



The FDA's Food Safety Modernization Act (FSMA):
its requirements for Hazard Analysis and Risk-based Preventive Controls (HARPC)
in the Proposed Preventive Controls Rule for Human Food

HACCP vs. HARPC

The proposed rule, which is required by FDA's FSMA, would apply to many domestic and foreign firms that manufacture, process, pack or hold human food. These firms would be required to have written plans that identify hazards, specify the steps that will be put in place to minimize or prevent those hazards, identify monitoring procedures and record monitoring results and specify what actions will be taken to correct problems that arise. FDA would evaluate the plans and continue to inspect facilities to make sure the plans are being implemented properly.

Does the Preventive Controls Rule affect me?

No, if I have:

- a facility exempt from FDA's food facility registration, such as some farms
- a retail food establishment
- a restaurant

Yes, if I have:

- a facility that is a farm mixed-type facility which is required to register and would require me to be HARPC-certified.

To determine your status as a farm, we suggest you go to the FDA file providing more information and read "I have a Farm – Does the proposed preventive controls rule affect me?." It may be found at

<http://www.fda.gov/downloads/Food/GuidanceRegulation/FSMA/UCM365377.pdf> (PDF file 292Kb).

Highlight of the Proposed Rule

The proposed hazard analysis and risk-based preventive control (HARPC) requirements are similar to Hazard Analysis and Critical Control Points (HACCP) systems, which were pioneered by the food industry and are required by FDA for juice and

seafood. Operators of a facility would be required to understand the hazards that are reasonably likely to occur in their operation and to put in place preventive controls to minimize or prevent the hazards. Although this proposed rule aligns well with HACCP, it differs in part in that preventive controls may be required at points other than at critical control points and critical limits would not be required for all preventive controls.

HARPC vs. HACCP: Which Training Do I Need?

Under the proposal, each owner, operator or agent in charge of a facility (those required to register with FDA under Section 415 of the FD&C Act), with certain exceptions, would be required to comply with the requirements for hazard analysis and risk-based preventive controls. The preventive controls are **science- and risk-based** in that the rule would require controls only where necessary to prevent hazards to public health and exempt certain facilities from requirements or modify requirements for certain low-risk activities. Second, they are **flexible** in that firms could develop preventive controls that fit their products and operations, as long as they are adequate to significantly minimize or prevent all food safety hazards that are reasonably likely to occur.

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Exemptions and Modified Requirements for Preventive Controls for Human Food

This chart does not contain all of the information necessary to determine the proposed requirements for compliance in a particular circumstance. Consult the proposed rule for specific requirements.

Type of facility or operation	Hazard Analysis and Risk Based Preventive Control Requirements	Current Good Manufacturing Practices (CGMP)
Certain low-risk manufacturing/processing activities, packing or holding activities that are conducted by small or very small businesses on farms for specific foods. Examples including making jams and jellies, honey, and maple syrup.	Exempt	Must comply
Foods subject to the low-acid canned food (LACF) regulation.	Exempt	Must comply

The exemption for facilities producing low-acid canned food applies only to those microbiological hazards addressed by the LACF regulation.		
Foods subject to HACCP regulations (seafood and juice)	Exempt	Must comply
Dietary supplements	Exempt	Must comply with dietary supplement CGMPs
Alcoholic beverages at certain alcohol-related facilities, and certain prepackaged food sold in limited quantities along with alcoholic beverages at the same facilities.	Exempt	Must comply
A facility that has food sales averaging less than \$500,000 per year during the last three years. In addition, sales to qualified end users must exceed sales to others. A qualified end-user is either a consumer (in any location), or a restaurant or retail food establishment purchasing the food for sale directly to consumers that is located in the same State or not more than 275 miles away	Modified Preventive Control Requirements Apply: Facility must certify that it is a “qualified facility” and that it is implementing and monitoring preventive controls or complying with applicable non-Federal food safety law (which triggers a labeling requirement). Also must maintain records to support certifications.	Must comply
A very small business. Three options are being proposed to define a very small business: less than \$250,000, less than \$500,000, and less than \$1,000,000 in total annual sales of food, adjusted for inflation.	Modified Preventive Control Requirements Apply: Facility must certify that it is a “qualified facility” and that it is implementing and monitoring preventive controls or complying with applicable non-Federal food safety law (which triggers a labeling requirement). Also must maintain records to support certifications.	Must comply

Activities within the definition of “farm”	Exempt	Exempt
Facilities, such as warehouses, that only store packaged foods that are not exposed to the environment	<p>If refrigeration is not required for safety, the facility is exempt</p> <p>If refrigeration is required for safety, modified preventive control requirements apply: Requirements concerning temperature controls, including monitoring, verification and records.</p>	Must comply
Facilities such as grain elevators that store only raw agricultural commodities (other than fruits and vegetables) intended for further distribution or processing	Exempt (provided they are solely engaged in such storage)	Exempt
Facilities, such as warehouses, that store raw agricultural commodities that are fruits and vegetables intended for further distribution or processing.	Must comply	Exempt

For a more detailed description of this issue, please refer to FDA’s web site and the following link:

<http://www.fda.gov/food/guidanceregulation/fsma/ucm334115.htm#summary>

More Thoughts

The HARPC process controls seem to be the same as HACCP. Through our process and operating controls we do risk analysis on a regular basis on the whole operation including pre requisite and standard operating procedures. This seems to be one of the main differences with HARPC.

We have not been able to confirm this with the FDA and hopefully will soon, but it seems as if those who have HACCP plans should be in conformance with HARPC. There may be some adjustments per operation; however, HACCP has been used in processing for years and not mandated by FDA. This new ruling is somewhat confusing and we cannot pinpoint the details until the final ruling is made.

Perhaps some of the confusion stems from what appears to be that some of the Control Points will be treated as Critical Control Points. This will not cause much of an issue if you have a well written HACCP plan and should be able to make such adjustments easily. if even needed.

Suggestions

It is not completely clear at this point what will be required of everyone. We suggest that if you have never had HACCP training and need it in your present (or upcoming position), we would be happy to train and certify you. If you are already HACCP-certified and require re-certification, we are also happy to help you. Only WARFA certified students qualify for the discount.

At this time, we do not provide HARPC certification and will not until it is very clear just what specific points other than CCP you will need to be trained for and which specific critical limits would be required for which preventive controls.

In the meantime

HACCP certification is a great place to get most of the system ready; it gives you a scientific resource guide through the coursework to prepare you for HARPC requirements. HACCP1 Certification is only \$500 online, whether in person, in groups, or via Skype for personal contact.

[To individually take the coursework online:](#)

<http://www.haccped.com> > click on the Register link in Online WARFA certification (found at the top of the left hand side of the Home page) or click on the Registration button found in the left hand menu on any page. Find the coursework of choice on the Registration page and select your choice, then submit the form. This will take you to a Confirmation page where you pay for the coursework. Once your payment has cleared, we will email you with explanatory and log-in instructions to the coursework.

[To attend a HACCP Workshop in person:](#)

<http://www.haccped.com> > select the HACCP Workshop button in the left hand menu and check out the class schedule then read the details of what is covered in the class > select the Register button at the bottom of the page > Find the coursework of choice on the Registration page and select your choice, then submit the form. This will take you to a Confirmation page where you pay for the coursework. Once your payment has cleared, we will email you with explanatory and log-in instructions to the coursework.

[Alternative method:](#) Most of WARFA's site pages also provide a button called HACCP Workshops Yearly Schedule at the VERY top of each page, just to the right of the company logo. This button takes you to the HACCP Workshop page for a fairly detailed overview of what you will be learning (see instructions above)

[To request a Skype session:](#)

Please use the contact form at

<http://www.HACCPed.com/html/cont.html>

If you have any questions or comments, please contact:

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