



## September Newsletter



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## Training Opportunities

### [Basic HACCP](#)

November 1-2, Denver, Co

### [Advanced HACCP](#)

October 3-4, Fayetteville, AR

### [FSPCA Foreign Supplier Verification Programs \(FSVP\)](#)

October 4-5, Alhambra, CA

### [Developing & Implementing SQF Systems](#)

February 26-27, 2018, Dayton, OH

### [FSPCA Preventive Controls – PCOI](#)

November 14-16, Fayetteville, AR

November 27-29, Akron, OH

February 28-March 2, 2018, Dayton, OH

### [FSPCA Preventive Controls & HACCP](#)

October 18-20, Peabody, MA

**Register Now!**

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## Preventive Controls Rule Deadline is Here!

September 18th marks the enforcement date for the FDA Preventive Controls Rule for Human Food. As of that day, as defined under 21CFR 117, the FDA has the authority to require adherence to Good Manufacturing Practices and Food Safety Plans at large and small food companies. If you have not had training on this rule, please refer to [our training page](#) for future opportunities.

If you would like one of our HCG Consultants to review your Food Safety Plan or Food Safety System before you undergo an in-depth FDA visit, we have experience providing this service helping our clients ensure regulatory compliance.

For a full Food Safety Plan review, we recommend an on-site visit of 1-2 days at least once per year. Alternatively, if you are confident in your procedures, facility condition, and practices, and your primary concern is the documented Food Safety Plan, we can perform a desk review including written or verbal feedback on your Plan's strengths and weaknesses compared to regulatory expectations.

We can also provide assistance in the design and evaluation of your environmental monitoring program. The FDA is taking environmental samples more often. It is imperative, if you have ready-to-eat food that is exposed to the environment, to understand your facility status and to be prepared for what are being called "FDA Swab-a-thons".

To contact us for these services please [send us an email](#).

Contributed by [Cathy Crawford](#), HCG President

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## FDA Releases Sixth Chapter of Draft Guidance for the PC-Human Food Rule

On August 30, 2017, the FDA announced the availability of guidance for food facilities that explains how to establish and implement a heat treatment, such as baking or cooking, to prevent contamination by disease-causing bacteria ([see attached](#)).

This is the [sixth chapter](#) of the draft guidance, entitled "[Draft Guidance for Industry: Hazard Analysis and Risk-Based Preventive Controls for Human Food](#)," designed to help food facilities comply with the preventive controls for human food rule, mandated by the FDA Food Safety Modernization Act.

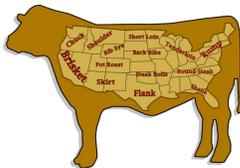
The final rule, entitled "[Current Good Manufacturing Practices, Hazard Analysis, and Risk-Based Preventive Controls for Human Food](#)," published on September 17, 2015, builds on previous food safety requirements and introduces others that together establish a more modern, preventive, and risk-based approach to food safety.

This draft guidance is intended to help food facilities comply with specific requirements of the rule, such as developing a written food safety plan, establishing preventive controls, and taking corrective actions. The FDA intends to publish at least 14 chapters of the guidance and will continue to announce the availability of each chapter as it becomes available.

A compliance date is approaching on September 18, 2017 for small businesses (those with fewer than 500 full-time employees) that are required to comply with the preventive controls for human food rule. To learn more about this and other FDA FSMA rules visit [FDA.gov/FSMA](#).

Contributed by [Bob Savage](#), HCG Senior Vice President

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## FSIS Compliance Guidelines for Minimizing the Risk of STECs in Raw Beef Operations

The Food Safety and Inspection Service (FSIS) published guidelines ([see attached](#)) to assist small and very small processing establishments that produce raw non-intact beef products (e.g., ground beef and mechanically tenderized beef), raw intact beef products intended for non-intact use, or raw intact beef products where the intended use is not clear. This guideline is designed to help establishments understand the adulterant status of STEC in beef products, design supportable control measures for STEC, develop ongoing verification measures to demonstrate that the HACCP system is functioning as intended to reduce STEC to below detectable levels, develop grinding logs to track products, and respond to positive STEC sample results.

Contributed by [Bob Savage](#), HCG Senior Vice President

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## FDA Releases Compliance Guide for Small Businesses under FSMA

## Produce Safety Rule

The FDA Small Entity Compliance Guides (SECGs) are designed to help small businesses meet federal standards. They are among the resources that the FDA is providing to support compliance with the new FDA Food Safety Modernization Act (FSMA) standards.

The FDA, on September 8th announced the availability of an [SECG to help small businesses comply with the Produce Safety Rule](#) mandated by FSMA ([see attached](#)).

The SECG provides information that can help small and very small businesses understand how the requirements of the [Produce Safety Rule](#) apply to them. Specifically, the SECG can help farmers determine whether they are eligible for a qualified exemption, which would modify the requirements they are subject to under the Produce Safety Rule. The SECG can also help them understand those modified requirements.

The main compliance dates for small businesses and very small businesses under the Produce Safety Rule are January 28, 2019, and January 27, 2020, respectively, but certain agricultural water requirements have extended compliance dates. Sprout operations also have different compliance dates, and sprout operations that are small businesses and very small businesses have compliance dates of January 26, 2018, and January 28, 2019, respectively. Businesses that intend to claim a qualified exemption by their primary compliance date were required to begin keeping documentation supporting their eligibility for a qualified exemption on January 26, 2016.

Contributed by [Bob Savage](#), HCG Senior Vice President

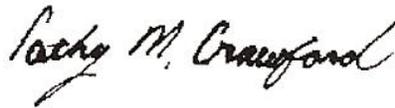
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## SECG Released by FDA for Intentional Adulteration Rule

On August 24th, a Small Entity Compliance Guide (SECG) was released to assist small businesses in meeting federal standards regarding the protection of the food supply against intentional adulteration. The guidance document can be found [here](#) and it provides guidance on rule 21 CFR 121. This SECG provides recommendations on developing a food defense plan as well as records management. Information regarding compliance dates as well as more information about this SECG, can be found [here](#).

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Best Wishes,



Cathy M. Crawford, President

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