



# FDA FOOD SAFETY MODERNIZATION ACT

## Hazard Analysis & Risk-Based Preventive Controls for Human Food

**Dates:** August 16-18, 2016

**Times:** August 16 and 17 (8am-5pm); August 18 (8am-4pm)

**Venue:** Pagoda Catering, C'est Si Bon Building, 2<sup>nd</sup> floor,  
1525 Rycroft Street, Honolulu, HI 96814 (enter from Kanunu Street; use Ross parking)

**Instructor:** Dr. Aurora A. Saulo

**Sponsored by the:**

Cooperative Extension Service Food Technology Program  
College of Tropical Agriculture & Human Resources  
University of Hawai'i at Ma'noa

Food facilities that manufacture, process, pack or hold human food (domestic and imported, 21 CFR 117.1) for distribution in the U.S. and required to register with FDA under sec. 415 of the FD&C Act are mandated to have a written food safety plan. The final regulations to implement the major provisions of the Food Safety Modernization Act (FSMA) were published on November 27, 2015. The date for compliance for the Hazard Analysis and Risk-based Preventive Controls for Human Food rule starts in the fall of 2016. It is recommended that you start preparing for compliance now to ensure that you will be compliant by the deadline.

### **Course of Instruction**

This course will provide the participants with the knowledge needed to develop and implement a Food Safety Plan that complies with the Hazard Analysis and Risk-based Preventive Controls for Human Food rule. It will discuss the key requirements of the rule, and different foods will then be used as models to develop food safety plans in the group exercises that the participants will be engaged. The group exercise format is similar to that used in the HACCP certification course. Participants who successfully complete all course requirements will meet the training requirement for Preventive Controls Qualified Individuals to develop and apply a food safety system (21 CFR 117.3).

The standardized curriculum used for this course was developed by the Food Safety Preventive Controls Alliance (FSPCA) and, to date, is the only curriculum recognized by the United States Food and Drug Administration (U.S. FDA) to meet their training requirements for FSMA Hazard Analysis and Risk-

based Preventive Controls for Human Food. The FSPCA is a broad-based public- and private-alliance created by the U.S. FDA and the Illinois Institute of Food Safety and Health (IFSH), to support the production of safe food. Consisting of key industry, academic, and government stakeholders, the FSPCA assists companies producing human and animal food to comply with the preventive controls regulations through their development of a nationwide core curriculum, training, and support of a technical assistance network (TAN) and outreach programs.

If you already have a HACCP plan, it is your obligation to determine if you meet all the requirements of the Hazard Analysis and Risk-based Preventive Controls for Human Food rule.

Those who attend all the sessions and satisfactorily complete all course requirements will be awarded two certificates. One certificate will be issued by the FSPCA, IFSH, and the Association of Food and Drug Officials (AFDO) providing evidence that successful participants meet the FSMA training requirements for *Preventive Controls Qualified Individuals*. The other certificate, issued by the University of Hawaii, is for satisfying FSMA training requirements for *Qualified Individuals* as per 21 CFR 117.4(b)(2)-(d). Please visit <http://www.foodsafetyhawaii.org> for additional information.

## Agenda

### Day 1 (8am-5pm)

- Chapter 1: Introduction to Course
- Chapter 2: Food Safety Plan Overview
- Chapter 3: Good Manufacturing Practices and Other Prerequisite Programs
- Chapter 4: Biological Food Safety Hazards
- Chapter 5: Chemical, Physical, and Economically Motivated Food Safety Hazards
- Chapter 6: Preliminary Steps in Developing a Food Safety Plan
- Chapter 7: Resources for Preparing Food Safety Plans
- Chapter 8: Hazard Analysis and Preventive Controls Determination

### Day 2 (8am-5pm)

- Chapter 8: Hazard Analysis and Preventive Controls Determination (cont'd)
- Chapter 9: Process Preventive Controls
- Chapter 10: Food Allergen Preventive Controls
- Chapter 11: Sanitation Preventive Controls
- Chapter 12: Supply Chain Preventive Controls

### Day 3 (8am-12pm)

- Chapter 13: Verification and Validation Procedures
- Chapter 14: Record-keeping Procedures
- Chapter 15: Recall Plan
- Chapter 16: Regulation Overview – GMP and Hazard Analysis and Risk-Based Preventive Controls for Human Food Examination

### (1-4pm) Principles of Food Hygiene and Food Safety

Definitions	Sanitary Operations	Equipment & Utensils	Warehousing & Distribution
Personnel	Sanitary Facilities &	General Processes &	Defect Action Levels
Plant & Grounds	Controls	Controls	

## Who may attend

The course is intended for food industry professionals responsible for or involved in developing food safety plans. Since an effective, written food safety plan is mandatory, and being able to discuss food safety plan with suppliers and customers is an effective marketing tool, others in the food industry will also benefit from taking this course, including farmers (who also do processing), wholesalers, supervisors, mid-level managers, technical and non-technical personnel, quality professionals, production personnel, marketing professionals, legal counsels, sales personnel, and those in the export/import business.

## Registration

Please complete the attached registration form and email it to [fstsa@hawaii.edu](mailto:fstsa@hawaii.edu). You may also register online at [FoodSafetyHawaii.org/Events](http://FoodSafetyHawaii.org/Events). Enrollment will be accepted on a **first-received** basis and will be limited in number due to group exercises. Registration fee is \$700 per person for the three-day workshop when payments are received by 12 noon on **Friday, August 5, 2016**.

- If paying by credit card, please indicate on the registration form and my student assistant will call you to complete the registration process.
- If paying by check, please make it payable to RCUH Project 0001139 and mail it to Food Technology Extension Program, 3190 Maile Way, St John 102, Honolulu, HI 96822. We must receive your checks by 12 noon on Tuesday, August 2, 2016.
- No walk-ins and no payments at the door will be accepted.
- For either mode of payment, we will confirm your registration after receipt of payment.

After August 5, the registration fee will be \$750 per person and only credit card payments will be accepted. The registration fee includes the cost of instruction, use of facilities, all workshop materials, and continental breakfast, lunch, and afternoon snacks for each day of the workshop. Lodging is not included. If we do not receive your registration fee by the deadline, please call first (808-956-8588) to determine if space is available.

## Reading Proficiency

English will be the medium of instruction. No translation assistance will be available. You may bring your own translator if the activity will not distract the other participants.

## Program Faculty

The instructor, Dr. Aurora A. Saulo, is a FSPCA Lead Instructor. To date, FSPCA Lead Instructors must be present to conduct these courses on *Hazard Analysis and Risk-based Preventive Controls for Human Food*.

## Course Venue

*Hazard Analysis and Risk-based Preventive Controls for Human Food* will be conducted at the C'est Si Bon on the second floor of Pagoda Catering, Kanunu St. between Keeaumoku and Kaheka (<http://www.pagodahotel.com/>). Parking is from the 4th floor of the parking structure on Kanunu Street beside Ross Store. The structure has a short vertical clearance of 6'. Please do not jaywalk.

For disability accommodations, please contact me.

Daytime temperatures average in the mid 80s Fahrenheit with lows in the 70s. Summer wear (e.g., shorts and t-shirts) are acceptable in most public areas. It is recommended to bring a **sweater** or a **light jacket** in the conference rooms.



**Cancellation/Substitution Policy**

Deadline for cancellation is Monday, August 8, 2016 at 12noon Hawaii. All cancellations must be in writing and will entail a handling fee of \$50 per registration. Cancellations received after the deadline are subject to the entire tuition charge. Substitutions may be made up to one week before the workshop.

The University of Hawai'i may cancel this workshop fourteen (14) days prior to the first day of the course if there is insufficient enrollment.

Questions regarding program content, certification requirements, and others should be directed to me..

**Dr. Aurora A. Saulo**

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Paying by credit card       Paying by check to arrive by \_\_\_\_\_

**TO REGISTER**

Participant Full Name for the certificate \_\_\_\_\_

Email address of participant (**not payer**) \_\_\_\_\_

Phone number of participant \_\_\_\_\_

Company Name \_\_\_\_\_

Company Address \_\_\_\_\_

Meal restriction (please check)  
o Food Allergy (please specify) \_\_\_\_\_  
o Vegetarian preferred \_\_\_\_\_

US \$700/person if received by August 5, 2016; US \$750/person if received after August 5, 2016

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