

# FSMA Food Safety Plan VS HACCP, HARPC

By

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# FSMA Full Regulation

The full regulation, ***21 CFR 117 – Current Good Manufacturing Practice, Hazard Analysis, and Risk-based Preventive Controls for Human Food***, includes

Subpart A – General Provisions

Subpart B – Current Good Manufacturing Practice (GMP)

Subpart C – Hazard Analysis and Risk-based Preventive Controls

Subpart D – Modified Requirements

Subpart E – Withdrawal of a Qualified Facility Exemption

Subpart F – Requirements Applying to Records That Must be Established and Maintained

Subpart G – Supply-chain Program



# FSMA Rules

Regulation	Proposal	Final (consent decree)
Preventive Controls (Human Food)*	January 16, 2013	August 30, 2015 <b>Sept 17, 2015<sup>◇</sup></b>
Preventive Controls (Animal Food)*	October 29, 2013	August 30, 2015 <b>Sept 17, 2015<sup>◇</sup></b>
Produce Safety*	January 16, 2013	October 31, 2015 <b>November 27, 2015**</b>
Foreign Supplier Verification Program*	July 29, 2013	October 31, 2015 <b>November 27, 2015**</b>
Third Party Accreditation	July 29, 2013	October 31, 2015 <b>November 27, 2015**</b>
Sanitary Transport	February 5, 2014	March 31, 2016 <b>April 6, 2016**</b>
Intentional Adulteration	December 24, 2013	May 27, 2016

*\*Supplemental proposals published September 2014; <sup>◇</sup>Final rule publication date; \*\*Final rule made public*



# 21 CFR 117 Subpart B

- Is where the new Good Manufacturing Practice (GMP) was relocated
- Is modernized and has specific changes
- Is the basic food safety law: contains the minimum requirements of food safety



# FSMA Food Safety Plan

- Is not a HACCP plan
- Is not a HARPC plan (even though this acronym fits the regulation title very well)
  - HARPC.com is a project of FDAImports.com, a consulting firm that is not related to the US FDA agency.
  - HARPC.com is a unit that is not related to the Food Safety Preventive Controls Alliance (FSPCA).
- To date, FSPCA is the unit that developed the only curriculum recognized by the US FDA as meeting the training requirements stated in the FSMA rule 21 CFR 117 Subpart C.



# FSMA Food Safety Plan vs. HACCP Plan

FSMA Food Safety Plan	HACCP Plan
Hazard analysis (required)	Hazard analysis (required)
Preventive controls to control food hazards <ul style="list-style-type: none"> <li>• Process</li> <li>• Sanitation</li> <li>• Allergen</li> <li>• Supply-chain</li> <li>• Recall plan</li> <li>• Others</li> </ul>	Critical Control Points (CCPs) to control food hazards
Process Preventive Controls	CCPs
Sanitation Preventive Controls	Controlled by GMP, prerequisite programs, SSOP
Allergen Preventive Controls	Controlled by GMP, prerequisite programs, Allergen Control Program
Supply-chain Preventive Controls	Controlled by Letters of Guaranty, Certificate of Analysis, audits, etc.



# FSMA Food Safety Plan vs. HACCP Plan (cont'd)

FSMA Food Safety Plan	HACCP Plan
Parameters and values (parameters are not numerical and min/max values are numerical)	Critical limits (usually measurable)
Implementation Procedures: <ul style="list-style-type: none"> <li>Monitoring required for preventive controls</li> </ul>	Monitoring required for CCPs
Implementation Procedures: <ul style="list-style-type: none"> <li>Corrective actions or corrections</li> </ul>	Corrective actions (only)
Implementation Procedures: <ul style="list-style-type: none"> <li>Verification (required when supplier controls a hazard)</li> </ul>	Verification required for CCPs
Records for all preventive controls	Records for process controls
Recall Plan (required if hazards and preventive controls are identified)	Recall Plan (not required)

# What's New in a FSMA Food Safety Plan— Another way of looking at it

Element	HACCP Plan	Added in FSMA Food Safety Plan
Hazard analysis	Biological, chemical, physical	Chemical hazards to include radiological; consider economically motivated hazards
Preventive controls	CCPs for processes	Process CCPs + controls at other points that are not CCPs
Parameters and values	Critical limits	Parameters and minimum/maximum values
Monitoring	Required for CCPs	Required as appropriate for other preventive controls
Corrective actions or corrections	Corrective actions	Corrective actions or <b>corrections</b> , as appropriate
Verification	For process controls	As appropriate for all preventive controls; supplier verification required when supplier controls a hazard
Records	For process controls	As appropriate for all preventive controls
Recall plan	Not required in the plan	Required when a hazard requiring a preventive control is identified; AND required by auditors





# What about the courses HACCP, HARPC, PCQI, PCHF?

- **HACCP:** stands for Hazard Analysis and Critical Control Point systems. This is still an excellent course on food safety but FSMA mandates a FSMA food safety plan for all those registered with the US FDA and distribute their product in the USA. HACCP does not satisfy the FSMA teaching requirements.
- **HARPC:** stands for Hazard Analysis and Risk-based Preventive Controls course. It is a good acronym that fits the title of the FSMA rule very well but I owned by FDAImports.com. FDAImports.com still has to use the curriculum developed by FSPCA for their course to meet FSMA teaching requirements.



# What about the courses HACCP, HARPC, PCQI, PCHF? (cont'd)

- **PCQI:** stands for Preventive Controls Qualified Individual. That is the status of the individual who satisfies all course requirements of the *Hazard Analysis and Risk-based Preventive Controls for Human Food* course.
- **PCHF:** stands for Preventive Controls for Human Food. This is the correct abbreviated name of the *Hazard Analysis and Risk-based Preventive Controls for Human Food* course that some also call PCQI. The curriculum was developed by FSPCA and is the only curriculum recognized by the US FDA to date as meeting FSMA training requirements for a Food Safety Plan.



# FSMA Food Safety Plan vs HACCP Plan -- Summary

- A **written** FSMA Food Safety Plan, specific to the facility, is required, and includes a hazard analysis
- When hazards requiring a preventive control are identified, the following are required, as appropriate:
  - Preventive controls determined through the hazard analysis process
    - Process
    - Food allergen
    - Sanitation
    - Supply-chain
    - Others
    - Recall plan
  - Implementation procedures
    - Monitoring
    - Corrective actions
    - Verification procedures (e.g., validation studies)



# FSMA Food Safety Plan vs HACCP Plan -- Summary

- The format of the form to use is flexible.
- I show different formats in the courses I conduct.
- Visit my website for updates and more information:  
<http://www.FoodSafetyHawaii.org>

