



This message is being sent in response to the following submitted inquiry:

This FDA page (<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-questions-and-answers-guidance-facilitate-implementation-haccp-system-seafood>) says question 13.

Question: Are central kitchens covered by the Seafood HACCP Regulation? The answer is no. In regards to FDA FSMA PC; commissaries ARE considered manufacturers subject to FSMA PC. Would this mean a commissary that makes grilled salmon and distributes it to their own retail restaurants do NOT need Seafood HACCP, but DO need FSMA PC (assuming over 1 million in gross sales)? Thanks for clarifying.

The Food and Drug Administration's (FDA) Food and Cosmetic Information Center (FCIC)/Technical Assistance Network (TAN) has prepared a response for case number 210852.

Response: **INQUIRY:** This FDA page (<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-questions-and-answers-guidance-facilitate-implementation-haccp-system-seafood>) says question 13. Question: Are central kitchens covered by the Seafood HACCP Regulation? The answer is no. In regards to FDA FSMA PC; commissaries ARE considered manufacturers subject to FSMA PC. Would this mean a commissary that makes grilled salmon and distributes it to their own retail restaurants do NOT need Seafood HACCP, but DO need FSMA PC (assuming over 1 million in gross sales)? Thanks for clarifying.

RESPONSE: The Answer to Question 13 in FDA's [Guidance for Industry: Questions and Answers for Guidance to Facilitate the Implementation of a HACCP System in Seafood Processing](#) referenced in your inquiry states:

“Central kitchens are processing centers that ship only to their own outlets, usually grocery stores or retail chains. They are considered a retail entity and are, therefore, exempt from the [seafood HACCP] regulation even if they ship in interstate commerce, provided they ship only to their own retail outlets. However, if they ship to another company's outlet, they are considered processors, as defined by [21 CFR § 123.3](#), and therefore subject to the regulation.”

Thus, a commissary that makes grilled salmon and distributes it to their own retail restaurants is not subject to the seafood HACCP regulations in 21 CFR Part 123. However, the commissary that manufactures, processes, packs, or holds human food (e.g., grilled salmon) and distributes it to its own restaurants and retail outlets for consumption in the United States must register with FDA (see [21 CFR Part 1, subpart H](#)) and is subject to the [Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food rule](#) ([21 CFR part 117](#); 80 Fed. Reg. 55908) (CGMP & PC rule), unless an exemption applies (see [21 CFR § 117.5](#) for exemptions). Note that the exemption provided by the CGMP & PC rule in [21 CFR § 117.5\(b\)](#) with respect to fish and fishery products does not apply to a commissary that is not subject the seafood HACCP regulations in [21 CFR part 123](#). Also note that FDA has provided guidance regarding the registration status of central kitchens (See [Questions and Answers Regarding Food Facility Registration \(Seventh Edition\): Guidance for Industry](#), section B.3.1).

Thank you for contacting FDA's FCIC/TAN.

View popular Food Safety Modernization Act (FSMA) [questions and answers](#) identified by the Technical Assistance Network (TAN), on our [website](#).

This communication is intended for the exclusive use of the inquirer and does not constitute an advisory opinion (21 CFR 10.85(k)). Also note that this response is not intended to be a comprehensive list of all applicable requirements. Please check FDA's web page (www.fda.gov) regularly for guidance reflecting our current thinking. Additional information on FSMA can be found on FDA's FSMA web page (www.fda.gov/fsma). This communication may contain information that is protected, privileged, or confidential. If you have received it in error, please immediately delete all copies.

****Please do not reply to this email box. If you would like to submit a follow-up question or need clarification to this inquiry, please click here www.fda.gov/fcic and reference this inquiry's case number.**

In order to improve our service, we'd like your opinion about your experiences using the FSMA TAN - <http://cfsan.force.com/Responsesurvey>

