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Inside

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Are Your Corrective Actions Correct?

FSIS inspector and plant official having a discussion inside a processing plant. *(USDA photo)*

By Denise Amann

What should you do if you observe a deficiency at your establishment, such as a deviation from a critical limit as outlined in your Hazard Analysis and Critical Control Point (HACCP) plan, the occurrence of an unforeseen hazard, or the direct contamination or other adulteration of your product?

You're required to perform and document corrective actions when you see these deficiencies. Taking corrective actions is critical because it is a way you are ensuring that adulterated product does not leave your plant.

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Register for Upcoming Regulatory Education Sessions and "How To" Workshops

By Jane Johnson

Since 2006, FSIS has been conducting regulatory educational seminars on a variety of topics that have provided owners, operators, and managers of small and very small plants with information to enhance the design and implementation of their food safety systems. In January 2009, the Agency began conducting a series of "How To" workshops to provide small plants with the practical tools and methods for proper application and compliance with FSIS regulations.

According to Stephanie Wilkins, chief training officer for the FSIS Center for Learning, "We've structured these workshops and their content delivery based on feedback that we received from small and very small plant owners and operators. Our trainers enjoy interacting with the small plant personnel at these workshops, and they provide an opportune time for constructive dialogue."

The "How To" workshops are being held in various locations throughout the country and cover topics such as developing food defense plans, effective sanitation practices, humane handling of livestock, and controlling *Salmonella* and *Campylobacter* in poultry plants, just to name a few. For more information or to register for one of the workshops or regulatory educational seminars, visit FSIS' Web site at *www.fsis.usda.gov/News_&_Events/Outreach_Sessions_SVS_Plants/index.asp.* Or, call the Office of Outreach, Employee Education, and Training at (800) 336-3747 for further assistance.

Food Safety Resources

By Sally Fernandez

Supporting Documentation for HACCP Decisions is a resource designed especially for operators of small plants to aid in the scientific documentation of HACCP decisions during hazard analysis, validation of plans, and corrective action. The book is organized by HACCP process category so that you can validate and demonstrate the effectiveness of the process steps once you have identified specific hazards and critical control points.

The information is organized in easy-to-read tables of process steps, potential hazards, process parameters, decision criteria, and scientific documentation. Where available, a Web site is given to allow Internet access to the scientific publications.

This edition was updated in early 2007, but new research and documentation is constantly evolving. Regular updates are made to the online version on the Ohio State University Meat Science Web page at *http://extension.osu.edu/~meatsci/currentprog.html.*

To order your free copy, complete and submit the online order form at *www.fsis.usda.gov/Science/HACCP_Resources_Brochure/index.asp*. You can also fax the order to (202) 690 6519. For more information, call (800) 336-3747.

Briefs

By Sheila Johnson

Podcasting

Don't forget to check out the latest educational podcasts related to various food safety issues for plants and consumer education information. If you haven't signed up yet for a free subscription, visit *www.fsis.usda.gov*. For assistance or details concerning FSIS podcasts, send an email to *podcast@fsis.usda.gov* or call FSIS' Congressional and Public Affairs Office at (202) 720-9113.

Regulatory Web Seminars

FSIS sponsors a seminar series targeted to owners and operators of small and very small plants. The seminars cover a variety of technical topics concerning FSIS policies and new technologies of interest to industry. The Agency welcomes your participation at these free sessions.

The seminars are conducted via Net Meeting, which utilizes Internet access for viewing the presentations and a telephone line for the audio portion. Preregistration is required to participate in these seminars and online registration forms are available on FSIS' Web site at *www.fsis.usda.gov/News_&_Events/Regulatory_Education/index.asp.*

You can view the content of past presentations by visiting *www.fsis.usda.gov/News_&_Events/Reg_Education_Videos/index.asp*. Here you can download presentations ranging from a *Review of FSIS Compliance Guidelines for the Production of Safe Meat and Poultry Jerky Products in Small and Very Small Plants* to *E. coli O157:H7 Reassessment and Best Practices*. For assistance, either with registering or to obtain copies of previous seminar presentations, contact the Office of Outreach, Employee Education, and Training at (800) 336-3747.

What's All the Buzz About Validation?

By Denise Amann

"Validation is that element of verification focused on collecting and evaluating scientific information to determine if the HACCP plan, when properly implemented, will effectively control the hazards." (National Advisory Committee on Microbiological Criteria for Foods, 1997)

Simply put, validation is proving that what you're doing at a particular step in your process is working to reduce that hazard to acceptable levels. Validation activities are typically performed at two different times within the process – initial validation and ongoing validation.

Initial validation is used to determine if the Hazard Analysis and Critical Control Point (HACCP) plan is scientifically and technically sound. This process would include identifying all potential hazards and documenting scientific evidence that each potential hazard has been effectively controlled at your plant.

Ongoing validation should be performed as needed internally or by an unbiased, independent authority. Situations that may necessitate ongoing validation include unforeseen hazards, significant product or process changes, and evidence of a loss in process control.

Laboratory research yields valuable information on validation of controls to guide food processors. Even so, laboratory research and data are not a true substitute for actual in-plant process validation [Niebuhr, S.E, Laury, A., Acuff, G.R., and J. S. Dickson. 2008. "Evaluation of nonpathogenic surrogate bacteria as process validation indicators for *Salmonella enterica* for selected antimicrobial treatments, cold storage, and fermentation in meat." *Journal of Food Protection*. 71(4):714-718]. That is, there must be data showing the effectiveness of the controls as applied in *your* plant. In-plant process validation will be unique to your system and will document the effectiveness of your food safety interventions and processes.

How do you obtain the data necessary for in-plant process validation? Actual pathogens cannot be taken into food processing establishments for obvious reasons. Therefore, validation activities typically attempt to predict the distribution and number of pathogenic organisms before and after a chosen intervention or process step by monitoring non-pathogenic indicator organisms. Research has revealed that certain non-pathogenic indicator organisms have responses to interventions similar to certain pathogenic organisms. This fact gives establishments the ability to validate a process internally with relatively basic laboratory capabilities. Common, frequently validated steps are carcass washing, evisceration, prechilling, postchilling, and any critical control point.

The results of a validation study provide benefits beyond fulfilling FSIS' HACCP requirements (9 CFR 417.4). In an effective HACCP system, validation results give you a real measure of your control over your process by mapping the reduction of pathogenic and non-pathogenic organisms on product at different stages of processing. Ongoing validation results can also be used to pinpoint the source of a problem and allow you to make necessary adjustments before the process becomes out of control.

Ultimately, frequent ongoing validation of your system lessens the need to rely on end-product test results. In the long run, it's more cost-effective and will increase consumer confidence in the safety of your product.

If you have any further questions or need more information about validation, call the Office of Outreach, Employee Education, and Training at (800) 336-3747.

Where You Can Obtain Assistance on Validation

By Beth McKew

Now that you understand what validation is and recognize the need to validate your HACCP plan, where do you go from here?

As stated in the previous article, you can validate your plant's processes yourself, or you can hire a third party to perform validation studies for you. If you decide that performing validation studies yourself is the way to go, there are numerous resources available to help you decide, for example, what steps in your process are most appropriate to validate and which indicator organisms are appropriate for the product and interventions in your plant.

There are HACCP contacts and coordinators in most States to provide technical advice, assistance, and resources and to conduct activities to support HACCP implementation in small and very small plants. The contact is generally the State meat and poultry program director or another representative of the State government. Coordinators are affiliated with universities and provide additional one-on-one advice and assistance to small and very small plants. Coordinators also develop and provide training and HACCP seminars. You can find a listing of HACCP contacts and coordinators at: *www.fsis.usda.gov/contact_us/state_haccp_contacts_&_coordinators/index.asp*. Or, if you need assistance obtaining the list of HACCP contacts and coordinators, call the Office of Outreach, Employee Education, and Training at (800) 336-3747.

Additionally, industry organizations such as the American Association of Meat Processors (AAMP) and the International HACCP Alliance may be able to refer you to resources in your area to assist you with validation. To contact AAMP, call (717) 367-1168 or visit *www.aamp.com*. The International HACCP Alliance may be reached at (979) 862-3643 or *www.haccpalliance.org/sub/index.html.*

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Deficiencies that require corrective actions fall into two general categories – HACCP and Sanitation Standard Operating Procedure (SSOP). For example, let's say you have a deviation from a critical limit. This would require HACCP corrective actions. Therefore, the actions you need to take must:

1. Identify the cause of the deviation;
2. Ensure that the critical control point is under control after the corrective action is taken;
3. Take measures to prevent recurrence of the deviation;
4. Document that no product that is injurious to health or otherwise adulterated as a result of this deviation has or will enter commerce; and
5. Maintain detailed records of corrective action.

All five of the corrective action requirements must be implemented and documented by your plant for each deviation that occurs.

If there's an unforeseen hazard, which is defined as a potential hazard deemed not likely to occur in your hazard analysis for a documented reason, this is considered a HACCP noncompliance. Because it's typically not related to a critical control point, the required corrective actions for an unforeseen hazard are more focused on product acceptability and distribution. You're required to reassess your HACCP plan to determine if the unforeseen hazard is likely to occur again and should be incorporated into your plan.

If your plant fails to prevent direct contamination or adulteration of product, you're required to perform SSOP corrective actions. Examples of corrective actions include:

1. Changing the process and holding the product for further evaluation.
2. Empowering the monitoring personnel to stop the process when a deviation occurs. They should have the authority to hold all products not in compliance.
3. Relying on an approved alternate process that can be substituted for the one that is out of control at the specific critical control point.

"Oftentimes, an establishment may choose retraining as a method of preventing recurrence," said Cheryl Hicks, Executive Associate of FSIS' Office of Field Operations. "You may use retraining as a preventative measure multiple times. However, if retraining sessions do not prevent recurrence of problems of similar cause, FSIS may not accept training as an effective preventative measure." Proposed future training activities should be properly documented and made available to FSIS inspectors upon request.

It's important to remember that the required HACCP verification activities include the direct observation of corrective actions. FSIS Directive 5000.1, Revision 3, states that plants should "directly observe corrective actions frequently enough to verify that these actions are being performed in a manner that meets the applicable regulatory requirements." This verification activity is documented in a manner similar to other direct observation verification activities at your plant. If not at every occurrence, the frequency used to observe corrective actions directly should be supported with documentation.

The Interactive Knowledge Exchange (IKE) provides an excellent resource for you to examine corrective actions further (see *Small Plant News*, November 2007). For access to an IKE scenario related to the direct observation of corrective actions, visit *www.fsis.usda.gov/PDF/IKE_02-08.pdf.*

Finally, you have the right to appeal all or part of any noncompliance report. This appeal should be addressed with your inspector. For more information about the appeal process, visit *www.fsis.usda.gov/Regulations_&_Policies/Policies_on_Regulatory_Decisions/index.asp* or contact the Policy Development Division at (800) 233-3935 or the Office of Outreach, Employee Education, and Training at (800) 336-3747.

Commonly Asked Questions & Answers

Q. *What is the FSIS form number to authorize the manufacture of brands by the establishment, and what is the applicable regulation that pertains to issuing this certificate?*

A. The FSIS form number for the authorization certificate for brands is FSIS Form 5200-7, *Authorization Certificate* [formerly MP-216], and is only available from the Beltsville Document Center. Requirements regarding the issuance of a brand authorization certificate are outlined in 9 CFR 317.3 (*Code of Federal Regulations*).