

# **Preventing Foodborne Illness: The Farm-to-Fork Focus of the FSMA**



by

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## Preventing Foodborne Illness: The Farm-to-Fork Focus of the FSMA

What are the costs of foodborne illnesses? A recent Fortune.com article placed the annual cost of medical treatment, lost productivity, and illness-related mortality for affected consumers at \$55.5 billion.<sup>1</sup> The industry takes a hit as well to the tune of \$7 billion in annual costs from food withdrawals, rejections, and recalls. A large portion of these costs result from internal reworking, commodity loss, inventory replacement, removing goods from shelves, lost sales, and public relations or customer confidence repair.<sup>2</sup>

The Food Safety Modernization Act (FSMA) was developed and sponsored by the Food and Drug Administration (FDA) and signed into law on January 4, 2011<sup>3</sup>. For the past 70 years, food safety regulations focused on responding to contamination. The new regulations shift the regulatory focus from identifying the source of a problem after an outbreak to preventing foodborne illness. The regulations extend prevention requirements to

cover the U.S. food supply chain from farm-to-fork. In short, the new law requires greater transparency from the entire supply chain and fundamentally changes the way food is regulated in the U.S. and abroad."<sup>4, 5</sup>

Foodborne illness refers to illnesses caused by pathogens as reported by the Centers for Disease Control (CDC). Although the CDC reports on 31 different

**Table 1: Five Pathogens Cause 91% of Foodborne Illnesses Reported in the U.S.**

Pathogen	Est. # of Illnesses	%
Norovirus	5,461,731	58
Salmonella, nontyphoidal	1,027,561	11
Clostridium perfringens	965,958	10
Campylobacter spp.	845,024	9
Staphylococcus aureus	241,148	3
<b>Subtotal</b>		<b>91</b>

Per [\*CDC 2011 Estimates of Foodborne Illnesses in the United States\*](#)

<sup>1</sup> Beth Kowitt, "The food industry's \$55.5 billion safety problem," Fortune.com, September 25, 2015. Online at: <http://fortune.com/2015/09/25/food-industry-contamination/>

<sup>2</sup> Barbara Levin, "The ROI of Food Safety and Quality Assurance Technology Solutions," Food Safety News, September 17, 2012.

<sup>3</sup> FDA Food Safety Modernization Act (FSMA). Online at: <http://www.fda.gov/Food/GuidanceRegulation/FSMA/>

<sup>4</sup> Katie Moore, *The Final FSMA Rules are Here: It's Time to Comply*, Food Safety Magazine, February 25, 2016. Online: <http://www.foodsafetymagazine.com/signature-series/the-final-fsma-rules-are-here-ite28099s-time-to-comply/>

<sup>5</sup> See the Addendum for an overview of the FSMA and its key elements.

pathogens<sup>6</sup>, the five listed in Table 1 above cause the most illnesses, hospitalizations, and deaths in the U.S. Two meat products, chicken and ground beef, account for the most outbreaks and are rated the highest risk to consumers.<sup>7</sup> The minimum growth temperatures for the two most common pathogens, salmonellae and pathogenic *E. coli*, are listed at 44.6° F. The minimum growth temperatures for the most common pathogens are listed in the Table 2 below<sup>8</sup>:

**Table 2: Minimum Growth Temperatures for Selected Foodborne Pathogens**

Minimum growth temperatures for selected foodborne pathogens.

	Minimum Growth Temperatures	
Salmonellae <sup>1</sup>	7C	44.6F
Pathogenic <i>E. coli</i>	7-8C	44.6-46.4F
<i>L. monocytogenes</i>	-0.4C	31.3F
<i>Y. enterocolitica</i>	-1.3C	29.7F
<i>Campylobacter jejuni</i>	32C	89.6F
<i>Staphylococcus aureus</i>	7C	44.6F
<i>Bacillus cereus</i> <sup>2</sup>		
psychrotrophic strains	4C	39.2F
<i>Clostridium perfringens</i>	12C	53.6F
<i>Clostridium botulinum</i>		
nonproteolytic	3.3C	38F
proteolytic	10C	50F

- 1 One report of initial growth on bacon at 5C but then the population decreased.
- 2 While growth of *B. cereus* occurs in milk at refrigeration temperatures (e.g., <7C), there is no evidence for this in meat and poultry.
- 3 Parasites (e.g., *Trichinella spiralis*, *Taenia* spp., *Toxoplasma gondii*) and viruses do not multiply in meat and poultry products.

<sup>6</sup> Scallan E, Hoekstra RM, Angulo FJ, Tauxe RV, Widdowson M-A, Roy SL, et al. *Foodborne illness acquired in the United States—major pathogens*. Emerging Infectious Diseases [by the Centers for Disease Control and Prevention]. 2011 Jan. [http://wwwnc.cdc.gov/eid/article/17/1/p1-1101\\_article](http://wwwnc.cdc.gov/eid/article/17/1/p1-1101_article)

<sup>7</sup> Sarah Klein and Caroline Smith DeWaal, *Risky Meat*, Center for Science in the Public Interest, 2013, p. 6.

<sup>8</sup> R.B. Tompkin, *The Significance of time-temperature to growth of foodborne pathogens during refrigeration at 40-50°F*, Presented at the Joint FSIS/FDA Conference on Time/Temperature, Nov. 18, 1996, Washington, DC., p1.

## Temperature and FSMA

The FSMA builds on the existing food safety regulatory environment. Many food-processing organizations already comply with various temperature-related regulatory requirements covered by FSMA. For example, the new regulations are consistent with many elements of the existing global Pathogen Reduction and Hazard Analysis and Critical Control Point (PR/HACCP) and Current Good Manufacturing Practice (cGMP) requirements. Together, they provide an already established structure for temperature monitoring, data retention, and instrument cleanliness.

The FSMA provides an improved, prevention-oriented framework to implement and monitor quality and process improvements, consistent with PR/HACCP, cGMP, and other existing requirements. It also improves the framework for companies to monitor and remedy food safety issues. Many specific requirements regarding temperature already exist in PR/HACCP requirements and specific guides provided by the USDA for processing meat.

Regulatory oversight for meat and poultry facilities still remains primarily under the jurisdiction of the USDA Food Safety and Inspection Service (FSIS). USDA regulations regarding meat and poultry are based on PR/HACCP and cGMPs. However, such facilities may need to also comply with FSMA if they either produce foods that combine meats and produce together such as pizza, soup, and ready-to-eat meals or supply product to such a facility. FSMA's supply chain rule "mandates that a manufacturing/processing facility have a risk-based supply chain program for those raw material and other ingredients for which it has identified a hazard requiring supply chain applied control."<sup>9</sup> Any PR/HACCP (USDA) or HARPC plan (FSMA-FDA) will certainly list biological hazards, specifically, the leading foodborne pathogens. It is thus quite possible that a number of meat and poultry facilities will be dual-regulated.

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<sup>9</sup> FSMA Final Rule for Preventive Controls for Human Food, available at: <http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334115.htm> - Key Requirements

### **The Real Key to FSMA**

The real key for the food supply chain is that compliance with these requirements is a high priority under FSMA. Existing temperature guidelines, for instance, from 21 C.F.R., state that “all food manufacturing, including packaging and storage, shall be conducted under such conditions and controls as are necessary to minimize the potential for the growth of microorganisms, or for the contamination of food.<sup>10</sup> One way to comply with this requirement is by carefully monitoring physical factors such as time, temperature, humidity, aw, pH, pressure, flow rate, and manufacturing operations such as freezing, dehydration, heat processing, acidification, and refrigeration to ensure that mechanical breakdowns, time delays, temperature fluctuations, and other factors do not contribute to the decomposition or contamination of food.”<sup>11</sup>

In line with the distinct possibility of dual-regulation, a later section refers to heating processes for products such as breading, batters, sauces, gravies, and similar products. These products must be heated to a required temperature and then either rapidly cooled or moved to a subsequent manufacturing step without delay. For temperature monitoring, it's therefore critical to cool to an adequate temperature during the manufacturing process.

FMSA and FSIS rules require, when applicable, that companies establish maximum and/or minimum values to control selected hazards. For meat, maintaining the product at the specified temperature is critical. As noted above, temperatures impact pathogen development and accurately monitoring temperatures is essential to reducing their presence in food. FSMA requires farm-to-fork monitoring of temperatures as a preventive measure.

#### **Examples Where Meat Temperature Matters**

The following three typical production scenarios in the meat processing supply chain illustrate the importance of temperature monitoring. In the first example, meat leaving the slaughterhouse for processing is packaged in combo boxes or

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<sup>10</sup> 21CFR110.80(b)(2) online at:

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcr/CFRSearch.cfm?fr=110.80>

<sup>11</sup> CURRENT GOOD MANUFACTURING PRACTICES (cGMP's), 21 CFR § 110 Food and Drug Administration (FDA) Regulations, p. 10, published by FSIS and online at: <http://www.fsis.usda.gov/OPPDE/rdad/FRPubs/00-014R/FDA-GMPRegs.htm>

bins that are four feet square. The meat must be maintained at or below freezing for the journey to the processing plant. Quality technicians measure core temp at the center of the box prior to shipping and again when it arrives at the processor.

The second example is a continuous production line for processed meats where process temperatures must be maintained within specification. Depending on the particular process step, it is important to measure the core temperature of meats. These can range from lows of 32°F to highs of 160°F. Speed of measurement is critical due to the automated production line. QC technicians have a limited “window of opportunity” of perhaps 10-15 seconds to insert a probe and obtain a stable reading.

The third example measures temperatures in the meat smoking process, a common production step for many processed meats. Like the continuous production line, speed of measurement is critical. Temperatures are usually not monitored inside the oven. Instead, the QC technicians must open the oven doors, take several measurements, record the results, and close the doors to continue cooking. The longer the doors are open, the more heat is lost, and therefore, the longer total cooking time required.

### **Gathering QC Temperature Data: New Way vs. Old**

QC technicians have recorded temperature measurements in food processing plants using paper, pencil and a clipboard for at least 50 years or more. The technician then either manually enters the data later in a database or files it in antiquated paper filing cabinets. Finding non-compliant results can take hours, if not days, to sort through paper reports from suppliers, PDFs, emails, spreadsheets, etc. to identify the few results that may require action. In the meantime, the product is on hold, causing production delays and interrupting the sales process.<sup>12</sup>

Manually recording temperature in this analog way also introduces errors. These include transposing numbers when writing the temperature and transcription errors during data entry. Even good typists make about 8 errors per 100 words.<sup>13</sup> In addition, paper documents can be misplaced, misfiled, inadvertently thrown out, and are subject to destruction by fire or other in-plant disaster. In addition, manual filing systems require extensive factory or office floor space for physical filing systems.

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<sup>12</sup> *Ibid.*, Barbara Levin, Food Safety News, September 17, 2012.

<sup>13</sup> Average Typing Speed Infographic, <http://www.ratatype.com/learn/average-typing-speed/>

In short, totally paper-based processes are time-consuming, inefficient, and insecure. If the data gathered on the production floor is then entered into a local database or spreadsheet, the responsibility for retaining the QC data transfers to corporate IT. Or the data may be retained in a dedicated offline computer, making the data subject to disk failure, damage, or in-plant disaster such as a fire or inadvertent automated sprinkler system activation.

### **The ROI of Automated Temperature Measurement**

Automated temperature control systems will facilitate compliance with the FSMA.

*As Food Safety Magazine notes,*

A main component of these new FSMA regulations encompasses data tracking, management and control mechanisms. Investing in manufacturing and quality software that sufficiently monitors products throughout the entire production process, and provides accurate records for the FDA and state government officials, is imperative for future compliance with FSMA. The good news is that cloud-based technology now exists to help food manufacturers meet FSMA requirements while working to prevent foodborne outbreaks and quickly limit outbreaks when they do occur.<sup>14</sup>

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<sup>14</sup> Katie Moore, *Ibid*



Ideally, an automated system is a compact, lightweight, water and dust-resistant unit that an inspector can easily carry. As recommended in the prior quote, it connects easily to a cloud-based system via non-proprietary wireless connectivity such as Bluetooth®<sup>15</sup>. It operates at the push of a button to measure, record, and save the temperature reading, time, and location. Of course, the digital thermometer must also be easy to clean and sanitize.

An automated temperature measurement system delivers an immediate return on investment. For example, when making measurements in a smokehouse, the technician only needs to insert the probe to gather the data. This eliminates the time used to record the temperature on a clipboard, reducing the time smokehouse doors are open. It also eliminates the paper, pencil, and clipboard as potential sources of contamination.

In an automated system, data is immediately accessible up and down the supply chain. Since there's no manual data entry, recording and transcription errors are eliminated, resulting in far more efficient and accurate data collection. Data is also stored safely away from the production facility in a secure cloud environment. Perhaps the biggest benefit is that rapid data access can identify non-compliant readings almost instantly. This systems approach allows production managers to dramatically shorten their response time to compliance issues and reduce production downtime.

## Conclusion

Temperature measurement is an important element of an FSMA-compliant preventive control process. One big positive step is to eliminate the pencil and clipboard from food processing temperature measurements. It's crucial to

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automate data collection, including temperature readings. Doing so addresses FSMA requirements for science-based, in-process temperatures to reduce pathogens. Cloud-based data solutions make it easy for suppliers and producers to capture the data in a single acquisition step, import it into a database, and make it available throughout the supply chain. Attention now focuses on the supply chain as FSMA enforcement begins in September for all but the smallest food and beverage vendors.

*About TEGAM:*

*TEGAM, Inc. specializes in the design, manufacture, and support of a diverse line of electronic test equipment, including thermometers and temperature calibrators, ohm and bond meters, and RF power sensor calibration systems. Founded in 1979, TEGAM supports its governmental and commercial customers in the U.S. and throughout the world through its commitment to quality and customer service. Visit [tegam.com](http://tegam.com) to learn more about TEGAM.*

## Additional Resources

1. Helpful and informative charts on HACCP meat data.  
Food and Agriculture Organization – UN, Meat Processing Hygiene.  
<http://www.fao.org/docrep/010/ai407e/ai407e25.htm>
2. The ROI of Food Safety and Quality Assurance Technology, Food Safety News.  
<http://www.foodsafetynews.com/2012/09/the-roi-of-food-safety-and-quality-assurance-technology-solutions/#.VurmOGQrKV4>
3. The painful cost of food safety problems at Chipotle  
Wall Street Journal, Chipotle Food-Safety Problems May Cost it up to 7% of Customers  
<http://blogs.wsj.com/cfo/2016/03/17/chipotle-food-safety-problems-may-cost-it-up-to-7-of-customers-cfo/>
4. Infographic on the financial impact of a recall, CDCfoundation.org.  
<http://www.cdcfoundation.org/businesspulse/food-safety-infographic>
5. CDC 2014 Food Safety Progress Report.  
<http://www.cdc.gov/foodnet/pdfs/progress-report-2014-508c.pdf>
6. Tracking and Reporting Foodborne Disease Outbreaks, CDC.  
<http://www.cdc.gov/features/dsfoodborneoutbreaks/>
7. Risky Meat, Center for Science in the Public Interest,  
[https://www.cspinet.org/foodsafety/PDFs/RiskyMeat\\_CSPI\\_2013.pdf](https://www.cspinet.org/foodsafety/PDFs/RiskyMeat_CSPI_2013.pdf)
8. Food Technology & Processing – Bacterial Food Poisoning  
Texas A&M AgriLife Extension  
<http://aggie-horticulture.tamu.edu/food-technology/bacterial-food-poisoning/>
9. Modeling pathogen growth in meat products: Future challenges,  
[https://www.researchgate.net/publication/222704572\\_Modeling\\_pathogen\\_growth\\_in\\_meat\\_products\\_Future\\_challenges](https://www.researchgate.net/publication/222704572_Modeling_pathogen_growth_in_meat_products_Future_challenges)
10. Foodborne outbreak response page, CDC,  
<http://www.cdc.gov/foodsafety/outbreaks/investigating-outbreaks/key-players.html>
11. cGMP, Hazard Analysis, and Risk-Based Preventive Controls for Human Food  
Federal Register Vol. 80, No. 180  
<https://www.gpo.gov/fdsys/pkg/FR-2015-09-17/pdf/2015-21920.pdf>
12. Current FDA/FSIS cGMPs  
21 CFR §110  
<http://www.fsis.usda.gov/OPPDE/rdad/FRPubs/00-014R/FDA-GMPRegs.htm>

## **ADDENDUM: Overview of FSMA**

The FDA has identified five key elements of the FSMA:<sup>1</sup>

1. **Preventive Controls** —The FSMA provides the FDA with a legislative mandate to require comprehensive, prevention-based controls across the food supply chain. As examples, the act requires mandatory preventive controls for food facilities and mandatory produce safety standards.
2. **Inspection and Compliance** —The FSMA provides the FDA with the ability to conduct oversight and ensure compliance with new requirements and to respond when problems emerge. Examples include establishing a mandated inspection frequency (based on risk); giving the FDA access to industry records and food safety plans; and requiring certain testing to be conducted by accredited labs.
3. **Response** —The FSMA provides the FDA with the ability to respond to problems when they emerge. Examples include giving the FDA mandatory recall authority for all food products; expanding the FDA's authority to administratively detain products that are in violation of the law; giving the FDA the authority to suspend a facility's registration, effectively prohibiting the company from selling any products within the United States; establishing pilot projects so the FDA can enhance its product tracing capabilities; and requiring additional recordkeeping by facilities that “manufacture, process, pack or hold” foods designated as “high-risk.”
4. **Imported Food Safety** – The FSMA provides the FDA with the ability to help ensure that food imports meet U.S. food safety standards. Examples include requiring importers to verify that their foreign suppliers have adequate preventive controls; establishing a third-party verification system; requiring certification by a credible third party for high-risk foods as a condition for entry into the United States; establishing a voluntary qualified importer program for expedited review and entry from participating importers; and giving the FDA the right to refuse entry into the United States of food from a foreign facility if the FDA is denied access to the facility or the country where the facility is located.

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<sup>1</sup> Renee Johnson, *Implementation of the FDA Food Safety Modernization Act (FSMA, P.L. 111-353)*, The Congressional Research Service. Online: <http://nationalaglawcenter.org/wp-content/uploads/assets/crs/R43724.pdf>

5. **Enhanced Partnerships** — The FSMA provides the FDA with the authority to improve training of state, local, territorial, and tribal food safety officials. Examples include requiring the FDA to develop and implement strategies to enhance the food safety capacities of state and local agencies through multi-year grants, as well as strategies to enhance the capacities of foreign governments and their industries; and giving the FDA the authority to rely on inspections of other federal, state, and local agencies in meeting its increased inspection mandate for domestic facilities.