Welcome to Our Inaugural Newsletter

Covance Microbiological and Food Safety Consulting is pleased to introduce our inaugural newsletter, *The Consultant’s Corner*.

As part of Covance Laboratories Nutritional Chemistry and Food Science division, we view ourselves as an extension of your food safety team. While we may not be on site, we are mindful of what is occurring in the industry, in government and when needed, in your plant. At Covance, we are committed to the advancement of food safety through education and training and will share our insights with you through the forum of this newsletter.

In each issue, you will find items of interest relating to FDA and USDA regulations, highlights of Food Safety Program Best Practices and a list of upcoming Covance outreach programs where you will have the opportunity to meet some of our scientists and support staff serving you.

You will have access to some of our recent talks or published articles, as well as to a feature article designed to assist and support you in your food safety efforts. Your feedback and suggestions for future topics are welcome, so that, together, we can explore what matters to you.
The FDA has announced, or perhaps admitted, that the current Good Manufacturing Practices (cGMPs) as outlined in 21 CFR 110 do not adequately address the safety issues associated with the manufacturing, processing, packing, or holding food products. Indeed, “high-profile outbreaks of foodborne illness…striking one in six Americans each year have caused a widespread recognition that we need a new, modern food safety system that prevents food safety problems in the first place.” The FDA, through the proposed Food Safety Modernization Act (FSMA), is attempting to decrease risk by imposing regulations on how facilities manage their food safety systems. They have data to suggest that governmental oversight is helpful. For example, between 1976 and 1997, the average size of a Listeria monocytogenes outbreak was 53.8 cases. After PulseNet, between 1996 and 2004, the average outbreak involved 21.5 cases and with the CDC Listeria initiative in conjunction with PulseNet (2004 to 2008), the average outbreak was reduced to 7.2 cases. These data suggest that increased surveillance decreased food safety cases in the U.S. from 1976 to 2008. Why then are there still multistate outbreaks that include numerous deaths, as in 2011 when the largest Listeria outbreak occurred due to contaminated cantaloupes that sickened 1,476 and killed 33? The fundamental question is this: Will GMPs included in FSMA be enough to control the risk of cross-contamination for hazards in food manufacturing?

FSMA Proposed Revisions
The FSMA changes would require facilities to have a written Food Safety Plan to include the following elements: a risk-based hazard analysis, preventive controls for hazards determined to be reasonably likely to occur, monitoring, corrective actions, verification, and associated records and documentation.

Concomitant to a risk-based hazard analysis, proposed FSMA regulations also state that there must be formalized and documented supporting preventative control programs that reduce or eliminate identified hazards. Hazard plans are only the start of a food safety process because they merely outline the hazards and controls to minimize or reduce their risk. Once the hazards have been identified, it is incumbent upon the plant to devise preventative control programs to address activities of the manufacturing process that can reduce or eliminate them. These programs, outlined in FSMA include Manufacturing Process, Allergens, Sanitation, and Recall. It is also stated that the facility must develop “other” programs “as needed.”

Proposed cGMPs
While FDA is not specifically requiring cGMPs as a Preventive Control Program (at this time), subparts of the current 21 CFR 110 may be redesignated and included in 21 CFR 117. Primary proposed provisions include programs that address: allergens, personal hygiene, plants and grounds, sanitary operations, sanitary facilities and controls, equipment and utensils, warehousing and distribution, and employee training.

While these specific cGMPs are outlined, the challenge to plants will be to fill in the outline with a detailed program that is thorough and designed specifically for the plant, product produced, equipment used, plant condition and layout, and workforce followed by verification of the outcome, scientifically, for efficacy. How can this be done? The short answer is to learn from past and shared practices that have been already proven based on the principle that food safety is not competitive. The long answer is to try something (anything) and do not stop until the system is
proven to be effective through a rigorous verification process (environmental monitoring program, allergen testing program, visual inspection system, metal detection, etc.). So where do we start? For the purposes of this article, we will focus on food safety as it relates to microbiology, since it is one author’s specified training.

First, the principle of cross-contamination must be conveyed to production, sanitation, maintenance, and quality assurance employees. Cross-contamination relative to microorganisms, allergens, chemicals, or extraneous matter is the act of transferring an item from one place to another. Cross-contamination can occur through different methods (see Table 1).

<table>
<thead>
<tr>
<th>Vehicle</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Air</td>
<td>▶ Air hoses</td>
</tr>
<tr>
<td></td>
<td>▶ Vents</td>
</tr>
<tr>
<td></td>
<td>▶ Fans to cool workers</td>
</tr>
<tr>
<td></td>
<td>▶ Cooling units</td>
</tr>
<tr>
<td>Water</td>
<td>▶ Sanitation hoses that are &gt;40 psi</td>
</tr>
<tr>
<td></td>
<td>▶ Drain backups</td>
</tr>
<tr>
<td></td>
<td>▶ Roof/door leaks</td>
</tr>
<tr>
<td></td>
<td>▶ Leaking hoses and pipes</td>
</tr>
<tr>
<td></td>
<td>▶ Equipment</td>
</tr>
<tr>
<td>Direct Contact</td>
<td>▶ Forklift tires or any vehicular traffic leaving a production room and re-entering</td>
</tr>
<tr>
<td></td>
<td>▶ Shoes coming in from the exterior of a production room into the production room</td>
</tr>
<tr>
<td></td>
<td>▶ Pallets</td>
</tr>
<tr>
<td></td>
<td>▶ Employee gloves, aprons</td>
</tr>
<tr>
<td></td>
<td>▶ Dust (especially during construction)</td>
</tr>
</tbody>
</table>

Secondly, include an environmental monitoring system that has a site list consisting of product contact (Zone 1), non-contact (adjacent to product contact; Zone 2), and indirect contact (floors, motors, chain drives, walls; Zone 3) for each piece of production equipment and test all vehicular traffic and traffic ways into/out of a post-lethality and/or exposed product production room. Additionally, the program is to include specific activities to be conducted when there is an out-of-specification result, such as an investigation by a multifunctional team, and implement corrective and preventative actions. A corrective action is an activity conducted immediately to reduce the risk, such as an intensified cleaning procedure. This procedure is above and beyond the routine cleaning and sanitizing. A preventative action is an activity that will prevent future adverse results. We refer to preventative actions as one of the “4Rs,” namely, repair, redesign, replacement, and/or removal. All too often, an adverse event means that the site is cleaned and sanitized, as per the usual procedure, and that is all. On the contrary, this is a call to investigate, immediately reduce risk, and implement one of the 4Rs. Further, all activities are to be documented. We will outline a few of the cGMP programs followed by components that we know are the “secrets” to their success.

**Food Allergen Controls**

Currently, there are no cures for those with food allergies or sensitivities. Avoidance is needed to prevent allergic reactions. The FDA recommendations will include that food processing establishments handling any of the major food allergens develop and adopt a food allergen control plan that emphasizes the prevention of “cross-contact” during processing. Since allergens are part of a food and itself not a contaminate, FDA will be reserving the term “cross-contact” as the unintentional transfer of allergenic proteins from a food containing that protein to food that does not. The terms “contamination” and “cross-contamination” will then be reserved for food that has been adulterated with bacteria, foreign matter, or other-than-allergen proteins.

**Allergen Best Practices. Verify the cleaning of food contact equipment after allergen use.**

When testing for allergens, use a test kit that will identify the allergen in question. For example, barley, rye and wheat cannot be distinguished with some of the commercial gluten methods. However, there are some commercial methods that are not suitable for barley so verification using barley as a control is a critical component of the verification. Similarly, some processing will destroy the test kit’s ability to recognize an allergen. Do not verify allergens using ATP, which is not a protein, unless the ATP is validated against specific allergen ELISA test kits. An ATP assay will not be as specific as an ELISA test and further, it may not be as sensitive.

**Personal Hygiene**

Driving up to some plants, we have witnessed employees taking breaks outside wearing lab coats and hair nets; walking
into production rooms after going on the roof, loading dock, trash compactors; and sitting on picnic tables and leaning on or sitting in their cars with hair nets and ID tags. All of these seemingly innocent activities reduce the effectiveness of a lab coat, hair net, bump helmet, gloves, and shoes. Place an emphasis on protection against cross-contamination of food contact surfaces starts with limiting non-production room exposure.

**Personal Hygiene Best Practices.** Many biological contaminants, such as *Listeria*, are carried into food manufacturing rooms, either via people or equipment. Outer garments, such as smocks or lab coats, and shoes must be restricted to the more sensitive areas of the plant, such as ready-to-eat (RTE) rooms, and offer the best protection when they are not removed from production area. An anteroom, located just prior entering the RTE room, or an area immediately inside the production will allow employees to don, doff, store their outer garments and shoes, and wash and sanitize hands and shoes. If there is no space for an anteroom, another alternative is to allow an area for donning and doffing of shoes in exchange with captive footwear. This practice will assist with *Listeria* ingress.

**Sanitary Operations**
The proposed cGMPs will require that cleaning and sanitizing of utensils and equipment be conducted in a manner that protects against cross-contact and contamination of food, food contact surfaces, or food-packaging materials, as well as non-food contact surfaces. Additionally, it would require that all food-contact surfaces, including utensils and food-contact surfaces of equipment, be cleaned as frequently as necessary to protect against cross-contact and contamination of food.

**Sanitary Operations Best Practices.** A post-sanitation inspection is needed where equipment used for the manufacture of food is visually inspected for cleanliness and then swabbed. Swabbing may be either for ATP (conducted after cleaning) or for indicator microorganisms such as aerobic plate count, coliforms, enterobacteriaceae (after sanitation), or a combination of both. The sanitation manager should be armed with the ATP swabs as a management tool to quickly assess cleaning and immediately re-clean when failing tests are returned. Remember to perform a baseline study on the ATP swabs for each plant. Then, immediately after sanitation, the QA team can swab for indicator organisms. Both provide what we described earlier as a verification that the sanitation standard operating procedures are working as intended. Additionally, full equipment disassemblies and inspections (to include swabbing) must be conducted on a routine basis (start with quarterly and readjust as the swabs indicate) for equipment used in support of food manufacturing and starting in the high-risk areas.

**Training**
FDA analysis of recalls has indicated that ineffective employee training was a root cause of 24 percent of cGMP-related primary recalls in the 2008 to 2009. As a result, proposed provisions will require that supervisors and workers are appropriately trained and possess the necessary knowledge and expertise in food hygiene, food protection, employee health, and personal hygiene to produce safe food products. Specifically, each person who is engaged in food manufacturing, processing, packing, or holding (including...
HACCP Training Offered

Hazard Analysis and Critical Control Point (HACCP) certification and training are key components of any company’s food safety plan. When you choose our education program, we will work together and give you tools that help you:

► Complete the requirements for HACCP certification and understand HACCP principles
► Identify the resources needed to develop, implement and maintain an HACCP plan
► Understand and identify process step hazard assessment and steps required to determine critical control points.

Covance’s Introductory and Advanced HACCP certification courses are accredited by the International HACCP Alliance. Courses run as a 2-day program that can be customized to your products/processes and held at your facility. Alternatively, you can attend one of our standard HACCP courses held in Madison, WI or Battle Creek, MI and, when you send more than one employee, you will benefit from our volume discounts.

Training Best Practices. While there is a need for classroom training and presentations, in order to be truly effective, interactive training that is conducted as close to the jobsite as possible is ideal.

When evaluating employees for understanding, practical exercises and direct observations are preferred over written tests. Short, frequent training bursts are also a good idea. For example, we know of one plant that conducts two four-minute training discussions daily on the plant floor from a list of topics, chosen at random, and documented. Also, while yearly training is important, the best practice is to provide constant (hour-by-hour/day-by-day) encouragement by on-the-floor management.

Companies should develop an approach to food safety by combining the efforts of HACCP, preventative controls and GMPs into one entwined system (Figure 1) where each part works in concert with the others and the entirety is proven effective through scientific verification.

So, what do you think? Will GMPs alone be enough to control the risk of cross-contamination in food manufacturing operations?

Meet Your Consultants

With more than 20 years of experience, each of your Microbiological and Food Safety Consultants provide assistance to food manufacturers in all areas of regulation and food safety.

► Microbiological Harborage Site Investigation
► USDA Notice of Suspension/FDA Form 483 Guidance
► HACCP Development and Validation
► Sanitation Program Development, Verification and Validation
► SQF and BRC Certification Consulting
► Process Authority Review
► 3rd Party Audit Consulting
► Customized, Company-Specific Education Programs (GMPs, HACCP, Sanitation, Food Microbiology, Traceability and Recall)

Continued on next page.
When you choose to work with our expert consultants, together we will explore new ways to meet all your food safety needs.

Dr. Virginia Deibel, PhD  
*Director of Microbiology*

Virginia obtained her BS and MS and PhD from the University of Wisconsin. Her PhD major was food microbiology, minoring in bacteriology.

Virginia has worked for more than 20 years with contract laboratories and has specialized in food safety controls for pathogens, including *Listeria*, *Salmonella*, *E. coli* and *Staphylococcus*, as well as other pathogens of concern. In that capacity, she has developed and reviewed pathogen control programs for food and packaging establishments, and conducted microbiological investigations for pathogens and spoilage organisms in food production plants. She has also served as an expert witness in several food safety legal cases.

A certified British Retail Consortium (BRC) Consultant, Virginia can be reached at: Virginia.deibel@covance.com or 608.347.0083.

Tim Lombardo  
*Lead Staff Scientist Food Safety/Food Microbiological Consulting*

Tim earned his BS from Sam Houston State University in Huntsville, Texas. Upon graduation, Tim was commissioned as a Lieutenant in the US Army, serving with distinction overseas (Iraq, Kuwait, Germany) and domestically.

Tim has worked in food manufacturing facilities for more than 20 years, holding key plant-level and corporate-level leadership positions in production/manufacturing, quality control and sanitation.

Tim is an International HACCP Alliance Certified HACCP Manager and a Process Authority, certified in Aseptic and Thermal Processing.

A certified Safe Quality Food Institute (SQFI) Consultant, Tim can be reached at Tim.lombardo@covance.com or 608.218.0510.

Dr. Jean Schoeni, PhD  
*Lead Staff Scientist – Research*

Jean is a graduate of University of Wisconsin-Madison, with a PhD in Food Microbiology and Toxicology, including a minor in Bacteriology. She has conducted food safety research projects for more than 30 years and has experience with all major foodborne pathogens and spoilage organisms. Jean is also BRC certified and a Lead Instructor for the International HACCP Alliance. Dr Jean Schoeni conducts challenge, inoculation pack and process validation studies that provide scientific support to a production process.

In addition to her work at Covance, Jean also teaches in the Biotechnology department at Madison College. She can be reached at jean.schoeni@covance.com or 608.210.5386.

**CONTACT US**

Covance Microbiological Laboratories  
855-83 MICRO  
(855) 836-4276  
marlo.dobrient@covance.com

**UPCOMING EVENTS**

**HACCP Certification**  
March 17-19  
Covance Laboratories  
Madison, WI – Learning Center

June 16-18  
Covance Laboratories  
Madison, WI – Learning Center

October 6-8  
Covance Laboratories  
Madison, WI – Learning Center