

## FSMA Best Practices:

### 7 Practical Food Safety Prevention and Traceability Tools

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## The Heart of the FSMA: Keeping People Safe

A recent outbreak of E.coli across 11 states, traced back to Chipotle restaurants, highlighted a growing concern over foodborne illness. A 2015 Morbidity and Mortality Weekly Report noted that “progress has been made in decreasing contamination of some foods and reducing illness caused by some pathogens. However, little or no recent reductions for most infections have occurred.”<sup>1</sup>



It is this lack of progress and the preventable human suffering due to foodborne illness that are the primary drivers behind the Food Safety Modernization Act (FSMA) rule. As demonstrated by the outcomes of several outbreaks over the past few years, it has become clear that food manufacturers will be held responsible for food safety. For example:

- Two Colorado farmers were sentenced to five years’ probation along with 100 hours of community service and were ordered to pay \$150,000 in restitution in 2014 in connection with the deaths of 33 people due to a listeriosis outbreak. The outbreak was traced back to contaminated cantaloupe.<sup>2</sup>
- Two former egg executives were sentenced to three months in jail along with \$6.8 million in fines in 2015 due to their company’s involvement in a salmonella outbreak resulting in at least 1,939 illnesses.<sup>3</sup>
- Several employees – including the owner – of the Peanut Corporation of America were sentenced to jail terms ranging from 3 to 28 years in 2015 for their involvement in a peanut butter-related salmonella outbreak linked to 9 deaths and 714 illnesses.<sup>4</sup>

Foodborne illness also represents a significant economic burden, due to hospitalizations, doctors’ office and emergency room visits, and lost productivity. According to a report by the

<sup>1</sup> Crim, S., et al. (2015). Preliminary incidence and trends of infections with pathogens transmitted commonly through food – foodborne diseases active surveillance network, 10 U.S. sites, 2006-2014. Retrieved from [http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6418a4.htm?s\\_cid=mm6418a4\\_w](http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6418a4.htm?s_cid=mm6418a4_w)

<sup>2</sup> Sanchez, R. (2014, 4 February), At sentencing, cantaloupe growers apologize for deadly listeria outbreak. *CNN*. Retrieved from <http://www.cnn.com/2014/01/28/justice/cantaloupe-listeria-deaths-sentencing/>.

<sup>3</sup> Newman, J. (2015, 13 April). Former egg executives receive three-month sentence. *Wall Street Journal*. Retrieved from <http://www.wsj.com/articles/former-egg-executives-receive-three-month-sentence-1428961984>.

<sup>4</sup> Dennis, B. (2015, 21 September). Former peanut executive sentenced to 28 years in prison. *The Washington Post*. Retrieved from [https://www.washingtonpost.com/national/health-science/former-peanut-executive-sentenced-to-28-years-in-prison-for-outbreak-that-killed-nine-people-sickened-hundreds/2015/09/21/aba7500e-60a7-11e5-8e9e-dce8a2a2a679\\_story.html](https://www.washingtonpost.com/national/health-science/former-peanut-executive-sentenced-to-28-years-in-prison-for-outbreak-that-killed-nine-people-sickened-hundreds/2015/09/21/aba7500e-60a7-11e5-8e9e-dce8a2a2a679_story.html).

United States Department of Agriculture (USDA), approximately 48 million people become ill from foodborne illnesses in the U.S. each year. Only 20% of those cases -- 9.4 million -- can be traced back to a specific pathogen. This small portion of cases represents an annual economic burden of \$15.5 billion. Moreover, \$13.95 billion is caused by just five pathogens.<sup>5</sup>

Recognizing that a reactive stance to food safety isn't enough, the U. S. Food and Drug Administration (FDA) developed the FSMA to establish preventive and traceability measures within the food manufacturing industry.

## Food Safety Prevention and Traceability: A Win/Win Approach for Consumers and the Supply Chain

For food manufacturers, new regulations can seem costly and time-intensive but the FSMA's focus on prevention and traceability can benefit everyone – consumers as well as food suppliers, producers and distributors.

### Protecting Your Loyal Customers

Consumers are becoming more astute about foodborne illnesses, with news stories about food recalls being shared across social media and popular news sites.

Establishing verifiable, valid food safety processes and methods keeps your products and brands out of the news and off the recall lists. As a result, your products are more attractive to informed consumers.

### Encouraging Risk Management

Food safety encourages risk management, which is simply a good business practice. Risk management ensures you're using objective methods to anticipate and mitigate risks that could lead to contaminated food product. Implementing preventive methods that will help you identify potential problems upstream in the manufacturing process means you can react sooner. The result is not just safer foods, but fewer recalls and fewer production halts while you trace a problem to its source.

**“The FDA Food Safety Modernization Act squarely puts in place the public health principle of prevention as the foundation of all our food safety efforts.”**

-Dr. Kathleen F. Gensheimer, M.D., M.P.H.  
Chief Medical Officer, Outbreak Director  
Food and Drug Administration

<sup>5</sup> Hoffman, S., Macculloch, B., & Batz, M. (2015). Economic burden of major foodborne illnesses acquired in the United States. *Economic Information Bulletin*, 140. Retrieved from <http://www.ers.usda.gov/media/1837791/eib140.pdf>.

## Improving Efficiency and Quality as a Result of Food Safety

One of the FSMA's key preventive methods is process control, which helps you ensure your processes result in safe food products. But process control data can also help you uncover inefficient processes that, once corrected, not only result in safe food for consumers but improved productivity and process yield. By expanding your food safety and quality program to your suppliers, you can control for potential hazards before raw ingredients leave your suppliers' facilities, ensuring that ingredients are ready to use when they enter your facility.

### Quantified Benefits across the Supply Chain

In support of the FSMA, the FDA authorized the Institute of Food Technologists (IFT) to conduct two pilot programs that traced foods from restaurants to suppliers. In their report, IFT researchers identified supply chain benefits due to improved traceability methods, as demonstrated by the table below.

Clearly, traceability methods alone can result in outcomes that benefit food manufacturers by improving process efficiency and product quality, resulting in an expanded consumer base. These outcomes will no doubt improve with the addition of preventive measures. In short, compliance with the FSMA is a win/win proposition for the consumer and the producer.<sup>6</sup>

**Table 1. Benefits of Recordkeeping Identified by % Pilot Participants**

Recordkeeping Benefits	Growers (n=2)	Processor (n=6)	Distributors (n=8)	Retailers (n=4)
Improved Brand Reputation	100%	33%	62%	50%
Increased Consumer Confidence	0%	67%	75%	25%
Expanded Markets	50%	33%	50%	25%
Improved Supply Chain Management	50%	67%	62%	100%
Insurance Cost Reduction	50%	33%	12%	0%
Supply Chain Confidence	0%	83%	75%	25%
Decreased Spoilage	50%	67%	75%	25%
Process Improvement	100%	33%	100%	100%

\*If the response to an individual benefit was left blank, it was treated as a "does not identify this benefit" answer in the calculations above. (Percent of Pilot Participants Identifying the Recordkeeping Benefit)

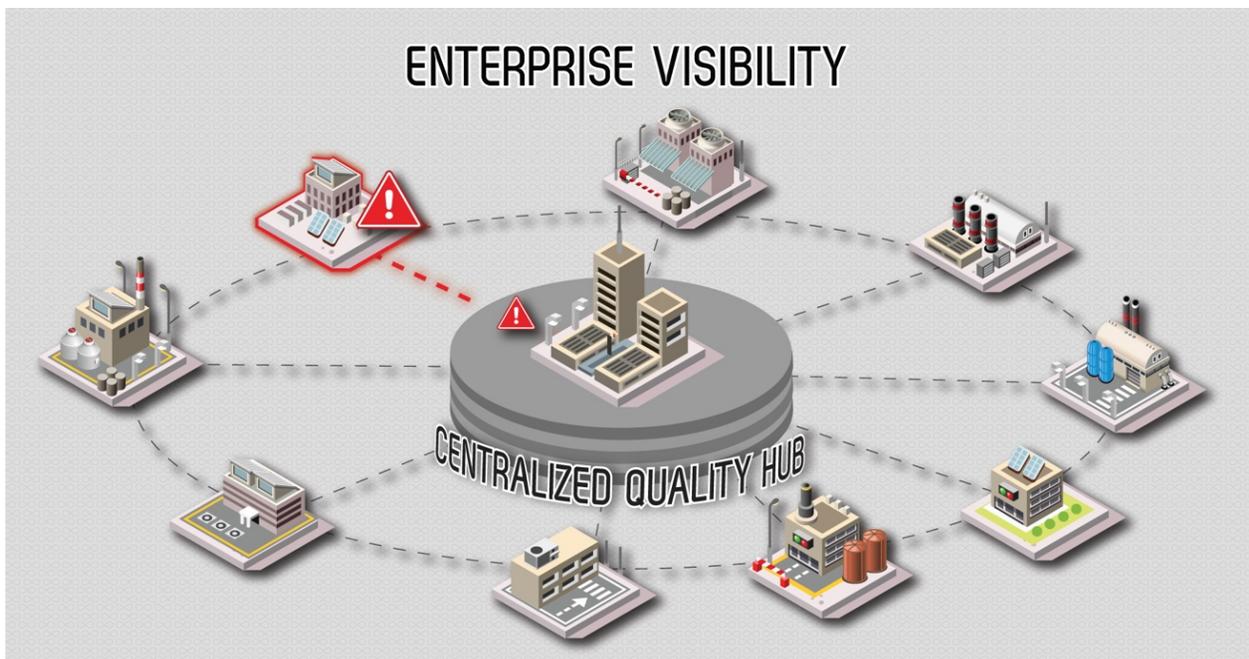
<sup>6</sup> McEntire, J., Bhatt, T. (2012). Pilot projects for improving product tracing along the food supply system – final report. Retrieved from <http://www.fda.gov/downloads/Food/GuidanceRegulation/UCM341810.pdf>

## 7 Practical Tools for Food Safety

Complying with the requirements of the FSMA can seem overwhelming. Simply establishing a few critical tools will support FSMA compliance while allowing you to experience the benefits of a proactive food safety approach, such as improvements in process efficiency and cost savings.

### 1. Centralized Quality Hub

Solving problems upstream in the production process is much harder when you're monitoring multiple data views across lines, plants, and sites. Siloed data makes it nearly impossible to truly know where potential problems exist. Centralizing your product quality and safety data in one place gives you visibility into your entire enterprise. You can then identify potential issues and focus your time and resources on solving those problems. Centralized data also helps you trace final product lots back to raw ingredients and suppliers quickly and easily.



### 2. Universal Naming Conventions

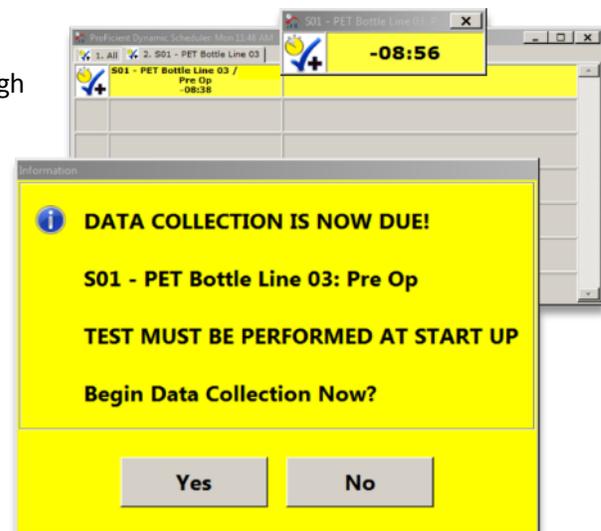
Monitoring food quality and safety requires access to data that can be easily sifted to quickly identify potential problems. One small way to make data easy to navigate is the use of universal naming conventions. Without establishing universal naming standards, one type of food produced at two plants can be stored in a database as two different items. Pulling together data

on that one food item in both plants requires knowledge of each plant's naming conventions and some extra time setting up your report to be sure you're including all relevant data. And, even then, you may not be sure you've got all the data you need.

The solution is simple; all it takes is a set of naming convention standards across your lines, plants, and sites. Key parameter names should be consistent across your production process such as part names, line/machine names, test names and employee names. With common naming conventions and a centralized data hub, you can produce a report that allows you to quickly identify which plant and line produced the problematic product. The aggregated data can be quickly retrieved across the enterprise, ensuring you can correct the problem sooner – long before the food reaches the hands of consumers.

### 3. Dynamic Sampling Reminders

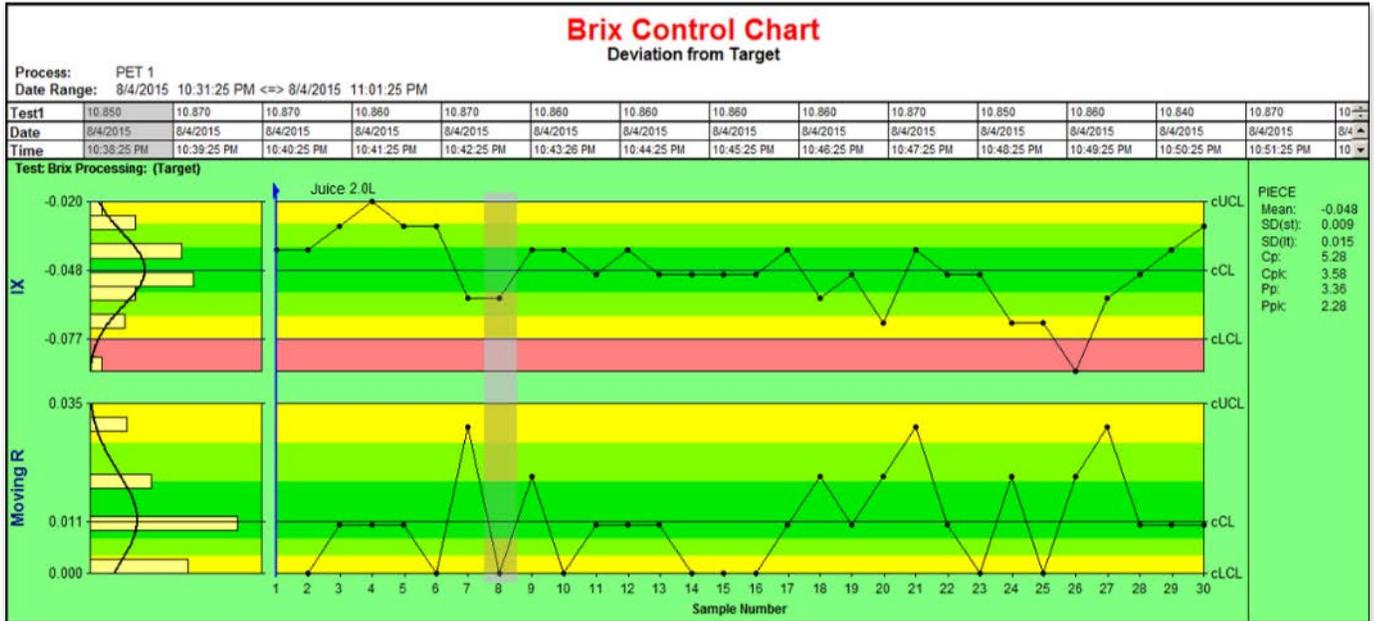
Sampling and testing food early in the production process is critical to food safety. It's no longer enough to sample or inspect food once it has come off the production line. With automated sampling reminders, busy operators in complex manufacturing environments can make sure quality and safety checks take place on time. By ensuring timely checks take place, you can correct problems before ruined product has to be scrapped. The result is improved quality and safety, resulting in higher process yield and less waste at the end of the line.



### 4. Real-Time Statistical Process Control (SPC)

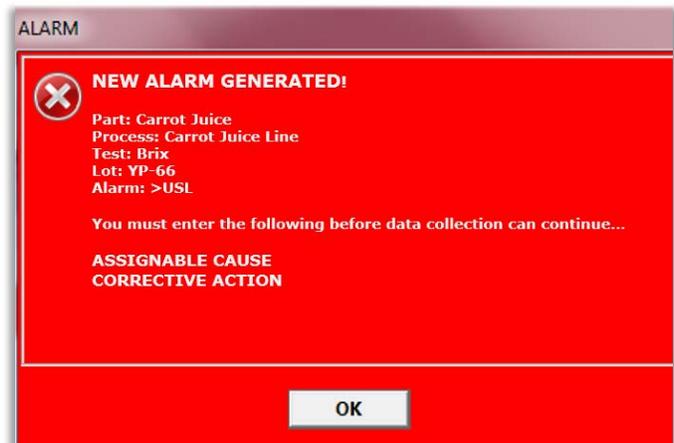
Prevention isn't possible if you're reviewing old data about products that have already come off the line or you're reviewing defect data with little-to-no context. With SPC data and control charts that update in real-time, you can catch potential problems before they result in ruined food. You gain access to manufacturing intelligence upstream in the production process, enabling true prevention. Moreover, the downstream results are better, safer food products.

Control charts allow you to use SPC data to quickly identify and resolve problems upstream in the food manufacturing process.



## 5. Automated Alarms

Automated alarms can be used to alert key personnel when tests violate specification, warning or control limits. Alarms help you stay on top of potential problems without constant monitoring of every line in every plant. You can also require that plant floor operators enter an assignable cause and corrective action code to document the reason for an alarm and how it was resolved. This helps you ensure that problems identified during production are being addressed and corrective actions are being documented. This documentation also allows you to track and trend chronic problems over time for in-depth troubleshooting.



## 6. Lot Genealogy Reports

With lot genealogy reports, you have a complete view of the incoming/outgoing product relationship. This allows you to track raw material lot codes throughout manufacturing operations. For investigation purposes, genealogical “trees” can be created. These reports allow you to determine:

- Materials used in the production of a certain finished lot
- Where incoming raw materials were consumed
- Root causes of non-conforming lots
- Information critical to responding to product recalls
- Which final lots were created from incoming lots

Lot Genealogy allows you to view summary statistics of final products by lot. For a deeper view, you can also look at the component lots and their summary statistics for a complete summary of your product.

**Lot Genealogy Reports help you track your food product and the raw ingredients used from your suppliers, for complete food traceability.**

Cookie Lot Summary Report														
Includes Lot Genealogy of all Component Lots														
<b>CCC-311 (Chocolate Chip Cookies): Closed</b>														
Test	USL	TAR	LSL	Count	Mean	SD (ft)	Minimum	Maximum	OOS	Events	Pp	Ppk	Start Time	Finish Time
Carbohydrate	5.1500	5.0000	4.8500	10	4.9807	0.048007	4.8989	5.0594	0	0	1.04	0.91	09/04/12 - 05:03:11pm	09/04/12 - 05:03:18pm
Cholesterol	3.1000	3.0000	2.9000	10	2.9941	0.019627	2.9581	3.0185	0	0	1.70	1.60	09/04/12 - 05:03:11pm	09/04/12 - 05:03:18pm
Cookie Diameter	4.2500	4.0000	3.7500	10	4.0041	0.064100	3.8668	4.0959	0	0	1.30	1.28	09/04/12 - 05:03:11pm	09/04/12 - 05:03:18pm
Cookie Thickness	0.7000	0.5000	0.4000	10	0.4910	0.046253	0.4287	0.5819	0	0	1.08	0.86	09/04/12 - 05:03:11pm	09/04/12 - 05:03:18pm
Cookie Weight	30.0000	26.5000	23.0000	10	26.8593	0.731682	26.0105	28.1714	0	0	1.59	1.43	09/04/12 - 05:03:11pm	09/04/12 - 05:03:18pm
Fat	12.5000	12.0000	11.5000	10	12.0769	0.147726	11.8638	12.2779	0	0	1.13	0.95	09/04/12 - 05:03:11pm	09/04/12 - 05:03:18pm
Lot Association	----	----	----	2	1.0000	0.000000	1.0000	1.0000	----	----	----	----	09/04/12 - 05:02:56pm	09/05/12 - 05:31:36pm
Sodium	3.1000	3.0000	2.9000	10	3.0006	0.011329	2.9791	3.0184	0	0	2.94	2.92	09/04/12 - 05:03:11pm	09/04/12 - 05:03:18pm
<b>CC-221 (Chocolate Chips): Open</b>														
Test	USL	TAR	LSL	Count	Mean	SD (ft)	Minimum	Maximum	OOS	Events	Pp	Ppk	Start Time	Finish Time
Chip Diameter	4.2500	4.0000	3.7500	5	3.9946	0.059959	3.9215	4.0528	0	0	1.39	1.36	09/05/12 - 09:50:27pm	09/05/12 - 09:50:27pm
Chip Height	7.0000	5.0000	3.0000	5	4.9610	0.231430	4.7437	5.3434	0	0	2.88	2.82	09/05/12 - 09:50:27pm	09/05/12 - 09:50:27pm
Lot Association	----	----	----	6	1.0000	0.000000	1.0000	1.0000	----	----	----	----	09/04/12 - 04:59:25pm	09/05/12 - 09:50:19pm
Weight/100	30.0000	24.0000	18.0000	5	24.0101	2.007119	21.9023	26.1683	0	0	1.00	0.99	09/05/12 - 09:50:27pm	09/05/12 - 09:50:27pm
<b>CB-401 (Cocoa Butter): Open</b>														
Test	USL	TAR	LSL	Count	Mean	SD (ft)	Minimum	Maximum	OOS	Events	Pp	Ppk	Start Time	Finish Time
Free Fatty Acids	1.7500	1.6300	1.5000	5	1.6588	0.028424	1.6101	1.6829	0	0	1.47	1.07	09/04/12 - 03:48:16pm	09/04/12 - 03:48:16pm
Iodine Value	40.0000	37.5000	35.0000	5	37.9515	1.128946	36.6846	39.1522	0	0	0.74	0.60	09/04/12 - 03:48:16pm	09/04/12 - 03:48:16pm
Saponification Value	196.0000	192.0000	188.0000	5	192.1051	0.385835	191.8210	192.7443	0	0	3.46	3.36	09/04/12 - 03:48:16pm	09/04/12 - 03:48:16pm
Solidification Point	28.3000	24.1000	20.0000	5	24.4108	1.007843	23.3275	25.7282	0	0	1.37	1.29	09/04/12 - 03:48:16pm	09/04/12 - 03:48:16pm
<b>S-111 (Sugar): Open</b>														
Test	USL	TAR	LSL	Count	Mean	SD (ft)	Minimum	Maximum	OOS	Events	Pp	Ppk	Start Time	Finish Time
% Purity	100.0000	95.0000	92.0000	5	94.8517	0.959278	93.5940	95.8579	0	0	1.39	0.99	09/04/12 - 04:56:01pm	09/04/12 - 04:56:01pm
Color	5.5000	3.2500	1.0000	5	4.0000	0.707107	3.0000	5.0000	0	0	1.06	0.71	09/04/12 - 04:56:01pm	09/04/12 - 04:56:01pm
Grain Size	31.0000	29.0000	25.0000	5	29.3637	0.612357	28.5414	29.8603	0	0	1.63	0.89	09/04/12 - 04:56:01pm	09/04/12 - 04:56:01pm
<b>F-765 (Flour): Open</b>														
Test	USL	TAR	LSL	Count	Mean	SD (ft)	Minimum	Maximum	OOS	Events	Pp	Ppk	Start Time	Finish Time
% Protein	11.0000	9.0000	7.0000	5	9.5846	2.052009	6.8673	12.5679	2	1	0.32	0.23	09/04/12 - 03:48:44pm	09/04/12 - 03:48:44pm
<b>S-111 (Sugar): Open</b>														
Test	USL	TAR	LSL	Count	Mean	SD (ft)	Minimum	Maximum	OOS	Events	Pp	Ppk	Start Time	Finish Time
% Purity	100.0000	95.0000	92.0000	5	94.8517	0.959278	93.5940	95.8579	0	0	1.39	0.99	09/04/12 - 04:56:01pm	09/04/12 - 04:56:01pm
Color	5.5000	3.2500	1.0000	5	4.0000	0.707107	3.0000	5.0000	0	0	1.06	0.71	09/04/12 - 04:56:01pm	09/04/12 - 04:56:01pm
Grain Size	31.0000	29.0000	25.0000	5	29.3637	0.612357	28.5414	29.8603	0	0	1.63	0.89	09/04/12 - 04:56:01pm	09/04/12 - 04:56:01pm

## 7. Cloud-Based Food Safety Management

Cloud-based quality management technologies offer distinct benefits for food manufacturers. Supported by world-class hosting partners, these solutions are highly secure and available. For manufacturers with limited IT resources, they eliminate the burden of hardware and software maintenance.

These technology solutions also enable food safety prevention across the supply chain. With enterprise data views that include suppliers' operations, your suppliers can remedy potential issues before product reaches your facilities. Data visualizations and reports provide quick and easy proof of compliance in the event of an audit. With a quality management solution, food safety prevention and traceability become an embedded part of your manufacturing processes.

### Automated Prevention and Traceability in Action

One of North America's largest produce suppliers adopted a quality management solution to monitor and regulate their processes and supply chain more closely. As a result, they achieved two important goals: They gained an enterprise view of their operations and enabled a proactive approach to food safety and quality.

**A produce manufacturer aggregated enterprise data across 10 plants, enabling a proactive approach to food safety and quality.**

Previously, their 10 facilities produced separate data sets, making it difficult to track enterprise-wide trends. With their quality management solution, they were able to aggregate data across all of their plants into a single database for analysis. They use the platform's quality check reminders to ensure timely quality tests occur. They use the platform's email alert functionality to make sure key personnel are alerted of potential issues.

The software also helps the company monitor its suppliers. This produce manufacturer is able to better monitor quality of fruits and vegetables coming in so they can comply with the FDA's regulations regarding raw foods.

## Conclusion

While the FSMA is driven by the human need for food safety, prevention and traceability in food manufacturing can have positive operational outcomes as well. The FSMA's prevention and traceability regulations offer an opportunity to invest in the tools that drive higher levels of manufacturing productivity and quality. Moreover, with cloud-based solutions, extending your prevention and traceability controls to your suppliers has never been easier.



## About InfinityQS International, Inc.

InfinityQS International, Inc.® is the global authority on Manufacturing Intelligence and enterprise quality. The company's Manufacturing Intelligence platform, ProFicient, delivers real-time visibility from the shop floor, across the enterprise and into the supply chain, allowing top manufacturers to take control of quality. Powered by a centralized statistical process control (SPC) analytical engine, ProFicient manufacturing quality software leverages Manufacturing Intelligence to help global manufacturers improve product quality, decrease costs, maintain compliance and make smarter, data-driven business decisions. Headquartered near Washington, D.C., with offices in Seattle, London, Koblenz, and Beijing, InfinityQS was founded in 1989 and now services more than 40,000 active licenses with over 2,500 of the world's top manufacturers including Kraft Foods, Ball Corporation, Boston Scientific, Graham Packaging, and Medtronic. For more information, visit [www.infinityqs.com](http://www.infinityqs.com).