/ag_industry.asp

[10] CalFERT 2007. Op cit.

[11] Commodity Specific Food Safety Guidelines for the Production and Harvest of Lettuce and Leafy Greens. June 13, 2009. At: http://www.wga.com/DocumentLibrary/scienceandtech/California%20GAPs%20-%20metrics%20071009.pdf

characterize as draconian and not based on sound science.[12] For example, some require the removal of all possible wildlife habitat from around growing fields. An environmental scientist with the Central Coast Regional Water Quality Review Board criticized demands to create 450-foot dirt buffers around fields, noting that they remove one of the chief means of preventing pollution from entering streams and rivers.[13]

Despite these voluntary efforts, there continue to be incidents of tainted leafy greens; most recently, loose spinach was recalled in September 2009 due to *Salmonella* contamination. The product, which was grown in Salinas Valley by a signatory to the LGMA, was distributed to 12 states and 3 provinces in Canada.[14]

Testing of Bagged Salads

In light of the 2006 outbreak and on-going concerns with contaminated leafy greens, consumers are left with lingering questions about the safety of bagged salad (and, in particular, spinach). To help assess the safety and cleanliness of bagged salads, Consumers Union (CU) undertook a research project, funded by The Pew Health Group, to test bagged salad for disease-causing bacteria (*Salmonella*, *E. coli* 0157:H7, and *Listeria monocytogenes*), as well as for commonly recognized indicator organisms (total coliforms, fecal coliforms, generic *E coli*, and *Enterococcus*) that are used to assess the efficacy of sanitation and signal conditions that could pose a potential public-health problem.[15]

CU shoppers purchased 208 bags and clamshells of leafy greens in the New York City metropolitan area (Westchester, Rockland, Orange, Dutchess, Putnam counties, the Bronx and Manhattan, in New York; Fairfield County in Connecticut; and Bergen County in New Jersey) during the eight days of August 24-27 and August 31-September 3, 2009. Shoppers were instructed to buy products that were as close to one day before their "use-by" dates as possible, from those available in the stores. Samples were immediately taken to CU headquarters in Yonkers in insulated boxes packaged with ice packs. They were shipped via UPS overnight delivery on the day of their purchase in insulated boxes that were kept at refrigerator temperature (with ice packs) for arrival and processing at an outside laboratory the next morning.

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[12] Lochhead, C. 2009. Crop ponds destroyed in quest for food safety. *San Francisco Chronicle*, July 13. At: http://articles.sfgate.com/2009-07-13/news/17218619_1_food-safety-cookie-dough-food-borne

[13] Ibid.

[14] http://www.fda.gov/Safety/Recalls/ucm182964.htm

[15] White, AS, Godard, RD, Belling, C, Kasza, V and RL Beach. 2010. Beverage obtained from soda fountain machines contains microorganisms, including coliform bacteria. *International Journal of Food Microbiology*, 137(1): 61-66.

Test Results for Pathogens

Given the relatively small number of samples we were able to test, it is no surprise that we found none of the three pathogenic bacteria (*E. coli* 0157:H7, *Salmonella*, *Listeria monocytogenes*) in our samples. These results were consistent with those from prior testing by the U.S. Department of Agriculture (USDA). In 2001, USDA began testing fresh produce for pathogens, particularly *E. coli* O157:H7 and *Salmonella*, as part of its Microbiological Data Program (MDP).[16] When USDA tested bagged lettuce in 2007, none of the 1,039 samples tested positive for *E. coli* O157:H7, and 6 were positive for *Salmonella.*[17] In 2008, USDA tested 2,078 samples of bagged lettuce and an additional 2,078 samples of fresh unwashed, and bagged prewashed spinach and got positive results for pathogens (*Salmonella*) in 25 samples of the lettuce and 4 samples of the spinach. USDA was able to determine the specific type of *Salmonella* for just two of these samples.[18] Given that the USDA found pathogens in approximately one in 140 samples in 2008, it was not surprising that we did not detect any major disease-causing organisms in this relatively small sample of 208 bags. Of course, had we found even a single positive, we would have contacted federal food safety authorities immediately.

Test Results for Indicator Organisms

Consumers Union also tested for four more types of bacteria: total coliforms, fecal coliforms, generic *E. coli*, and *Enterococcus*. These indicator bacteria are generally not pathogenic; they live in the digestive tract of many kinds of animals, including humans and persist in the environment. These bacteria are commonly used by public health practitioners as markers of poor sanitation and bacterial contamination from environmental sources like soil or from animal or human feces. Levels of these organisms are often used as an indirect measure of the potential for dangerous fecal pathogens to be present.[19]

The Food and Drug Administration, which has authority over the safety of leafy greens and all other produce items, has set no federal performance standards or bacterial limits for any indicator organisms in these commodities. Several industry experts we consulted suggested that for leafy greens, more than 10,000 colony-forming units per gram (CFU/gm) of *Enterococcus*, or more than 10,000 most probable number per gram (MPN/gm) of total coliforms are unacceptable levels. CU found that 39 percent of the

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[16] USDA. Quick Facts about MDP. http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELDEV3004399

[17] USDA/AMS. 2008. *Microbial Data Program: Progress Update and 2007 Data Summary.* At: http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5067866

[18] Table 10 in USDA/AMS. 2009. *Microbial Data Program: Progress Update and 2008 Data Summary*. At: http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5079908

[19] However, there is increasing evidence that *Enterococcus* may cause illness itself, especially in hospitals see Enterococcal infections at: http://emedicine.medscape.com/article/971259-overview

packages tested (82 of 208) exceeded that level for total coliforms and 23 percent (48 of 208) exceeded the suggested limit for *Enterococcus.*

Levels for these two indicator organisms varied widely in the bags and packages tested, from undetectable to more than one million CFU/gm or MPN/gm, for *Enterococcus* and total coliforms, respectively. No brands were immune from high levels: for every brand of which we tested at least four samples—including Dole, Fresh Express, Earthbound Farm Organic, and regional and store brands—at least one sample registered a relatively high level of one of these indicator organisms, e.g. more than 100,000 CFU/gm or MPN/gm. Indeed, 12.5 percent of the samples had total coliform counts that exceeded our upper limit of detection of 1 million MPN/gm; how much above the upper limit these sample are we do not know.

Though all brands with at least four tested samples had one or more packages with relatively high levels of bacteria, there were statistically significant differences in average levels among brands. The brand averages for total coliform levels ranged from $10^{2.5}$ for the lowest brand up to 10^{5} for the highest brand, and brand averages for *Enterococcus* levels ranged from $10^{2.1}$ for the lowest brand up to $10^{4.3}$ for the highest. Whether the greens were organic, came in a clamshell or a bag, or included "baby greens" made no statistically significant difference in the results. However, the packages with the higher bacteria levels did have a few similarities: many contained spinach, and many were within one to five days from the "use-by" date. By contrast, packages six to eight days from their "use-by" date fared better.

We know of two other research studies—by FDA and USDA—that have looked at the presence of indicator bacteria in bagged salads. The FDA study looked at 100 samples of bagged spinach or lettuce mixes purchased in the Washington, D.C. area in 2007. In general, the FDA found slightly higher levels of bacteria than Consumers Union. In the FDA study, 55 percent of the bagged mixes had total coliform counts that exceeded 10,000 MPN/gm (compared to 39 percent in the Consumers Union study) and 16 percent of the samples contained detectable generic *E. coli* (compared to 2.5 percent in the Consumers Union study). [20]

The USDA data come from the MDP, which tested 4,034 samples of bagged lettuce and bagged spinach for total coliforms in 2008. The USDA tests produced quite different results than the Consumers Union study, though given the substantial differences in the design of each study, differences are not surprising. The MDP data showed that only 0.8 percent (34 of 4,034) of the bagged samples had total coliform counts that exceeded 10,000 MPN/gm,[21] compared to 39 percent in the Consumers Union tests. The differing results could be accounted for by different sampling locations and sources (USDA's samples came from warehouses or distribution centers, whereas Consumers Union's came from retail), and sample make up, to name a few possibilities.

[20] Valentin-Bon, I, Jacobson, A, Monday, SR and PCH Feng. 2008. Microbiological quality of bagged cut spinach and lettuce mixes. *Applied and Environmental Microbiology*, 74(4): 1240-1242.
[21] See Table 9 in USDA/AMS 2009. Op cit.

Standards for Indicator Organisms in Other Countries and for Other Products

As noted above, there are no U.S. government standards for bacterial indicator organisms in packaged or loose leafy greens. However, such standards do exist in several other countries, and there are U.S. government standards for these bacteria in other food products and for water. The standards for other products are not necessarily applicable to greens, and the standards for greens from other countries do not necessarily apply to products at retail. However it is still informative to look at these existing standards[22] and compare them to the levels CU found in bagged salads. Government standards are summarized in Table 1; Consumers Union test results appear in Table 2. Such comparisons lead to the following observations:

- A number of samples tested by Consumers Union exceeded the legal limit for fecal coliform bacteria in ready to eat salads in Brazil and France. Some 5 percent (10 of 208) exceeded the Brazilian standards of 100 CFU/gm, while 2 percent (4 of 208) exceeded the French standard of 1000 CFU/gm.

- Three-quarters of the samples tested by Consumers Union exceeded the legal limit for total coliforms in ready to eat vegetable salads in Israel of 100CFU/gm.

- Some 16 percent (33 of 208) of samples tested contained fecal coliforms; the US EPA standard for fecal coliforms in drinking water is zero.

While the standards for leafy greens from other countries, or for water or other foods in the U.S., might not be appropriate for bagged salads, these other standards for indicator organisms do raise questions about why standards have not been established for bagged salads in the U.S. Such standards are needed to provide benchmarks for evaluating the adequacy of efforts to manage hygiene and bacteria.

It is also worth noting that some tested samples compared poorly even to standards for composted soil amendments, which one would expect to be significantly less strict than standards for food. Two percent (4 of 208) of samples were so contaminated with fecal coliforms that they would not be regarded as acceptable for use as soil amendments under the California Leafy Greens Marketing Agreement.

[22] The food standards are of the form of X number of bacteria (or colony forming units, e.g. CFUs) per gram. The water (either drinking or recreational) standards are of the form of X number of bacteria per 100 milliliters. Since for water, 1 gram equals 1 milliliter, a standard such as 500 bacteria per 100 milliliters (ml) would translate to 5 bacteria per gram (assuming the food has the same density/specific gravity as water). While this assumption may not be true for foods such as meat, the water content of lettuce and spinach are 96% and 92%, respectively (http://www.ca.uky.edu/enri/pubs/enri129.pdf). Thus the latter are roughly comparable. Also, there is an assumption that number of bacteria per unit measurement is roughly equivalent to CFUs per unit measurement.

Table 1: Government and Industry Standards for Bacterial Indicator Organisms in Selected Foods and in Water

Government/ Industry Body	Food/water regulated	Total coliforms	Fecal coliforms	Generic *E. coli*	*Entero-coccus*
Brazil	RTE salads		100 CFU/gm		
UK, Ireland	RTE salads			100 CFU/gm	
France	RTE salads		1,000 CFU/gm		
Germany	Salad vegetables			100 CFU/gm	
Switzerland	Leafy salad			10 CFU/gm	
Israel	Salad vegetables	100 CFU/gm			
USDA/AMS	Lean ground beef gov't purchases	500 CFU/gm		100 CFU/gm	
USDA/AMS	Graded pasteurized milk and dry milks (RTE)	10 CFU/gm			
USDA/AMS	Graded butter, cottage cheese, ice cream (RTE)	10 CFU/gm			
CA Dept. Food and Agriculture	Raw milk	10 CFU/gm			
Jack-in-the-Box	Ground beef			100 CFU/gm	
US EPA	recreational water - freshwater single sample				150 CFU/ 100 ml
US EPA	Drinking water		0 CFU/ 100 ml	0 CFU/ 100 ml	
CA Leafy Greens Marketing Agreement	Soil amendment		1,000 MPN/gm		

RTE = Ready To Eat. Compiled by Consumers Union (see footnotes 24-34)

NOTE: Colony Forming Units (CFU) and Most Probable Number (MPN) per gram are roughly comparable measures.

Table 2: Results of Consumers Union Tests of 208 Samples of Packaged Leafy Greens: Number of Samples with Each Level of Contamination

Level	Total Coliforms MPN/gram	Generic *E. coli* MPN/gm	*Enterococcus spp.* CFU/gm	Fecal Coliforms MPN/gm
< LOD	10	199	27	175
≥ LOD, ≤ 10^1	15	2	11	13
> 10^1, ≤ 10^2	26	3	20	10
> 10^2, ≤ 10^3	26	0	51	6
> 10^3, ≤ 10^4	49	0	51	4
> 10^4, ≤ 10^5	35	0	32	0
> 10^5, ≤ 10^6	21	0	12	0
> 10^6	26	0	4	0
Total	208	204	208	208

NOTE: Colony Forming Units (CFU) and Most Probable Number (MPN) per gram are roughly comparable measures.[23]
LOD = Limit of Detection, which is 3 CFU/gm and 3 MPN/gm.

We urge the FDA to develop performance standards for bagged salads that will provide safety and hygiene performance benchmarks. In order to establish standards that will be most effective in protecting consumers, FDA should take into account standards in other countries, and for other foodstuffs, as well as existing knowledge about relationships between production practices, environmental conditions, patterns of contamination, and growth of pathogens and indicator organisms.

Comparison to Standards for Bagged Salads in Other Countries

A number of different countries have fecal coliform standards for ready-to-eat salads and vegetables. In Brazil, the limit for minimally processed salads is 100 CFU/gm [24] (Table

[23] Massa, S, Grandi, M, Poda, G, Cesaroni, D, Cangamella, F and LD Trovatelli. 1989. Coliform detection from river waters: comparison between MPN and MF techniques. *Water, Air and Soil Pollution*, 43: 134-145. and Gronewold, AD and RL Wolpert. 2008. Modeling the relationship between most probable number (MPN) and colony-forming units (CFU) estimates of fecal coliform concentration. *Water Research*, 42(13): 3327-3334. At: http://www.stat.duke.edu/~rlw/mpn-cfu.pdf

[24] Fröder, H., Martins, CG, de Souza, KLO, Landgraf, M, Franco, BDGM and MT Destro. 2007. Minimally processed vegetable salads: microbial quality evaluation. *Journal of Food Protection*, 70(5): 1277-1280(4).

1). In France[25], the limit for ready-to-eat vegetables, including salads, is 1,000 CFU/gm. As shown in Table 2, 10 of the 208 samples Consumers Union tested (or 4.8 percent), exceeded the Brazilian standard, while 4 samples (or 1.9 percent) exceeded the French standard for fecal coliforms.

The U.K.,[26] Ireland[27] and Germany[28] have set a standard for generic *E. coli* in bagged salads at 100 CFU/gm. As shown in Table 2, Consumers Union found that five packages of leafy greens contained generic *E. coli*, but none at levels above the 100 CFU/gm limit. Switzerland[29] however, has a standard of 10 CFU/gm for generic *E. coli* for leafy salads. Three samples (1.5 percent) in the Consumers Union tests exceeded this limit.

Israel has set a standard for total coliforms in salad made from vegetable material with chili pepper of 100 CFU/gm.[30] As shown in Table 2, some 75 percent (157 of 208) of the samples Consumers Union tested exceeded the Israeli standard for total coliforms.

Comparison to U.S. Standards for Other Food Items

Various U.S. federal and state agencies have set total coliform standards for various food items, including lean ground beef patties[31], raw milk[32], pasteurized milk products, dry milk, butter, cottage cheese, and ice cream.[33]

As shown in Table 2, some 63 percent (131 of 208) of tested samples exceeded 1,000 CFU/gm of total coliforms, the USDA allowable limit for lean ground beef. An even larger percentage, 88 percent (183 of 208) of samples had more bacteria than would be allowed in California in raw milk, or that is allowed under the USDA standard of 10 CFU/gm for milk and other pasteurized dairy products.

Comparison to U.S. Standards for Drinking Water

The EPA Clean Water Drinking Act (CWDA) mandates bacterial standards for public drinking water and sets a "maximum contaminant level" (MCL) of zero for generic *E. coli* and fecal coliforms. If any sample tests positive for either generic *E. coli* or fecal

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[25] Nguyen-the, C and F Carlin. 1994. The microbiology of minimally processed fresh fruits and vegetables. *Critical Reviews in Food Science and Nutrition*, 34: 371-401.
[26] Gilbert, RJ et al. 2000. Guidelines for the microbiological quality of some ready-to-eat food sampled at point of sale. *Communicable Disease and Public Health*, 3: 163-167.
[27] Ibid.
[28] Lund, BM. 1993. The microbiological safety of prepared salad vegetables. *Food Technology International Europe*, pp. 196-200.
[29] See Table E-5 in Committee on Review of the Use of Scientific Criteria and Performance Standards for Safe Foods. 2003. *Scientific Criteria to Ensure Safe Food.* National Academy Press, Washington, D.C.
[30] Ibid.
[31] http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5066604
[32] CDFA. 2008. New coliform standard for milk sold raw to Consumer At: http://www.cdfa.ca.gov/AHFSS/Milk_and_Dairy_Food_Safety/pdfs/ColiformStandardMilkConsumedRaw.pdf
[33] See Table G-2 in Committee on Review of the Use of Scientific Criteria and Performance Standards for Safe Food. 2003. Op cit.

coliforms, this constitutes an acute violation and the public must be notified within 72 hours.

Some 2.5 percent (5 of 204) and 16 percent (33 of 208) of tested samples exceeded the zero-tolerance drinking water MCL for generic *E. coli* and fecal coliforms, respectively (Table 2).

Comparison to California Standard for Soil Amendments

The California Leafy Greens Marketing Initiative has published a number of standards/metrics[34]. For composted soil amendments containing animal manure or animal products, the level of fecal coliforms must be less than 1,000 MPN/gm. Some 1.9 percent (4 of 208) of our samples exceeded the 1,000 MPN/gm limit for composted animal manure and thus would be too contaminated to use as a soil amendment for companies that have signed on to the California Leafy Greens Marketing Initiative.

Recommendations

Congress is poised to enact comprehensive food-safety legislation for FDA- regulated products. The bill passed in the House and the one pending in the Senate as of January 2010 both include provisions requiring the FDA to develop safety standards for the growing and harvesting of produce, as well to set performance standards for "high-risk" foods. The bills also require FDA to inspect facilities producing the riskiest products (which will likely include bagged salads) at least once a year, and requires those facilities to prepare food safety plans. Specific direction to the agency in legislation would provide FDA with a clear mandate to better ensure the safety of fresh produce. The Senate should pass this legislation as soon as possible so that the two bills can be reconciled in conference and be signed by the President.

At the same time, FDA has already begun the process of developing produce safety regulations, and the agency has indicated that it plans to issue proposed regulations by October 2010. These on-farm safety standards for produce are likely to include measures aimed at possible sources of bacterial contamination (agricultural water, soil amendments, animals, and workers). FDA is also in the process of finalizing commodity-specific guidance on leafy greens.

While these are all good developments, FDA should take some additional steps to better ensure the safety of bagged salads and all leafy greens. First, FDA should officially declare that any known pathogens (including *Salmonella* and *E. coli* O157:H7) in leafy greens are "adulterants," thereby making contaminated products unfit for sale. Second, the agency should consider establishing performance standards for indicator organisms

[34] Commodity Specific Food Safety Guidelines for the Production and Harvest of Lettuce and Leafy Greens. June 13, 2009. At: http://www.wga.com/DocumentLibrary/scienceandtech/California%20GAPs%20-%20metrics%20071009.pdf

(such as fecal coliforms, total coliforms, generic *E. coli*, and *Enterococcus*) in leafy greens. It should also adopt standards limiting the bacteria load in wash water, as well as finished product standards for bagged salads.

In developing such standards, FDA should consider the indicator organisms and limits set by other countries. The United Kingdom, Ireland and Germany have selected generic *E. coli* as an indicator and set the limit at 100 CFU/gm for ready-to-eat leafy greens. Switzerland set their generic *E. coli* limit at 10 CFU/gm. France and Brazil have selected fecal coliforms and set limits of 1,000 CFU/gm and 100 CFU/gm, respectively. Israel has a standard for total coliforms of 100 CFU/gm in salads made from vegetables including chili pepper.

Leafy greens are an essential part of a healthy diet, and the popularity of bagged leafy greens attest to the valuable role they play in providing good nutrition to the public. Consumers deserve, however, to have bagged greens in their supermarkets that will not make them sick. Both FDA and the producers need to do more to insure that disease-causing bacteria are not present, and that bagged salads are a healthful product.