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FLASH

Questions from the Industry

September 2018

>> QUESTION:

Our U.S.-based facility manufactures various ready-to-eat refrigerated sauces for distribution in the U.S. As per the Preventive Controls for Human Foods Final Rule (part of the U.S. Food Safety Modernization Act (FSMA), our trained food safety team undertook a hazard analysis and identified in addition to a production schedule, we needed Sanitation Preventive Control to assure we effectively clean our fillers in-between product runs when we change from product containing unique allergens. FSMA doesn't seem to require we prove the cleaning and sanitation process was effective, but shouldn't we do this anyway?

>> ANSWER.

Yes. It is important that you can prove to yourselves and any other external party that your cleaning programs, regardless of whether you classify them as general sanitation or Sanitation Preventive Controls, are effective (validated) and are being carried out as designed (verified). This is all about validation and verification. As per FSMA, neither general sanitation or Sanitation Preventive Controls have to be validated (21 CFR117.160(c)). Many facilities choose to do so whether as general practice, or to meet the requirement of validating pre-requisite programs (sanitation is usually classified as a prerequisite program or a GMP) under a Global Food Safety Initiative (GFSI) - recognized food safety scheme (e.g., SQF, BRC, FSSC 22000, IFS, etc.). Validation is the scientific proof a facility has to prove a control measure should be and is effective at controlling the specified food safety hazard. Simply put, it is the proof the SPC is effective at removing the target (whether allergen or pathogen) it was designed to remove. FSMA requires SPCs be verified (ref., 21 CFR117.155). Verification is the scientific proof a facility has in order to prove a control measure has been carried out consistently and in accordance with its design. Simply put, it is the proof activity(ies) is in place, is being followed according to plan and is being carried out consistently. This follows validation and should be done at a consistent frequency. You should also keep in mind you should re-validate as needed, when there is a significant change in the facility, equipment, process, etc. that may impact those responsible for carrying out the sanitation activity to achieve the expected results.

Because you are manufacturing a ready to eat product (RTE), you should also evaluate whether you need a Sanitation Preventive Control to address potential post-processing contamination from environmental pathogens as part of your hazard analysis. The FDA's Draft document " Control of Listeria monocytogenes in Ready-To-Eat Foods: Guidance for Industry" provides further information for RTE products.

UPCOMING TRAINING

FSMA/PCQI Preventive Controls for Human Foods (November 2018, Eagan MN)

2019 Course Schedule Coming Soon!

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WORLD CLASS SERVICE & EXPERTISE: ECOLAB F&B TRAINING

Are you equipped with a consistent approach? Making the right sanitation choices has never been more critical to **protecting food safety and product quality** while boosting your profits and operational efficiency! Our consultants can also help you develop, implement and verify your food safety programs and help you prepare for an audit.

COMPREHENSIVE TRAINING COURSES

We offer training courses to help you and your employees stay current and strengthen your food safety programs. Our breadth of resources and integrated business model help ensure consistency across your operation. Courses include: Implementing SQF Systems, Advanced SQF Practitioner, Advanced HACCP, Preventive Controls for Human Foods (FSMA/PCQI), Internal Auditing, FSSC 22000. Click here for the full training schedule and register for the nearest course.

DO YOU HAVE A QUESTION?

Contact us for more information on food safety management programs and consulting services, inquiries about on-site training at your location for large groups, educational webinars, e-learning modules and other specialized training.

Every day, the Ecolab Technical Customer Service line receives hundreds of calls from customers seeking help on a wide variety of issues including the GFSI recognized programs like BRC Food, SQF, FSSC 22000. Email us your questions.

Click here to download past issues of the Food Safety Institute *Flash* newsletter.

ABOUT THE EXPERT

Dr. Tatiana Lorca manages food safety training programs for Ecolab. She is a registered SQF Trainer, FSMA/PCQI lead instructor and IHA approved HACCP Trainer. Previously, she was the technical manager for the SQF (Safe Quality Food) Institute, a division of the Food Marketing Institute. Email Tatiana