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Produce-associated foodborne disease outbreaks, USA, 1998–2013

S. D. Bennett, S. V. Sodha, T. L. Ayers, M. F. Lynch, L. H. Gould and R. V. Tauxe

Division of Foodborne, Waterborne, and Environmental Diseases, Centers for Disease Control and Prevention, Atlanta, GA, USA

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Author for correspondence:
S. D. Bennett, E-mail: iyk3@cdc.gov

Abstract

The US Food Safety Modernization Act (FSMA) gives food safety regulators increased authority to require implementation of safety measures to reduce the contamination of produce. To evaluate the future impact of FSMA on food safety, a better understanding is needed regarding outbreaks attributed to the consumption of raw produce. Data reported to the US Centers for Disease Control and Prevention's Foodborne Disease Outbreak Surveillance System during 1998–2013 were analysed. During 1998–2013, there were 972 raw produce outbreaks reported resulting in 34 674 outbreak-associated illnesses, 2315 hospitalisations, and 72 deaths. Overall, the total number of foodborne outbreaks reported decreased by 38% during the study period and the number of raw produce outbreaks decreased 19% during the same period; however, the percentage of outbreaks attributed to raw produce among outbreaks with a food reported increased from 8% during 1998–2001 to 16% during 2010–2013. Raw produce outbreaks were most commonly attributed to vegetable row crops (38% of outbreaks), fruits (35%) and seeded vegetables (11%). The most common aetiologic agents identified were norovirus (54% of outbreaks), *Salmonella enterica* (21%) and Shiga toxin-producing *Escherichia coli* (10%). Food-handling errors were reported in 39% of outbreaks. The proportion of all foodborne outbreaks attributable to raw produce has been increasing. Evaluation of safety measures to address the contamination on farms, during processing and food preparation, should take into account the trends occurring before FSMA implementation.

Introduction

Each year in the USA, millions become ill from eating contaminated foods and hundreds of foodborne outbreaks occur [1]. A previous review of foodborne outbreaks reported to the US Centers for Disease Control and Prevention (CDC) found that produce accounted for a growing proportion of outbreaks and outbreak-associated illnesses during the 1970s through the late 1990s [2]. In the recent years in the USA, produce has been a commonly reported source of foodborne outbreaks and surveillance reports suggest that produce may account for a higher proportion of multistate foodborne outbreaks compared with other food categories [3–9].

Because fruits and vegetables are recommended as key components of a healthy diet, ensuring the safety of these food items for consumers is imperative [10]. Strengthening safety measures in the production of fruits and vegetables is one focus of the Food Safety Modernization Act (FSMA), enacted in 2011 [11]. The final FSMA Rule *Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption* (hereafter referred to as produce safety rule) was published in 2015 [12]. However, the final rule provides staggered sets of compliance dates based on business size. Many of these dates have not yet passed and will occur in the next few years. In FSMA, the United States Congress directed the Food and Drug Administration (FDA) to promulgate standards for the safe production and harvesting of produce. The produce safety rule focuses on known safety risks, such as staff hygiene, microbial levels in agricultural water, use of animal waste in fields and equipment sanitation [12]. The annual occurrence of foodborne outbreaks attributed to raw produce may be useful in assessing the impact of FSMA activities. We reviewed raw produce-associated outbreaks reported to CDC during 1998–2013 to better understand the changes in the epidemiology of produce-associated outbreaks since the last major review and to describe the baseline before the implementation of FSMA.

Methods

A foodborne disease outbreak is defined as two or more similar illnesses resulting from the ingestion of a common food. State, local, territorial and tribal health departments voluntarily submit foodborne disease outbreak reports to CDC's Foodborne Disease Outbreak Surveillance System (FDOSS). Data requested for each outbreak include number of illnesses,

Table 1. Interagency Food Safety Analytics Collaboration food categorisation scheme[a]

Food category	Food subcategory (examples)
Vegetables	
Fungi	Fungi (button and portabella mushrooms)
Herbs	Herbs (basil, cilantro)
Root and underground vegetables	Root vegetables (beets, carrots)
	Tubers (potatoes, yams)
	Bulbs (garlic, onions)
	Other (ginger, taro)
Seeded vegetables	Vine-grown vegetables (cucumbers, squashes)
	Solanaceous vegetables (peppers, tomatoes)
	Legumes (lima beans, snow peas)
	Other (okra, sweet corns)
Sprouts	Sprouts (alfalfa and mung bean sprouts)
Vegetable row crops	Flowers (artichokes, broccoli)
	Stem vegetables (asparagus, celery)
	Leafy vegetables (lettuce, spinach)
Fruits	Melons (cantaloupes, watermelons)
	Pome fruits (apples, pears)
	Stone fruits (apricots, cherries)
	Small fruits (blueberries, strawberries)
	Tropical fruits (bananas, mangos)
	Subtropical fruits (avocados, oranges)

[a]Adapted from the Interagency Food Safety Analytics Collaboration, Food Categories with Examples, at: https://www.cdc.gov/foodsafety/pdfs/IFSAC_Food_Categories_examples-H.pdf (accessed 30 December 2016).

hospitalisations and deaths; patients' demographics; implicated foods; aetiologic agent; locations of food preparation; and results of traceback investigations. Multistate outbreaks are defined as outbreaks by the food consumed in more than one US state or territory.

We reviewed the reported foodborne disease outbreaks that occurred during 1998–2013 to identify the outbreaks attributed to the consumption of raw produce, hereafter referred to as 'raw produce outbreaks'. Variables and free-text fields that accompany outbreak reports were manually reviewed to exclude the outbreaks attributed to produce consumed after a major processing (e.g., canning, concentration or pasteurisation) or cooking step. For outbreaks with limited information about whether the food was processed or cooked, we independently reviewed the list of reported foods to determine whether it was likely eaten raw and excluded those outbreaks where the food was most likely processed or cooked before consumption (e.g. asparagus, eggplant or potatoes). Single raw produce items were classified using a standard classification scheme developed by the Interagency Food Safety Analytics Collaboration into one of seven categories and, for some, a few subcategories (Table 1) [13]. Outbreaks that implicated more than one raw produce item (e.g. multiple fruits or 'fruit salad', multiple vegetables or 'vegetable platter') were not further classified into one of the seven single produce categories; however, they were included in the analyses of all outbreaks attributed to raw produce.

We divided the data into four-year time periods: 1998–2001, 2002–2005, 2006–2009 and 2010–2013 to assess the changes over time. Seasonality was determined by assigning the outbreak to the month of first illness onset. Aetiologic agents were reported as confirmed if they met specific laboratory-confirmation criteria designated for each [14]. For outbreaks attributed to multiple aetiologic agents, outbreaks were reported as a confirmed aetiology if at least one reported aetiologic agent met the criteria. Otherwise, outbreaks were reported as a suspected aetiology if one or more aetiologic agents were reported, but none met the specified confirmation criteria. Contamination by an ill food worker was identified if the source of food contamination was reported to be a food worker, or handling (either bare or glove-handed) of food or another mode of contamination by a food worker was reported as a factor contributing to the occurrence of the outbreak. Analyses were performed using SAS version 9.3 (Cary, NC, USA) and Microsoft Excel 2007 (Redmond, WA, USA).

Results

During 1998–2013, there were 17 374 foodborne disease outbreaks resulting in 345 434 outbreak-associated illnesses, 13 005 hospitalisations and 298 deaths reported to CDC. A food was reported for 9422 (54%) outbreaks; 972 (10%) of these outbreaks were attributed to the consumption of raw produce. Over the study period, the total number of foodborne disease outbreaks decreased by 38% (Fig. 1a). During the same period, the number of raw produce outbreaks decreased by 19%, from 271 outbreaks during 1998–2001 to 220 during 2010–2013 (Fig. 1a and Table 2), while outbreaks caused by other foods decreased by 62%. Thus, raw produce outbreaks accounted for an increasing percentage of outbreaks with a food reported, from 8% during 1998–2001 to 16% during 2010–2013 (Fig. 1b).

Raw produce outbreaks resulted in 34 674 illnesses (10% of total foodborne disease outbreak-associated illnesses reported), 2315 hospitalisations (18%) and 72 deaths (24%) during 1998–2013. The median number of illnesses resulting from raw produce outbreaks was 15 (range 2–1500), compared with seven (2–1939) illnesses resulting from outbreaks not attributed to raw produce (Table 2). From 1998–2001 to 2010–2013, the total number of illnesses attributed to foodborne outbreaks decreased by 44% and those illnesses attributed to raw produce decreased by 49% (Supplementary Fig. S1). The percentage of outbreak-associated illnesses attributed to raw produce among outbreaks with a food reported did not change over time; in 2010–2013, raw produce outbreaks accounted for 19% of illnesses (Fig. 1b). The percentage of hospitalisations and deaths resulting from raw produce outbreaks among outbreaks with a food reported increased to 120% and 432% between 1998 and 2013, respectively. Sex was known for 24 473 (71%) outbreak-associated illnesses attributed to raw produce; 58% of illnesses occurred among women. Age was known for 19 646 (57%) of illnesses; 81% of illnesses occurred among those ⩾20 years of age.

Reported foods could be categorised into a single produce food category in 612 (63%) outbreaks (Table 3). Foods that could not be categorised ($n = 360$) were most commonly 'salad' (226

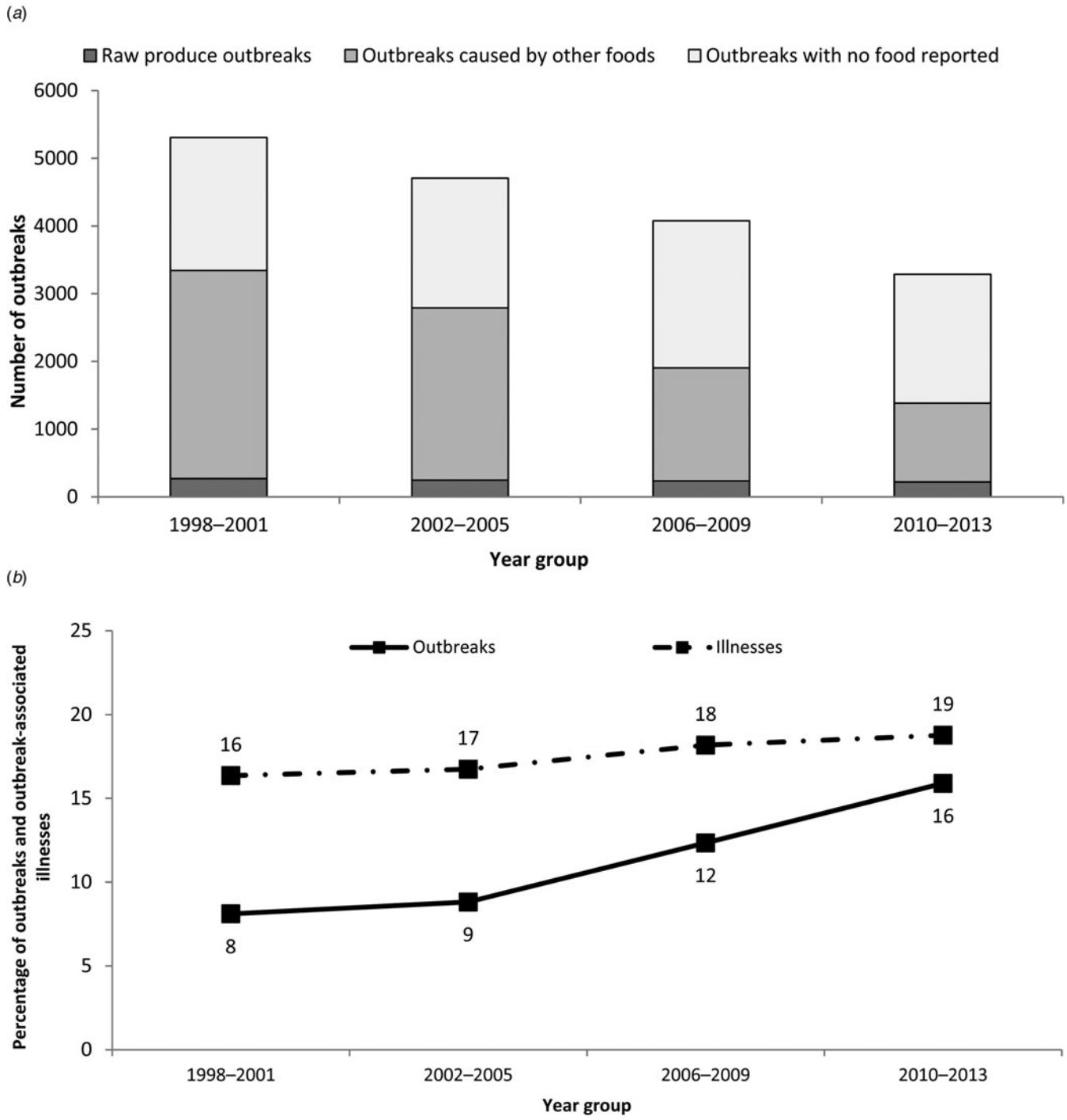

Fig. 1. (a) Number of foodborne disease outbreaks and number of outbreaks attributed to raw produce and other foods, USA, 1998–2013. (b) Percentage of raw produce outbreaks and illnesses among foodborne disease outbreaks with an implicated food, USA, 1998–2013.

outbreaks, 63%), Mexican-style dips or salsas (62, 17%) and mixed vegetables (57, 16%). The categories most commonly implicated in raw produce outbreaks were vegetable row crops (235 outbreaks, 38%), fruits (216, 35%) and seeded vegetables (66, 11%). These three categories also resulted in the greatest number of outbreak-associated illnesses, hospitalisations and deaths. Three subcategories (leafy vegetables, solanaceous vegetables and melons) were implicated in 52% of outbreaks (Table 3). The number of outbreaks attributed to vegetable row crops increased 25% by 2010–2013 compared with 1998–2001; outbreaks attributed to seeded vegetables also increased, by 122%, but the greatest increase occurred during the late 1990s and early 2000s (Table 2). Outbreaks attributed to fruits, root and underground vegetables, and herbs decreased during the study period. On average, outbreaks attributed to herbs resulted in the greatest number of illnesses (median number of illnesses reported per outbreak = 30), while those attributed to fungi were the smallest (median = 3 illnesses) (Table 2).

Table 2. Number of reported foodborne disease outbreaks and median number of outbreak-associated illnesses attributed to the consumption of raw produce, by category[a] and year group – Foodborne Disease Outbreak Surveillance System, USA, 1998–2013

Food category	1998–2001	2002–2005	2006–2009	2010–2013	Total
Vegetable row crops					
No. of outbreaks	52	57	61	65	235
Median no. of illnesses (range)	17 (3–300)	13 (2–935)	22 (2–238)	15 (2–94)	16 (2–935)
Fruits					
No. of outbreaks	73	38	51	54	216
Median no. of illnesses (range)	26 (2–736)	26 (2–212)	16 (2–594)	14 (2–261)	19 (2–736)
Seeded vegetables					
No. of outbreaks	9	21	16	20	66
Median no. of illnesses (range)	39 (10–886)	19 (2–510)	19 (2–1500)	26 (2–166)	23 (2–1500)
Sprouts					
No. of outbreaks	12	9	10	11	42
Median no. of illnesses (range)	36 (2–157)	15 (2–35)	20 (2–256)	20 (2–256)	20 (2–56)
Fungi					
No. of outbreaks	4	5	8	6	23
Median no. of illnesses (range)	3 (2–26)	4 (2–10)	3 (2–6)	3 (2–4)	3 (2–26)
Root and underground vegetables					
No. of outbreaks	8	4	5	1	18
Median no. of illnesses (range)	13 (2–96)	9 (6–136)	12 (5–31)	41 (N/A)	11 (2–136)
Herbs					
No. of outbreaks	7	3	1	1	12
Median no. of illnesses (range)	35 (8–486)	20 (13–592)	11 (N/A)	27 (N/A)	30 (8–592)
Total raw produce outbreaks					
No. of outbreaks	271	246	235	220	972
Median no. of illnesses (range)	19 (2–886)	15 (2–935)	15 (2–1500)	14 (2–261)	15 (2–1500)

No., number.
[a]Interagency Food Safety Analytics Collaboration (IFSAC) food categorisation scheme: https://www.cdc.gov/foodsafety/ifsac/projects/food-categorization-scheme.html.

A single confirmed or suspected aetiologic agent was identified in 778 (80%) outbreaks attributed to the consumption of fresh produce (572 confirmed and 206 suspected) (Table 4). Viruses were the most common aetiologic agents identified (439 outbreaks, 56%), followed by bacteria or their toxins (293, 38%). Overall, norovirus was most common (418 outbreaks, 54%), followed by *Salmonella enterica* (167, 21%) and Shiga toxin-producing *Escherichia coli* (STEC; 74, 10%). Among 161 *Salmonella* outbreaks with a reported serotype, Newport was most common (31 outbreaks, 19%), followed by Enteritidis (22, 14%) and Typhimurium (19, 12%) (Supplementary Table S1). Reported STEC serogroups were O157 (68 outbreaks, 92%), O26 (three, 4%), O145 (two, 3%) and O121 (one, 1%).

Among the 526 raw produce outbreaks with a reported aetiologic agent and a food that could be categorised, the aetiologic agent–food category pairs that resulted in the most outbreaks were norovirus in vegetable row crops (119 outbreaks, 23%), norovirus in fruits (93, 18%) and *S. enterica* in fruits (51, 10%) (Supplementary Table S2). The pairs that resulted in the most illnesses were *S. enterica* in seeded vegetables (4300 illnesses), norovirus in vegetable row crops (3478) and norovirus in fruits (3438).

Raw produce outbreaks were reported from 50 states, the District of Columbia and Puerto Rico. Multistate outbreaks accounted for 98 outbreaks (10% of all produce outbreaks) and 9733 illnesses. The number of reported multistate outbreaks nearly doubled from 19 outbreaks during 1998–2001 to 36 during 2010–2013. Most multistate raw produce outbreaks (95, 97%) were caused by bacterial pathogens. *Salmonella enterica* caused 67 (68%) outbreaks; the most commonly reported serotypes were Newport (14 outbreaks), Saintpaul (6) and Typhimurium (6). STEC caused 23 (23%) outbreaks; serogroups included O157 (19 outbreaks), O145 (two) and O26 (two). The remaining multistate outbreaks were caused by *Listeria monocytogenes* (three outbreaks), *Shigella sonnei* (two), hepatitis A virus (two) and *Cyclospora cayatenensis* (one). Vegetable row crops (28 outbreaks, 29%) were the most common food category reported, followed by fruits (25, 26%), sprouts (22, 22%), seeded vegetables (17, 17%) and herbs (two, 2%). Four multistate outbreaks were attributed to raw produce that could not be further classified; these foods included pre-packaged or bagged salad mixes (two outbreaks), salsa (one) and pre-packaged lettuce with grapes (one). The most commonly reported aetiologic agent–food category pairs were *S. enterica* in fruits

Table 3. Number and percentage of reported foodborne disease outbreaks, outbreak-associated illnesses, hospitalisations and deaths, attributed to the consumption of raw produce, by food category[a] – Foodborne Disease Outbreak Surveillance System, USA, 1998–2013

		Outbreaks		Illnesses		Hospitalisations		Deaths	
Food category[a,b]	Food subcategory[a,b]	No.	%	No.	%	No.	%	No.	%
Vegetable row crops		**235**	**38**	**7518**	**30**	**584**	**27**	**14**	**20**
	Leafy vegetables[c]	230	98	7411	99	571	98	9	64
	Stem vegetables	3	1	46	1	10	2	5	36
	Flowers	2	1	61	1	3	1	0	0
Fruits		**216**	**35**	**8676**	**34**	**604**	**28**	**47**	**66**
	Melons[d]	42	19	2949	34	420	70	43	91
	Small fruits	30	14	566	7	35	6	2	4
	Pome fruits	15	7	476	5	38	6	0	0
	Subtropical fruits	13	6	816	9	0	0	0	0
	Tropical fruits	8	4	396	5	47	8	0	0
	Stone fruits	2	1	19	0	1	0	0	0
	Not further categorised	106	49	3454	40	63	10	2	4
Seeded vegetables		**66**	**11**	**5854**	**23**	**718**	**34**	**5**	**7**
	Solanaceous vegetables[e]	47	71	5403	92	681	95	5	100
	Vine-grown vegetables	7	11	205	4	33	5	0	0
	Legumes	1	2	23	0	0	0	0	0
	Not further categorised	11	17	223	4	4	1	0	0
Sprouts[f]		**42**	**7**	**1434**	**6**	**137**	**6**	**2**	**3**
Fungi[g]		**23**	**4**	**106**	**0**	**52**	**2**	**3**	**4**
Root and underground vegetables		**18**	**3**	**505**	**2**	**18**	**1**	**0**	**0**
	Bulbs	9	50	161	32	7	39	0	0
	Root vegetables	7	39	333	66	7	39	0	0
	Not further categorised	2	11	11	2	0	0	0	0
Herbs[h]		**12**	**2**	**1362**	**5**	**15**	**1**	**0**	**0**
Food attributed to a single produce category[b]		**612**	**63**	**25 455**	**73**	**2128**	**92**	**71**	**99**
Food not attributed to a single produce category[b]		**360**	**37**	**9219**	**27**	**187**	**8**	**1**	**1**
Total		**972**	**100**	**34 674**	**100**	**2315**	**100**	**72**	**100**

No., number.
[a]Interagency Food Safety Analytics Collaboration (IFSAC) food categorisation scheme: https://www.cdc.gov/foodsafety/ifsac/projects/food-categorization-scheme.html.
[b]The denominator for the food category percentages is the 'food attributed to a single food category' total. The denominator for the 'food attributed to a single food category' and 'food not attributed to a single food category' percentages is the total. Denominators for the subcategories are their associated category total. Because of rounding, numbers might not add up to the total.
[c]Leafy vegetable types: romaine lettuce (20 outbreaks), leaf lettuce (15), iceberg lettuce (14), cabbage (nine), spinach (five), scallions and mesclun mix (four each), kale (two) and arugula (one); five outbreaks were caused by multiple types of leafy vegetables.
[d]Melon types: cantaloupes (19 outbreaks), watermelons (nine), mixed melon types (nine), honeydew (two); nine outbreaks were caused by more than one melon type.
[e]Solanaceous vegetable type: tomatoes (42 outbreaks) and peppers (three).
[f]Sprout type: alfalfa sprouts (24 outbreaks), clover and mung bean sprouts (five each), and bean sprouts (three).
[g]At least 14 raw fungi outbreaks (61%) were attributed to wild mushrooms.
[h]Herb type: cilantro (five outbreaks), basil (four) and parsley (three).

(24 outbreaks), STEC in vegetable row crops (20) and *S. enterica* in sprouts (18).

Raw produce outbreaks were reported throughout the year, but most commonly in April–July and in October (463 (48%) of raw produce outbreaks) (Fig. 2). Seasonal patterns were driven by the most common food categories; 50% of outbreaks attributed to vegetable row crops, fruits and seeded vegetables occurred during April–July and October (Fig. 2). In contrast, sprout outbreaks were reported more commonly in January–April (23 outbreaks, 55% of sprout outbreaks).

Food handlers were implicated in 377 (39%) of raw produce outbreaks. The most frequently reported errors were bare-handed contact by an ill food worker (193, 53%), glove-handed contact by an ill food worker (72, 20%) or other modes of contamination by an ill food worker (204, 56%). The most commonly reported aetiologic agent in outbreaks associated with food-handling errors

Table 4. Number and percentage of reported foodborne disease outbreaks, outbreak-associated illnesses, hospitalisations and deaths, attributed to the consumption of raw produce, by aetiology (confirmed or suspected)[a] – Foodborne Disease Outbreak Surveillance System, USA, 1998–2013

	No. of outbreaks				No. of illnesses				No. of hospitalisations				No. of deaths			
Aetiology	CE	SE	Total	%	CE	SE	Total	%	CE	SE	Total	%	CE	SE	Total	%
Bacterial																
Salmonella enterica[b]	161	6	167	21	10 373	29	10 402	33	1202	4	1206	53	15	0	15	21
Escherichia coli, Shiga toxin-producing[c]	72	2	74	10	2517	27	2544	8	570	10	580	26	12	0	12	17
Shigella[d]	17	0	17	2	2289	0	2289	7	46	0	46	2	1	0	1	1
Campylobacter[e]	13	3	16	2	653	24	677	2	17	0	17	1	0	0	0	0
Bacillus cereus	1	5	6	1	3	31	34	0	0	0	0	0	0	0	0	0
Listeria monocytogenes	4	0	4	1	183	0	183	1	173	0	173	8	39	0	39	54
Clostridium perfringens	1	2	3	0	190	51	241	1	0	0	0	0	0	0	0	0
Staphylococcus aureus enterotoxin	0	3	3	0	0	8	8	0	0	0	0	0	0	0	0	0
E. coli, Enteropathogenic	1	1	2	0	66	76	142	0	0	1	1	0	0	0	0	0
E. coli, Enterotoxigenic	1	0	1	0	58	0	58	0	0	0	0	0	0	0	0	0
Subtotal	**271**	**22**	**293**	**38**	**16 332**	**246**	**16 578**	**52**	**2008**	**15**	**2023**	**90**	**67**	**0**	**67**	**93**
Chemical and toxin																
Mycotoxins	15	3	18	2	78	10	88	0	41	10	51	2	2	1	3	4
Other – chemical/toxin	1	5	6	1	2	28	30	0	0	0	0	0	0	0	0	0
Heavy metals	1	0	1	0	21	0	21	0	0	0	0	0	0	0	0	0
Pesticides	1	0	1	0	14	0	14	0	2	0	2	0	0	0	0	0
Plant/herbal toxins	1	0	1	0	4	0	4	0	4	0	4	0	0	0	0	0
Subtotal	**19**	**8**	**27**	**3**	**119**	**38**	**157**	**0**	**47**	**10**	**57**	**3**	**2**	**1**	**3**	**4**
Parasitic																
Cyclospora	13	1	14	2	1067	8	1075	3	18	0	18	1	0	0	0	0
Cryptosporidium	4	0	4	1	166	0	166	1	4	0	4	0	0	0	0	0
Giardia	1	0	1	0	50	0	50	0	0	0	0	0	0	0	0	0
Subtotal	**18**	**1**	**19**	**2**	**1283**	**8**	**1291**	**4**	**22**	**0**	**22**	**1**	**0**	**0**	**0**	**0**
Viral																
Norovirus	250	168	418	54	9302	3260	12 562	39	69	41	110	5	2	0	2	3
Hepatitis A	14	0	14	2	1117	0	1117	4	48	0	48	2	0	0	0	0
Other viruses	0	7	7	1	0	156	156	0	0	0	0	0	0	0	0	0
Subtotal	**264**	**175**	**439**	**56**	**10 419**	**3416**	**13 835**	**43**	**117**	**41**	**158**	**7**	**2**	**0**	**2**	**3**

Single aetiology[f]	572	206	778	80	28 153	3708	31 861	92	2194	66	2260	98	71	1	72	100
Multiple aetiologies	3	10	13	1	244	156	400	1	14	2	16	1	0	0	0	0
Unknown aetiology[g]	–	–	181	19	–	–	2413	7	–	–	39	2	–	–	0	0
Total[f]	575	216	972	100	28 397	3864	34 674	100	2208	68	2315	101	71	1	72	100

No., number; CE, confirmed aetiology; SE, suspected aetiology.
[a]If at least one aetiology was laboratory-confirmed, the outbreak was considered to have a confirmed aetiology. If no aetiology was laboratory-confirmed, but an aetiology was reported based on clinical or epidemiologic features, the outbreak was considered to have a suspected aetiology.
[b]*Salmonella* serotypes causing more than five outbreaks were Newport (31 outbreaks), Enteritidis (22), Typhimurium (19, including one variant Copenhagen), Javiana (13), Saintpaul (12), Braenderup (six) and Muenchen (six); also see Supplementary Table S1.
[c]STEC serogroups O157 (68 outbreaks; 62 were H7, six were non-motile), O26 (3), O145 (2), O121 (1).
[d]*Shigella sonnei* (13), *Shigella flexneri* (two) and *Shigella boydii* (one); multiple species reported (one outbreak).
[e]*Campylobacter jejuni* (12 outbreaks) and *Campylobacter coli* (one); multiple species (one outbreak); unknown species (two outbreaks).
[f]The denominator for the aetiology percentages is the single aetiology total. The denominator for the single aetiology, multiple aetiologies and unknown aetiology is the total. Because of rounding, numbers might not add up to the single aetiology total or the total.
[g]An aetiologic agent was not confirmed or suspected based on clinical, laboratory or epidemiologic information

was norovirus (270, 82%); however, food-handling errors were reported in only 65% of raw produce outbreaks caused by norovirus. The most common food categories implicated were vegetable row crops and fruits, accounting for 188 (50%) of these outbreaks.

Discussion

During 1998–2013, both the number of reported foodborne disease outbreaks and those attributed to raw produce declined. However, raw produce outbreaks accounted for an increasing proportion of outbreaks in which a food was reported, representing 16% of outbreaks in our most recent data. Raw produce outbreaks caused a disproportionately higher number of hospitalisations and deaths compared with the outbreaks caused by other foods. This trend is similar to that observed in a summary of earlier produce outbreaks, though differences in methods make it difficult to directly compare these results [2]. Vegetable row crops, fruits, and seeded vegetables were the most common foods associated with raw produce outbreaks, and norovirus and *S. enterica* were the most common aetiologic agents implicated.

While efforts to reduce contamination of meat and shell eggs have led to a reduction in the contamination of these food types with *E. coli* O157, *L. monocytogenes* and *S. enterica* serotype Enteritidis, contamination of raw produce with these pathogens has resulted in a number of outbreaks each year attributed to the consumption of raw produce [15–17]. The increasing proportion of outbreaks attributed to raw produce might be related to changing consumer food preferences and practices, food production and distribution practices, or an increasing recognition that consumption of a variety of raw produce items can result in foodborne outbreaks. Also contributing to this trend are improvements to traceback methods that can implicate a single produce item among the many ingredients that are combined into more complex foods (e.g., tomatoes in salad or salsa) [2, 18]. Consumption of some fruits and vegetables increased during 1970–2005, but overall consumption has not changed significantly during the study period [19–22]. Increased consumption may not be accompanied by improved raw produce-handling practices. A food safety survey in 2010 documented different rates of washing fruits and vegetables depending upon the type of product, and found that washing was not always performed as per FDA recommendations [23]. The large number of outbreaks caused by norovirus, a human reservoir pathogen, suggest that poor food-handling practices during washing and food preparation may contribute to the occurrence of outbreaks associated with raw produce. For many pathogens, like *S. enterica* and *E. coli*, consumer washing may be of limited effectiveness because of the potential for internalisation of these pathogens [24–30].

Raw produce may become contaminated at many points along the farm-to-table continuum. In fields and packing houses, surfaces may become contaminated through contact with wild or domesticated animal faeces, contact with soil, irrigation water or splash from rain water that has been contaminated, contaminated water or equipment used during washing, application of chemicals, chilling, sorting, storage or packaging, or contaminated by hands of field or packing house workers [18, 31]. Further processing that cuts open the produce, such as slicing, dicing, shredding or peeling may result in cross-contamination through contaminated wash water, equipment and infected food handlers [2, 18, 31]. Once contaminated, pro-growth nutrients released during cutting, as well as time and temperature abuse during storage, may also

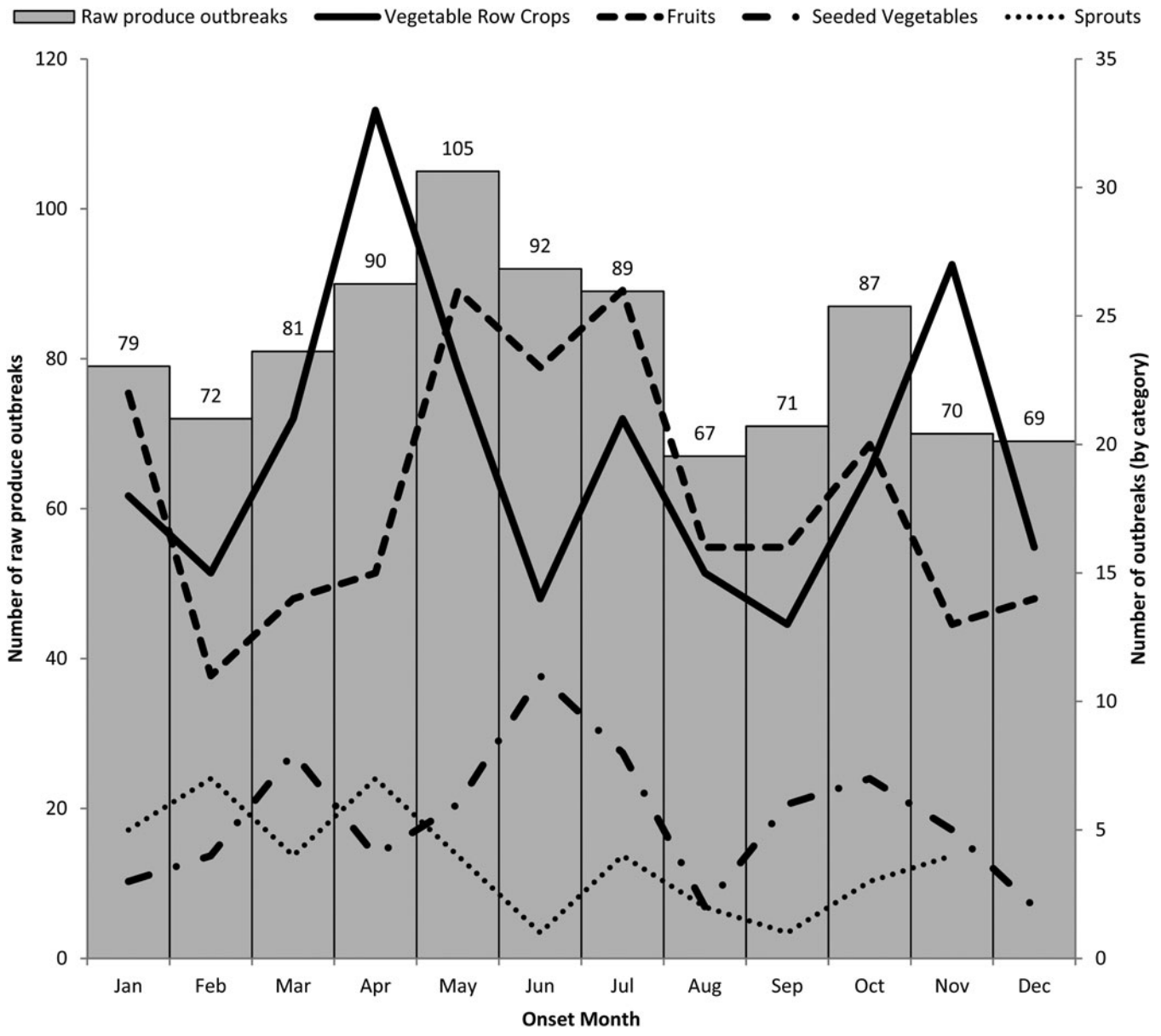

Fig. 2. Number of outbreaks attributed to raw produce by selected category and month, USA, 1998–2013.

result in the amplification of certain pathogen populations [2, 18, 31]. The lack of a pre-consumption kill step (e.g. cooking) and the difficulties food handlers and preparers face in washing or disinfecting produce served raw underscore the importance in promoting improved production and processing practices to reduce the contamination of raw produce products.

Even before the 2015 final FSMA produce safety rule was published, regulatory agencies and industries implemented multiple interventions to prevent contamination. For example, in 1999, the FDA published guidelines to help the sprouts industry achieve pathogen reduction on sprouted seeds and beans [32]. Increased awareness, education and adoption of these guidelines likely played a role in the decreased number of sprout-associated outbreaks during 2003–2007 [33]. In August 2006, FDA initiated the Lettuce Safety Initiative to help assess environmental factors that may contribute to *E. coli* O157:H7 contamination of leafy greens and the extent to which Good Agricultural Practices (GAPs) and other preventive controls are being implemented [34]. Soon after, large outbreaks of *E. coli* O157:H7 associated with spinach and lettuce occurred and the industry responded by approving the California Leafy Green Products Handler Marketing Agreement under the supervision of the California Department of Food and Agriculture [35]. This agreement makes the industry responsible for self-regulation and enforcement of best production practices. Modelled after the Leafy Greens Safety Initiative, FDA began the Tomato Safety Initiative in June 2007 with similar efforts to identify the environmental factors and agricultural practices that may lead to contamination [36]. Future studies will determine if the numbers and scopes of produce-associated outbreaks will change as a result of implementation of the produce safety rule.

While the occurrence of multistate outbreaks indicate contamination early in the farm to table chain, the large number of foodborne illness outbreaks associated with the consumption of raw

produce attributed to food handlers and the large number of outbreaks caused by norovirus, a human reservoir pathogen, suggests that contamination of implicated raw produce in these types of outbreaks may be occurring at the point of preparation and service. In addition to the FSMA produce safety rule, concurrent efforts to improve safe food-handling practices at points of preparation and service are needed to further reduce the occurrence of outbreaks associated with contaminated raw produce. Going forward, tracking these types of outbreaks by aetiology may offer some insight into the effect of efforts aimed at improving the safety of raw produce consumption. The FSMA produce safety rule may have a greater impact on reducing the contamination of raw produce by bacterial agents, while efforts aimed at the point-of-service may reduce the contamination of raw produce by viral agents.

This summary report has several limitations. The number of raw produce outbreaks may be underestimated as some outbreaks may be undetected, not investigated, or under-reported. It is difficult to directly compare the trends in reported outbreaks over time without understanding the systems used to collect the data. FDOSS is a passive surveillance system dependent upon voluntary reporting by local and state health departments. Over time, the systems used to report outbreaks transitioned from paper-based reporting (before 1998) to electronic web-based reporting resulting in an increase in the number of reported outbreaks. In 2009, CDC further enhanced the electronic system to allow reporting of outbreaks attributed to alternative modes of transmission (e.g. waterborne and person-to-person contact); this likely resulted in a decrease in the number of foodborne disease outbreaks reported thereafter, particularly among norovirus outbreaks, the most commonly reported aetiologic agent implicated in raw produce outbreaks [37]. Also, there may be increasing awareness of produce as a possible source of foodborne outbreaks caused by a variety of aetiologic agents. Misclassification of outbreaks as raw produce outbreaks is possible; the assignment of 'raw produce outbreak' relied on the data reported in multiple variables, free-text comment fields and required manual review by study authors. Finally, we were unable to determine the number of outbreaks associated with the raw produce imported from other countries limiting the conclusions on the impact FSMA will have on a safer produce production from international sources.

The proportion of all foodborne outbreaks attributable to raw produce has been increasing. Efforts focused on preventing contamination of produce along the farm-to-table continuum are being promoted as a result of the FSMA produce safety rule, which takes full effect over the next few years. Though various interventions within specific segments of the produce industry have been adopted and shown to be effective, additional research could help inform efforts to improve overall produce safety and meet the demand for safe fruits and vegetables. Ongoing reporting of foodborne outbreaks will provide an assessment of the effect these improvements have in protecting the health of the public.

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