#### **PEER-REVIEWED ARTICLE**

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### Survey of Environmental Monitoring Practices in Fresh Produce Packinghouses

#### ABSTRACT

Environmental Monitoring Programs (EMPs) have been historically implemented in processing facilities, with more recent application in raw agricultural commodity packing operations. EMPs verify effectiveness of sanitation programs and reduce harborage/niches of microorganisms. While benefits of EMPs are well recognized, there has not been a formal survey of produce packers adopting these programs to determine their scope, including information on sampling targets and frequency of sampling by environmental zone. Approximately 62.5% of produce packers (40/62 packinghouse; 5/10 field-pack) who responded to the survey indicated they had an EMP. ATP was the most common monitoring technique used for zone 1 surfaces, followed by generic Escherichia coli, Listeria species, and aerobic plate counts. A shift was noted towards addition and greater reliance on pathogen targets (e.g., Salmonella) for zones 2-4. While 100% of produce packers with an EMP had corrective actions (CA) identified, 42% reported never needing to implement a CA, suggesting produce packers were always in conformance. This result indicates a potential shortfall in EMP rigor, as occasional failures are expected. Overall, survey findings can be used as a baseline to assess changes in EMPs over time and to emphasize potential points of confusion when conducting outreach to the fresh produce industry.

#### **INTRODUCTION**

Unlike other food industries that have downstream processing activities that act as a "kill step" for foodborne pathogens, like cooking or pasteurization, there are limited opportunities for the fresh produce industry to employ activities that would achieve reductions in microorganisms of public health concern. In the absence of these control measures, fresh produce operations should implement food safety best practices, like sanitation programs, that reduce food safety risks by preventing cross-contamination. While cross-contamination of produce can occur at any point along the supply chain, outbreaks and recalls have been repeatedly traced back to cross-contamination in packing environments (*3*, *4*, *9*, *11*, *16–18*, *34*, *43*). In 2011, a multistate outbreak of

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listeriosis was traced to cantaloupes produced by a packer in Colorado (32). At least 146 persons from 28 U.S. states were infected with any of the four outbreak-associated strains of Listeria monocytogenes. The outbreak investigation highlighted a number of deficiencies related to food contact surfaces within the cantaloupe packinghouse (18). Of the 39 environmental swabs taken from the packinghouse, 13 were positive for the outbreak strain of L. monocytogenes, and 12 of those 13 positive swabs were from food contact surfaces. A year later, in 2012, a multistate outbreak of salmonellosis also linked to cantaloupe occurred and resulted in 261 illnesses, 94 hospitalizations, and 3 deaths in 24 U.S. states (33). Similar to the 2011 listeriosis outbreak investigation, FDA investigators determined that poor packinghouse sanitary design and sanitation programs contributed to the 2012 salmonellosis outbreak (37, 38). In 2019, whole peaches, nectarines, and plums were recalled due to L. monocytogenes being found in the packinghouse (44).

Environmental Monitoring Programs (EMPs) are a proactive approach to reduce microbial cross-contamination events. EMPs are designed to verify the effectiveness of the cleaning and sanitizing practices, ultimately preventing harborage of foodborne pathogens in the packing environment. Several prior studies have generated environmental data for produce environments throughout the supply chain including field packing lines, packinghouses, and distribution centers (7, 8, 12, 20, 22, 25, 45, 46). Data collected as part of an EMP may include source and concentration of indicators. EMPs vary by operation based on specific food safety program goals, but fundamentally EMPs should identify occurrences of potential contamination (e.g., pathogen harborage site, uncleaned food contact surface) and prompt implementation of a mitigation or control measure to reduce the likelihood of cross-contamination. If testing for foodborne pathogens like Listeria monocytogenes or Salmonella, or their closely related indicators (e.g., Listeria species), the goal of a successful EMP is to prevent repeated cross-contamination due to an established harborage point, ultimately alerting an operation to transient occurrences of an organism so that they can take prudent steps during cleaning, sanitizing, and retesting to document eradication. Successful food safety programs and EMPs trend data over time to determine which locations are more likely to have positive results or high populations, if there are certain weather conditions (e.g., rain, time of season) which are more likely to yield positive results, or if retraining needs to occur with the sanitation crew as employee turnover occurs which impacts knowledge and experience of those members (8, 20, 21, 23, 26, 47).

While not required by the Food Safety Modernization Act (FSMA): Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption (Produce Safety Rule, PSR) for fresh produce packers, environmental monitoring is a requirement in many third-party audit schemes relevant to fresh produce operations (19), including

those benchmarked to the Global Food Safety Initiative (GFSI), which require EMPs for microbiological hazards identified in the hazard analysis of the packinghouse (35, 36). Specific requirements of the EMPs vary by audit scheme, but the main goal for operations is to consistently control environmental hazards through sanitation programs, or corrective actions when necessary, and develop monitoring, verification, and validation activities for their packing environment using indicators or foodborne pathogens. It is important to consider that some produce facilities (e.g. fresh-cut) may fall under the FSMA Preventive Controls for Human Food Rule (39) which does require environmental monitoring as an approach for verification of sanitation controls in ready-to-eat foods that are at risk of environmental cross-contamination; however, these facilities were excluded from the study.

A nationwide anonymous survey of fresh produce packer practices was conducted to better understand (i) packers' knowledge of environmental monitoring requirements, (ii) the structure of EMPs in packing operations, and (iii) rationale for entities not implementing EMPs.

#### **METHODS**

Survey development and design. An anonymous questionnaire was developed by produce industry experts to determine how those involved in the packing of raw agricultural commodities conduct and maintain EMPs in their packinghouse environments (Supplemental Material 1). No identifying information was collected except self-identified demographics questions (Supplemental Material 1). The questionnaire was developed using the Qualtrics<sup>™</sup> software, Version June 2022 (Qualtrics, Provo, UT). The questions were beta-tested and reviewed prior to widespread dissemination by members of academia (authors and listed in acknowledgments), and members of the produce advisory committee representing growers, harvesters, packers, buyers, auditors, regulators, trade associations, legal counsel, consumer representatives, and consultants (5). The 28 questions were screened and approved by Virginia Tech's (#21-916), Rutgers University's (#Pro2021001482), University of Florida's (#202202794), and University of Georgia's (#PROJ-ECT00004712) Institutional Review Boards.

Survey dissemination. Email invitations containing a link to the online questionnaire in Qualtrics<sup>™</sup> were sent to proprietary email lists across produce safety organizations (Produce Safety Alliance, Western Growers Association, Center for Produce Safety, International Fresh Produce Association, Washington State Tree Fruit Association), USDA-funded FSMA centers (North Central Region Center for FSMA Training, Extension and Technical Assistance, Northeast Center to Advance Food Safety, Southern Center for FSMA Training, Outreach and Technical Assistance, Western Regional Center to Enhance Food Safety), social media platforms (Produce Safety Science, personal platforms

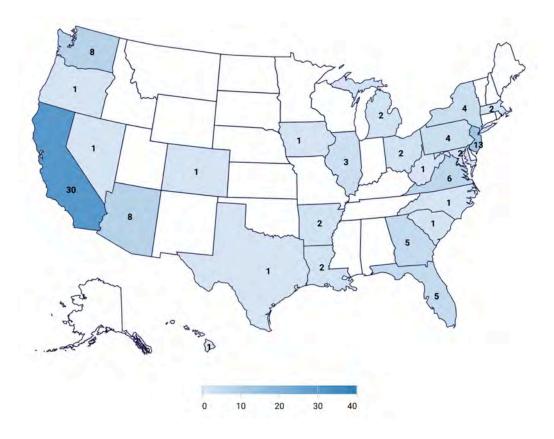


FIGURE 1. Map of survey respondents' operation location in the U.S. (N=107). N=3 respondents were outside the U.S., from Argentina, South Africa and Mexico (1 each). Blue to white shading indicates the number of respondents (legend bottom center) and counts (frequency of respondents) listed in black (no count indicates zero respondents).

of each author), local cooperative extension offices (Rutgers Cooperative Extension, University of Arizona Cooperative Extension, University of Florida Institute of Food and Agricultural Sciences Extension, University of Georgia Cooperative Extension, Virginia Cooperative Extension), and Produce Advisory Committee organizations (>30 members). The survey period (questionnaire open and accepting responses) was 81 days (June 13, 2022–September 1, 2022).

Statistical analysis. Response frequencies were calculated using Qualtrics<sup>™</sup> Stats iQ software, Version October 2022 (Qualtrics, Provo, UT) and Microsoft Excel (Microsoft, Redmond, WA) for each question. Descriptive statistics were used to determine frequencies and distribution of responses. Demographics including role in the industry, operation size, crop(s) packed, market channel, and operation location (e.g., state) were assessed to determine their association with EMP timing of sampling, frequency of sampling and corrective actions (*P*>0.05).

#### **RESULTS AND DISCUSSION**

**Survey respondents.** Data were collected from respondents which self identified they pack whole, intact produce and all questions were optional for each survey respondent. If a question did not apply to the respondent's

operation, they could skip the question (noted by the denominator). A total of 110 respondents completed the survey, 62 of which reported that they conduct packing activities in a packinghouse. Ten respondents reported they conduct field-packing activities and 38 respondents reported they did not conduct packing activities, instead identifying as university Cooperative Extension, upper management, buyers, or trade organization professionals. Respondents were from 25 U.S. states representing California (n=30), New Jersey (n=13), Arizona (n=8), Washington (n=8), Virginia (n=6), Florida (n=5), Georgia (n=5), New York (n=4), Pennsylvania (n=4), Illinois (n=3), Michigan (n=2), Ohio (n=2), Arkansas (n=2), Massachusetts (n=2), Maryland (n=2), Oregon (n=1), Nevada (n=1), Hawaii (n=1), Colorado (n=1), Texas (n=1), Iowa (n=1), North Carolina (n=1), South Carolina (n=1), and West Virginia (n=1), and 3 countries representing 1 each from Mexico, South Africa, and Argentina (Fig. 1). Respondents reported market channels with 46.4% selling wholesale, 26.8% exporting, 23.2% selling direct to consumers, and the remaining classified into "Other." Respondents reported sales in U.S. dollars in the following ranges: >\$5 million (45.8%), >\$1 million to \$5 million (16.6%), >\$25,000 to \$1 million (33.3%), and below \$25,000 (4.2%). A wide range of crops (n=59) were

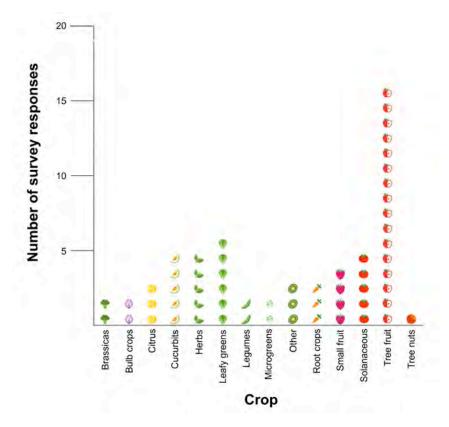


FIGURE 2. Fruit and vegetable crops packed as identified by survey respondents (n=59 different crops; survey respondents could select as many different crop types as they packed). Figure made with Food and Drinks Color Icons by Icon8

(https://speckyboy.com/freebie-colored-food-drink-icon-set/).

packed by respondents, some of whom packed multiple crops, including tree fruit (27.2%), leafy greens (10.2%), solanaceous (8.5%), cucurbits (8.5%), herbs (8.5%), small fruits (6.8%), citrus (5.1%), root crops (5.1%), bulb crops (3.4%), brassicas (3.4%), legumes (3.4%), microgreens (3.4%), tree nuts (1.7%), and other (5.1%; *Fig.* 2).

Environmental monitoring program rationale. Of those respondents who packed produce in a packinghouse, 64.5% (40/62) reported having an EMP. Fifty percent (5/10) of respondents who field-packed produce had an EMP. For packinghouses with an EMP, most packers cited regulatory requirements (66.7%) or buyer requirements (45.8%) as rationale for establishing the EMP. All respondents who field-packed produce had an EMP program because of buyer requirements, with two and one reporting regulatory requirements and part of risk mitigation efforts, respectively. This highlights a potential point of confusion and an outreach opportunity since there are not regulatory requirements of fresh produce packers who are covered under the Food Safety Modernization Act (FSMA) Produce Safety Rule to perform any environmental monitoring. While environmental testing for Listeria species or L. monocytogenes was proposed in 2013 as a requirement for all farms (comment 11, under general comments on the 2013

proposed FSMA Produce Safety Rule), it was ultimately not included in the final rule as a regulatory requirement (40). Farms may consider voluntarily implementing an environmental monitoring program for Listeria species or L. monocytogenes, as appropriate. Therefore, in the absence of regulatory requirements for environmental monitoring in raw agricultural commodity packing operations that are farms, federal draft guidance documents (41, 42) and industry-specific guidance, guidebooks, or whitepapers (1, 2, 30, 31) have been developed to support operations that want to develop and implement an EMP. As previously mentioned, some produce facilities (e.g. fresh-cut) may fall under the FSMA Preventive Controls for Human Food Rule (39) which does require environmental monitoring as an approach for verification of sanitation controls in ready-to-eat foods that are at risk of environmental cross-contamination, or to meet regulatory requirements of a country that is importing their produce. Outreach efforts should emphasize when EMPs are required for fresh produce operations based upon regulatory requirements (at time of this publication, the FDA had not released the final farm definition) and when EMPs are required by buyers based on various third-party audit standards. While buyer requirements impact ability to sell product, they are not regulatory requirements. Given

 TABLE 1. Percentage (frequency) of rapid test/chemical indictor, microbial indicator organisms, and foodborne pathogens tested for by zone in environmental monitoring programs for fresh produce packinghouses

Tested for <sup>a</sup>	Zone <sup>b</sup>							
	1 N = 57	2 N = 56	3 N = 54	4 N = 46				
Rapid Test/Chemical Indicator								
ATP	28.1 (16) °	8.9 (5)	5.6 (3)	6.5 (3)				
Microbial Indicator Organisms								
Aerobic plate count	15.8 (9)	10.7 (6)	7.4 (4)	8.7 (4)				
Enterobacteriaceae	1.8 (1)	0.0(0)	0.0 (0)	0.0 (0)				
Coliforms	10.5 (6)	12.5 (7)	11.1 (6)	13.0 (6)				
Generic E. coli	17.5 (10)	19.6 (11)	16.7 (9)	15.2 (7)				
Listeria species	15.8 (9)	25.0 (14)	31.5 (17)	34.8 (16)				
Foodborne Pathogens								
Listeria monocytogenes	1.8 (1)	7.1 (4)	9.3 (5)	6.5 (3)				
Salmonella	8.8 (5)	16.1 (9)	18.5 (10)	15.2 (7)				

<sup>a</sup>Respondent indicated what is tested for including rapid test/chemical indicator, microbial indicators, and or foodborne pathogens. <sup>b</sup>Zones were described according to United Fresh Environmental Monitoring Program Guidance Version 2 (30); and the N is the total number of responses per zone.

<sup>c</sup>Percentage (frequency).

that there are no regulatory requirements for EMPs for this segment of the supply chain (produce packers under the FSMA Produce Safety Rule) and yet 66.7% of respondents who have an EMP cite this as a rationale suggest several respondents are confused or misinformed on this point.

Among respondents that pack produce in a packinghouse that did not have an EMP (n=22), it was reported this was due to a lack of regulatory or buyer requirements or being cost prohibitive. Similar rationale for not having an EMP was observed for respondents that field-pack produce. Respondent data on EMP rationale did significantly differ by market channel (wholesale vs direct markets), but not operations of different sizes, crop packed, or state (P>0.05). This finding is likely linked to wholesale packers being subjected to buyer requirements including third party audits, compared to packers selling direct to consumers.

#### Sampling targets

Table 1 shows the frequency of environmental monitoring targets listed in surveys: aerobic plate count, total *Enterobacteriaceae*, coliforms, generic *E. coli*, *Listeria* species, *Listeria monocytogenes*, and *Salmonella enterica*, as well as adenosine triphosphate (ATP) broken down by zone (1–4). Zones were described according to United Fresh Environmental Monitoring Program Guidance Version 2 (30). ATP was the

most common monitoring technique used for zone 1 surfaces (28.1%; 16/57) followed by generic *E. coli* (17.5; 10/57), *Listeria* spp. (15.8%; 9/57), and aerobic plate count (15.8%; 9/57) (*Table 1*). Quantification of ATP has long been regarded as a real-time metric for evaluating sanitation of food contact surfaces, particularly for fresh produce operations (10, 14). This is due to the assertion that the presence of ATP is reliably linked to cell viability since ATP is an energy source present in all living organisms, including bacteria (*6*, 15, 27). While ATP is best used as a rapid screening tool for verification of an operation's sanitation (e.g., to ascertain if re-cleaning may need to occur prior to sanitizing), ATP concentration cannot be reliably linked to the presence of indicator organisms or foodborne pathogens (21, 28).

*Listeria* spp. (30.1%; 47/156), generic *E. coli* (17.3%; 27/156) and *Salmonella* (16.7%; 26/156) were the most frequently reported targets monitored for in zones 2 through 4 (*Table 1*). This result suggest a shift from monitoring ATP to microorganisms for non-food contact surfaces in packing operations. Furthermore, there was an increase in monitoring for foodborne pathogens in zones 2–4, compared to zone 1, with the highest monitoring frequency observed in zone 3 (9.30%; 5/54 and 18.5%; 10/54 for *L. monocytogenes* and *Salmonella*, respectively). Of note is the number of packinghouses monitoring for *Listeria* spp.

(15.8 to 34.8%) and *Salmonella* (8.80 to 18.5%) in zones 1-4, demonstrating a trend towards managing Listeria monocytogenes and Salmonella cross-contamination within the packinghouse, rather than general hygienic condition(s) of the building and equipment (*Table 1*). This trend aligns with the FSMA Preventive Controls for Human Foods Rule, as these two organisms were identified as the main source of cross-contamination in food facilities (39), and this may follow for fresh produce operations. Studies (7, 8, 24-26, 29) identified movement of *Listeria* from zone 4 into handling, packing, and storage areas as a key parameter driving Listeria prevalence in zones 1–3 for produce operations; in addition, to contamination rates on incoming produce, underscoring the importance of monitoring entry points into produce handling, packing and storage areas; as well as equipment that moves between zones 3 and 4. Similarly, industry developed guidance documents (1, 2, 30) also support monitoring of microorganisms in zones 2-4 to trigger corrections and prevent the likelihood of contamination of zone 1 surfaces.

#### Timing of sampling

Respondents were also asked when they collected environmental samples for environmental monitoring. Timing of sampling was not significantly associated with operations of different sizes, crop(s) packed, market channel, or state (P>0.05). Universally, it was reported that the timing of sample collection events for environmental monitoring programs in packing operations was post-sanitation/ pre-production. This trend was observed across zones 1 (66.7%; 14/21), 2 (60.1%; 14/23), 3 (56.5%; 13/23), and 4 (55.0%; 11/20). This finding aligns with current guidance by government and industry that suggests similar sampling timeframes (30, 42). There was a distinct trend of packinghouses opting not to collect samples during operational activities in zone 1 (76.2%; 16/21), compared to zones 2 (34.7%; 8/23), 3 (39.1%; 9/23), and 4 (35.0%; 7/20). Sampling after cleaning but prior to sanitizer application was reported for 23.8% (5/21) of respondents for zone 1, with all other zones reporting <10.0%. This is most likely driven by ATP swabbing and potential interference from sanitizers with that assay. Additionally, ATP swabbing is often performed as a cleaning verification step, prior to sanitizing, according to several guidance documents (1, 30) and published studies (13, 21) during produce handing and packing activities. Sampling at the end of production or in special circumstances (maintenance, interruption in operation) were far less frequently reported by respondents (<10.0%). Generally, these trends highlight that environmental monitoring programs in fresh produce packinghouses are being utilized to determine efficacy of sanitation activities and monitoring for routes of contamination during packing activities.

#### Frequency of sampling

No significant differences in sampling frequency were observed between operations of different sizes, crop(s) packed, market channel, or state (*P*>0.05); however, differences were observed between zones. For zone 1, most respondents were sampling weekly (36.0%; 9/25), followed by monthly (28.0%; 7/25) and daily (16%; 4/25) within the packing season. For zones 2, 3 and 4, the most popular sampling frequencies were monthly (zone 2: 42.3%; 11/26, zone 3: 38.5%; 10/26, and zone 4: 34.8%; 8/23, respectively), followed by weekly (zones 2: 38.5%; 10/26, zone 3: 23.1%; 6/26, and zone 4: 21.7%; 5/23, respectively). Zones 3 and 4 also observed quarterly sampling (15.4%; 4/26 and 21.7%; 5/23, respectively). As previously mentioned, the majority of respondents implemented an EMP because of their third-party audit standards, which likely impacted frequently of sampling. Several third-party audit standards require environmental monitoring on a weekly, monthly or quarterly schedules (U.S. Department of Agriculture, 2022). Less than 10% of respondents selected annual or bi-monthly sampling frequencies, and those that did, noted investigative sampling activities (e.g., root cause or research based sampling).

#### **Corrective actions**

Corrective action (CA) plans were in place for 100% (22/22) of EMP respondents for cases where quantifiable limits were above thresholds or where indicators or pathogens were present. However, 42% (9/21) of those respondents stated they had not implemented a CA over the past 12 months. This highlights a potential issue in rigor of testing programs, as transient organisms and natural variability that occurs during production will occasionally yield a failure to meet a quantifiable limit or detection of a foodborne pathogen or closely related indicator. Insufficient testing frequency, inappropriate sampling locations, or improper thresholds limits (e.g., too lenient) can all be potential sources impacting the success of the EMP. Several guidance documents (1, 2, 30, 31, 42) caution EMP programs that never find failures (detection of indicators/ pathogens, or threshold limit), as the goal of a successful EMP is to find problem areas before they lead to crosscontamination events.

*Table 2* describes the frequency of CAs by zone reported for survey respondents. Choices ranged from visual inspection, clean and sanitize as normal, intensified cleaning and sanitation, breakdown equipment and clean/ sanitize, vector swab adjacent locations, and re-swab, with respondents given the opportunity to select all the CAs by zone that they utilized. Across all zones 1–4, the top two CAs used were intensified cleaning and sanitation [22.4% (19/84) to 23.7% (14/59)] and re-swab the area [18.6% (11/59) to 22.6% (19/84)], respectively (*Table 2*). The least used CA across all zones was to clean and sanitize as normal [11.5% (10/87) to 14.3% (12/84)]. Respondents

## TABLE 2. Percentage (frequency) of corrective action(s) used by zone in environmental monitoring programs for fresh produce packinghouses

	Zone <sup>b</sup>				
Corrective Action(s) <sup>a</sup>	1 N = 84	2 N = 87	3 N = 85	4 N = 59	
Visual inspection	16.7 (14) °	14.9 (13)	15.3 (13)	13.6 (8)	
Clean and sanitize as normal	14.3 (12)	11.5 (10)	11.8 (10)	13.6 (8)	
Intensified cleaning and sanitation	22.6 (19)	23.0 (20)	22.4 (19)	23.7 (14)	
Breakdown equipment and clean/sanitize	14.3 (12)	16.1 (14)	15.3 (13)	15.3 (9)	
Vector swab adjacent locations	9.50 (8)	13.8 (12)	15.3 (13)	15.3 (9)	
Re-swab	22.6 (19)	20.7 (18)	20.0 (17)	18.6 (11)	

<sup>a</sup>Correction action(s) used if the environmental monitoring program target was out of compliance (e.g., *Listeria* spp. positive sample, ATP value exceeded threshold).

<sup>b</sup>Zones were described according to United Fresh Environmental Monitoring Program Guidance Version 2 (30); and the N is the total number of responses per zone.

<sup>c</sup>Percentage (frequency).

often selected multiple CAs within a zone, and across zone, highlighting packers are using multiple approaches simultaneously to alleviate issues as they arise. No significant differences in sampling frequency were observed between operations of different sizes, crop(s) packed, market channel, or state (P>0.05), demonstrating similar approaches being implemented by operations. Uniformity may exist across packing operations with CAs due to the development of guidance and informational documents or requirements of third-party audit standards (1, 30, 36, 47).

#### Limitations to the dataset

Respondents self-selected to participate in the study with question logic integrated so that questions could be skipped, limiting overall responses in some instances. Additionally, some respondents elected not to share certain demographic data. Both factors impacted the statistical power of this analysis by excluding those entries. Respondents also self-reported on all attributes as anonymous, so reported information could not be verified for accuracy. While the sample population of respondents may not be representative of the entire fresh produce industry, the dataset does provide baseline data and information to guide future EMP education, outreach, and extension efforts.

#### CONCLUSIONS

This survey sought to establish a baseline of information related to operations that pack whole, intact fresh produce who have implemented EMPs and to emphasize potential points of confusion when conducting outreach to the fresh produce industry. Approximately 62.5% of produce packers (40/62 packinghouse; 5/10 field-pack) who responded to the survey indicated they had an EMP. Of the respondents who had EMPs, these programs were in place primarily as a result of compliance with third-party audit standards and regulatory compliance. However, there was evident confusion about regulatory requirements for fresh produce operations handling, packing, and storing raw agricultural commodities (as operations under the FSMA Produce Safety Rule do not require environmental monitoring). Results found most of the EMPs focused on ATP for zone 1 surfaces, emphasizing its adoption by the produce packing industry for assessing cleanliness of food contact surfaces. While EMPs for zones 2–4 targeted primarily microbial indicator organisms (e.g., generic E. coli, Listeria spp., aerobic plate count), there was a trend towards monitoring for foodborne pathogens. Future outreach efforts should emphasize when EMPs are required for raw agricultural commodity produce operations, based upon regulatory requirements or third-party audit standards and the benefits of self-identifying problems through EMPs. Self-identifying problems can build a proactive food safety culture and help avoid unlikely consequences (e.g., outbreaks, recalls) across the industry.

#### SUPPLEMENTAL MATERIALS

Supplemental material for this article may be found at:

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# In Memory

IAFP was notified of the passing of member George Flick, Jr. The Association extends our deepest sympathy to his family and colleagues. IAFP has sincere gratitude for his contribution to food safety.