Food safety

FSMA Preventive Controls (21 CFR 117), PCQI

Two days to understand the FSMA preventive controls rule (21 CFR 117) and prepare the food safety plan expected by the FDA and your US importers. Hazard analysis, process, allergen, sanitation and supply-chain preventive controls, recall plan, verification and the role of the PCQI are worked on a product you export.

Duration : 2 days

Objectives

1. Explain the scope of 21 CFR 117 and what it means for a foreign site exporting to the United States
2. Carry out a hazard analysis under the rule, including hazards introduced intentionally for economic gain
3. Select and document preventive controls: process, allergen, sanitation, supply chain
4. Establish monitoring, corrections and corrective actions, verification and validation
5. Describe the role and responsibilities of the PCQI in maintaining the plan

Programme

Day 1 — morning

• FSMA and the FDA: facility registration, the importer's role, foreign supplier verification (FSVP)
• 21 CFR 117: current good manufacturing practice (CGMP) and risk-based preventive controls
• HACCP plan and FSMA food safety plan: what is common, what differs
• The PCQI: definition, routes to qualification, responsibilities

Day 1 — afternoon

• Hazard analysis: biological, chemical including allergens and radiological, physical
• Hazards introduced intentionally for economic gain, environmental pathogens in the production environment
• Exercise: hazard analysis of a product you export
• Mid-course quiz

Day 2 — morning

• Process preventive controls: parameters, limits, monitoring
• Allergen controls, sanitation controls and environmental monitoring
• Supply-chain program: when a hazard is controlled by the supplier
• Recall plan required by the rule

Day 2 — afternoon (workshop)

• Verification: validation, calibration, testing, record review, plan reanalysis
• Records: content, signature, retention, availability during an inspection
• Workshop: draft food safety plan for your product
• Knowledge test and presentation of the draft plan

Teaching methods

• Exercises on a product you actually export to the United States
• Line-by-line comparison between your HACCP plan and the expectations of the rule
• Guided reading of extracts of the regulatory text in English, commented in French
• Role play: a document request from an importer under the FSVP
• Mid-course quiz on the rule and final test

Assessment and documents

Mid-course quiz, knowledge test and a reaction survey at D+1. Numbered training certificate, verifiable online, attesting to the training attended; training report and the draft food safety plan handed to the company.

Bilingual materials for every participant; each classroom course comes with its digital twin on OmniLearn.

Good to know

For canned and acidified foods, the course “Acidified and Canned Foods (21 CFR 114/113)” covers the rules specific to these products. The course “HACCP According to Codex (CXC 1-1969, Rev. 2020)” is recommended for teams without a HACCP plan yet.

Practical information

Duration	2 days
Audience	Quality and food safety managers of sites exporting to the United States, HACCP team, management
Prerequisites	Knowledge of the HACCP method and the site’s processes
Group size	Groups of 6 to 12 participants, in-company
Format	In-company, face to face on your site
Language	French, Darija or English; bilingual materials
Funding	OFPPT special training contracts (TFP), GIAC, Maroc PME: we prepare the applications with you, at no extra cost.
Programme customisation	Programme adapted to your procedures, your equipment and your audience

Frequently asked questions

Does this course make me a PCQI?

The rule allows two routes: training under a standardised curriculum recognised by the FDA, or qualification gained through professional experience. This course is not that standardised curriculum and does not issue a PCQI certificate; it prepares your team to build and maintain the plan.

Is a Moroccan site subject to the rule?

A foreign facility that manufactures, processes, packs or holds food for the US market must in principle be registered with the FDA and is then subject to the rule, unless exempt. Your importer must for its part verify its foreign suppliers: it will ask you for evidence of the plan.

Isn’t a HACCP plan built for BRCGS or IFS enough?

It is a good base, but the rule has its own expectations: preventive controls that are not all CCPs, a supply-chain program, a recall plan, reanalysis, the role of the PCQI and the content of records. The workshop spots these gaps in your plan.

Can the training be given in English?

Yes, in French or English. The regulatory text is in English; the materials are bilingual and the extracts are commented in the language of the group.