

Bridging the CGMP Gap Between  
the U.S. Government, Academia, and the Food Industry

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In recent years, international attention has been directed towards food safety and the prevention of foodborne illnesses. According to the World Health Organization (WHO), millions of people worldwide suffer from food-borne diseases and illnesses resulting from the consumption of contaminated food which has become one of the most wide spread public health problems in the contemporary world (WHO 2007). Members of the food industry – meaning anyone from large mega-companies to small mom-and-pop operations – have felt the pressure of standardizing their food firms to conform to the Current Good Manufacturing Practices (FDA 2005). These are a set of regulations instituted by the U.S. Food and Drug Administration (FDA) and enforced by local, state, and federal agencies.

CGMPs directly regulate important aspects of the food industry including processors, manufacturers, transporters, warehouses, retailers or combination food firms. Contamination can potentially occur at every point in the food chain from harvest or slaughter to processing, storage, distribution, retail, final preparation, and serving. The CGMPs were established in the first place to guide, inform, and streamline this process, but are based on such issues identified by experts who cite deficient employee practices and training; poor plant and equipment sanitation; and poor plant maintenance, design, and construction, as food safety problems faced by members of the Food Industry. These are fundamental points that government in collaboration with industry must address in order to provide the public with a safe and wholesome food product from processing to consumption.

Case in point, the tainted peanut butter salmonella outbreak of 2008-2009. This was a major precursor in the government for increasing its focus on risk-based assessments.

Over a period of time, based on the risk-based assessments, it became imperative that more time and resources be directed to science, research, and food industry training. These measures were considered crucial in reducing potentially deadly offenses of foodborne illnesses in the future.

To date, readily-accessible technical information has been essentially limited to training guides provided by regulatory agencies, associations, and academia. While regulations aim for facts and generalities it would seem that most individuals initially comprehend them subjectively at best. Though beneficial for general inquiry and research, most of this material lacks specific information such as the selection, use, and frequency of appropriate cleaning methods, equipment, cleaning compounds, and sanitizers for maintaining hygienic conditions in food processing, preparation, and holding facilities; record-keeping guides for temperature and sanitation; most effective methods for insect and rodent control; and in-depth allergen control measures.

Out in the real world, most government inspectors/investigators are faced with the question, “Why do I have to do it that way?” or “How does this pertain to what we do in our business?”. Better yet, they may hear “I have been doing things this way for x number of years and none of my customers have ever gotten sick”. These questions and statements are only a small example of the disconnect that exists between industry, regulators, and their respected members. The solution lies within the verbiage, or more importantly, communicating the importance of the science behind the regulations, without sounding too scientific.

In communication theory, one of the most important aspects is to always remember who the audience is at all times. In this case, the audience are members of the food

industry who are expected to translate the knowledge of the CGMPs into practice. The goal of this research is twofold; to effectively communicate the need and nature of the CGMPs and to simply reconnect the regulations to the audience they were developed to assist. Further, a definition of perception is an individual's capacity for comprehension. We find that in the real world, an individual's comprehension does not always neatly fit inside the perimeters that the CGMPs provide. In some cases compliance with regulations does not allow for continuation of traditional processing methods, short-cuts, and individual bias when it comes to how firms may prepare, process, hold, and ship food products. That leaves it up to the government to find a means to bridge the gaps that exist between comprehension, perception, and reality. The main focus is to present information so that the ordinary person can understand and act upon the regulation on a consistent basis. The answer may lay not in the regulation itself, but Food Industry members' ability to relate to and understand the need for compliance.

By way of a historical background into the implementation of the CGMPs, around the beginning of the 20<sup>th</sup> century, the United States' primary causes of foodborne related illnesses and deaths were due to unsanitary processing and packaging of food, water, and milk products. In response, the United States Congress passed the Pure Food and Drugs Act in 1906, as a safety measure in an attempt to manage dangers inherent in the U.S. food supply. The passing of this legislation marked the first major federal consumer protection law with respect to food processing. The simple intent of the Act was to prevent poisoning and consumer fraud.

In 1938, after a battle about USDA jurisdictions with respect to the Act's enforcement, the Food, Drug, and Cosmetic Act (FDCA) replaced the 1906 Act, providing the

necessary identity and quality standard to protect consumers from fraud. This is important to note, as the FDCA laid the groundwork for today's food CGMPs.

Three interrelated issues arose during their development of the CGMPs that significantly shaped their current form: (1) there was concern that the regulations were unduly stringent and burdensome for small food companies without necessarily improving quality or safety of foods; (2) the contention that the regulations must prescribe conditions that reasonably relate to unsanitary conditions that may contaminate food and render it injurious to health; and (3) the last issue was the assertion that regulation did not have the force of law.

While most of these issues were resolved by the use of more general terms in the language of the regulations such as "adequate," "sufficient", and "suitable", the enforcement matter was rectified when the CGMPs were finalized in April of 1969 and published as part 128 of the Code of Federal Regulations (CFR). In 1977, Part 128 was recodified and published as Part 110 of the CFR.

The final product was a GMP regulation that was deemed very broad, not specifying what exactly a facility must do to comply, which naturally created enforcement problems for FDA and their state and local government counterparts. The FDA combated this issue by improving on the GMPs by making them a little more specific and detailed. These changes were finalized in 1986 and printed in 21 CFR 110, giving more in-depth regulation instructions in CFR parts 100 through 169.

The long-standing problem that has plagued the FDA and its quest to minimize the threat of foodborne illness and disease has not been the regulations themselves, but how they are communicated, understood, and enforced. The initial CGMPs left room for open

interpretation by firms and suppliers, thus presenting a challenge for government officials to enforce the law when violations occurred. The above-mentioned issues and perceptions that arose during the development of the regulation still surface today, creating a barrier of misunderstanding between the government and the Food Industry that fall within the jurisdiction of Title 21 of CFR 110.

The CGMPs cover every aspect of the food safety web. From employee personal hygiene and training; general maintenance of physical facilities and plant design; pest control; having and maintaining a potable water supply; cleaning, sanitizing, and storage of equipment and utensils; to quality assurance assessments. Each part and sub-part applies to all food processing and holding facilities, regardless of size, that handle FDA regulated food products.

The Code of Federal Regulations concerning the GMP's can be a daunting read for both employer and employees, but the information within the code is vital for public safety. Unfortunately, a majority of this knowledge can be lost in a world of generalities and misunderstanding of what is deemed compliant. In an effort to bridge what is expected and what is understood, it is important to match the regulation to the issues as they apply.

Employees are a food firm's greatest resource and at the same time it's greatest risk. Knowledgeable, well-trained, workers can ensure operational and financial success for the firm beyond measure, while generating corporate and public perceptions of trust and efficiency. However, those same workers can have a dire effect on not only business efficiency but also overall public health and safety, if they are not properly trained in the safe handling and personal hygiene procedures of the CGMPs. According to a recent

scholarly article, “An estimated 75 million cases of foodborne illness occur annually in the United States. A large majority of [foodborne illnesses] result from poor hygiene practices. For example, it has been documented that between 30 percent and 50 percent of persons do not wash their hands after using the restroom. Proper training of employees is the primary means to reduce food contamination in a processing plant” (Keener, K. 2007). The most effective way for a firm to ensure clean sanitary food products is to make sure its employees are fully trained and understand the importance of adhering to sanitary standards of the GMP's.

**I am not allowed to work if I am sick or have an open lesion/wound. Why?**

The simplest way to answer this question is "Disease Control". If an employee is sick or has an open-wound the employee should not handle food, come in contact with food surfaces, or touch packaging. Although some employees may feel pressure to work while sick or injured, this level of irresponsibility could have dangerous and expensive long-term effects on not only the company, but also the employee and the general public. These precautions are vital on all accounts but especially for those employee's who handle ready-to-eat food. The liability is greater on the employer, as it is responsible for giving employees adequate time to recover if their role puts them in direct contact with food. According to a news article in the Food Safety News (2012), an example of this occurred during a Norovirus outbreak in Blackford County, Indiana as recently as January 2012. Through surveillance work by government officials, it was determined that several employees of a Subway restaurant worked despite experiencing nausea, diarrhea, and vomiting. The outbreak involved 90 known victims who developed gastrointestinal

symptoms similar to the employees. Marler Clark, a Personal Injury Law firm, currently has the case in litigation.

Body fluid such as saliva, mucous, and blood released from the body during a sneeze, cough, open cut, or open sore can attach to food, food prep surfaces, and equipment. Once bacteria is introduced into the environment and onto surfaces, risk of exposure to other employees and customers increases tenfold. This bacteria becomes a breeding ground for viruses such as salmonella or norovirus and can have adverse affects to staff and consumers. In conclusion, if an employee who handles or comes into direct contact with food is sick for any reason, they should stay home, or be assigned to other tasks. whreby no contact with food or food preparation surfaces. Communication between the employee and management should always be consistent when it comes to this important measure of food safety, as the only way to ensure healthy, clean and sanitary food, is to train and maintain a healthy, clean, and sanitary staff.

### **Why are there regulations on hand washing and personal cleanliness?**

The Center for Disease Control and Prevention (CDC 2012) states, "Hand washing is easy to do and it's one of the most effective ways to prevent the spread of many types of infection and illness in all settings – from your home and workplace to child care facilities and hospitals. Clean hands can stop germs from spreading from one person to another and throughout an entire community." With that being said, hand washing is one of the most efficient and often over-looked actions to prevent the spread of disease and illness.

According to a joint publication between WHO and UNICEF (UNICEF and WHO 2009), nearly 1.5 million children under the age of five die each year as a result of

diarrheal diseases and respiratory infections stemming from inadequate sanitation, poor hygiene practices, and water quality. This makes diarrhea the second largest cause of death among children in the developing world. Human feces are the primary source of diarrheal bacteria, such as gastro-enteric infections, and some respiratory infections, such as pneumonia.

Often associated as being water-related, diarrheal diseases are primarily a result of fecal material entering the oral cavity. Human feces equating to approximately one gram can contain approximately one million bacteria and roughly 10 million viruses. These bacteria make people sick when they enter the mouth by way of hands that have been in contact with feces. These living organisms are then spread from an infected person to an uninfected person using various routes/vectors. Hands are a common vector for the transmission of fecal-oral diseases (Curtis, Cairncross, & Yonli 2000). Handwashing with soap after using the bathroom and before and after food handling can interrupt this diarrheal cycle. Acting as a vector, hands transmit disease-causing bacteria from person to person through direct contact or indirectly through surfaces and foods. Correctly handwashing with soap and clean water interrupts the disease cycle. By washing hands with soap and clean water for a specified time, the risk of diarrhea is significantly cut “from 30 percent to 50 percent” (Fewtrell et al., 2005) and that of respiratory tract infection “from 21 percent to 45 percent” (Curtis, V. & Cairncross, S. 2003). Handwashing will ultimately create a barrier between fecal matter, people, and food products, thus impacting and protecting them in the long run.

Handwashing with soap therefore embodies the foundation of public health. It is a low-cost and easily available practice that can be used to reduce the threat of harmful

bacteria from entering the food chain and infecting multiple people. This single practice can help to prevent the spread of disease by interrupting the spread of bacteria that cause disease. Together, soap and water form a challenging bond in attempts to rid a person of foodborne illnesses.

Handwashing with soap at key times has been shown to decrease the incidence of diarrhea in the general population by 48% (Cairncross, S., Hunt, C., Boisson, S., Bostoen, K., Curtis, V., Fung, I., & Schmidt, W., 2010) making it the most cost-effective of all major disease control interventions (The World Bank & WHO Disease Control Priorities Project).

Another important issue to consider is the impact that handwashing can have on a business. Handwashing with soap can mean more work days for employees. Each year children and adults miss countless days from school due to diarrheal illnesses. By integrating more frequent handwashing with soap in their daily routines, absenteeism from school and work could be drastically reduced. A study conducted by Bowen suggested that handwashing with soap at critical times could help reduce school absenteeism by around 42 percent (Bowen et al, 2007).

The CGMPs (CFR 2012) state that "Hands must be thoroughly (and sanitizing if necessary to protect against contamination with undesirable microorganisms) in an adequate hand washing facility before starting work, after each absence from each work station, and an at any other time when the hands may have become soiled and contaminated." Like medical professionals who scrub in and scrub out during a medical procedure, the same is expected of food handlers, whose role from preventing the spread

of bacteria and disease is just as important, and the code offers no leeway on the issue. Bacteria and germs occur naturally in body fluid, so proper hand washing when employee return from the restroom facilities is imperative. In a research article by the CDC, Norovirus accounted for 42% of all foodborne outbreaks, with 65% being transmitted by an infected carrier and 35% being attributed to bare-handed contact with food (CDC 2012). Employers can aid in hand washing education for employees by describing the correct amount of soap to use, water temperature, and lathering time.

In addition to handwashing, fingernails pose a risk to food firms. In the article, research was performed on 41 nurses with 21 wearing acrylic nails and 20 who wore their natural nails. After washing their hands and using an alcohol-based gel, harmful bacteria were found on “68 percent of those with acrylic fingernails” (Journal American Dental Association 1999) versus “26 percent of nurses without artificial nails” (Journal American Dental Association 1999). According to this same article in the JADA (1999), “researchers said the use of artificial nails by healthcare workers may increase the chances that harmful bacteria will be transmitted to patients and cause infection”.

### **Why do I have to wear all of this excess clothing?**

Under section (B) of the CFR outlining the guidelines of Cleanliness, the topics of hand washing and personal cleanliness have been addressed. Section B gives a list of (9) specifics that deal with cleanliness and while each one can be dealt with individually, for the purpose of dealing with this question we will group the remaining specifics together.

To answer the main question of this section, the proper labeling of excess clothing will be given its proper name of Personal Protective Equipment (PPE) (i.e. clean outer garments, hair guards, in-tact & impermeable gloves (optional), etc.). Again, the answer

to this question is the PPE's provide an additional protective barrier between the food, food contact surface, equipment, and the employee. They prevent bacteria, dirt, and debris from the employee's clothing or body from being transferred to any food product or device. In short, no one wants hair and any of its bacteria, old food particles, grime, threads, or buttons that fell off of an employee's shirt in their food or products. Any of the following events could endanger consumers, not to mention engulf one's business in expensive legal lawsuits and regulatory overview.

### **What is wrong with wearing my jewelry at work?**

The follow-up question about jewelry is just as straight-forward as the issue of protective clothing. An employee's unsecured jewelry can fall into food, equipment, and containers, resulting in serious consequences for the consumer. This serves as a physical hazard. What most people do not realize is the bacteria that live and proliferate on jewelry, especially rings. Rings are worn everyday and many people assume that handwashing is enough to remove any threat of harmful bacteria. The truth is that rings – plain wedding bands or intricate rings with stones, cuts, and grooves – harbor germs that can lead to the transmission of foodborne and other diseases.

Hands are already a haven for bacteria. There have been a number of studies conducted on the type and number of bacteria that remain on fingers where rings are present after handwashing. According to research conducted by Yildirim, I., Ceyhan, M., Cengiz, A., Bagdat, A., Barin, C., Kutluk, T. & Gur, D. (2008), “ring wearing increases the bacterial colonization of hands and alcohol-based hand disinfection might not significantly reduce contamination of the ring-wearing hands. The type of ring did not

cause any significant difference on the bacterial load. Wearing rings could increase the frequency of transmission of potential nosocomial pathogens.”

Recognizing such potential physical and bacteriological issues, the CGMPs require the removal of all jewelry. It is noted that if jewelry can not be taken off then it must be covered with a material that can be maintained in a clean and sanitary condition, to prevent cross-contamination. Though not in the main question, the CFR wraps up by explaining that clothing should always be stored in appropriate areas, other than where food is exposed or where equipment or utensils are being washed. Furthermore, employees should fully utilize their respective break rooms when it comes to consuming food, drinking beverage, chewing gum, using tobacco, etc. These actions are not to take place in any food prep area or where equipment is being stored or cleaned. The primary reason is that each action requires use of the hands and mouth thus creating another potential source for contaminating food products.

### **Who's Responsibility is it for me to be trained on the GMP's?**

The answer to this question is that the responsibility is "Shared." The U.S. Food and Drug Administration establishes and enforces the CFR along with their state and local counterparts, as well as provides guidance and training on means to maintain compliance with the regulations. The employer has the responsibility not only to inquire and become knowledgeable of all operational regulations, but also to pass this knowledge onto its employee's. Once employees are properly trained, it is each individual employee's responsibility to ensure that they are carrying out proper food safety behaviors on a daily basis. According to Green (2008), “Most food safety interventions provided knowledge to food workers with the expectation that workers will translate this knowledge into

practice”. Once employees have been trained on proper methods and practices of safe food handling and personal hygiene the focus shifts back the employer again to ensure training supplied on a consistent basis by knowledgeable and experienced supervisors (Keener, K. 2007). This includes conducting regular inspections of employee's hygiene and hygienic work habits. Violations should be handled as disciplinary actions and incentives given for superior efforts. Clayton, D., Griffith, C., Price, P., and Peters, A. (2002) found that 63% of food workers admitted they did not always carry out the food safety behaviors that they knew they should”. It is also the employer’s responsibility to ensure sanitary facilities and products such as soaps, disinfectant, working sinks, hairnets, etc, are properly stocked (Keener, K. 2007). If one link in the chain is overlooked or broken, the consequences can be severe. According to Green (2008), “Human behavior is complex, and multiple factors, not just knowledge, affect whether humans engage in any particular behavior”. Every entity and individual plays a role in the process from writing the regulation, training, compliance, and enforcement, it is all relative to larger goal of clean, sanitary, food products to consumers.

**If the inside of the operation is clean, why do I need to worry about if the grass is cut?**

It is often stated by individuals in the general public, "If that is what that place looks like on the outside, I really don't want to know what the inside is like!" Although, this is just a common observation, it is a major concern when food safety and sanitation is involved. CFR 110.20 (a) states, "Grounds about a food plant under the control of the operator shall be kept in a condition that will protect against contamination of food." To answer the question, filthy and unsanitary grounds, can ultimately lead to filthy and

unsanitary inside conditions. The following recommendations are a few ways to ensure an entities plant and grounds are in compliance with CFR standards.

Proper storage of equipment, removing litter, and waste, and maintaining grounds by cutting weed and grass around the immediate area not only increases the physical beauty of the facility, but also more importantly discourages the attraction of pests. Appropriate management of outdoor spaces is also necessary for any road or entry ways, parking lots, or additional area where food may be exposed.

Finally, and most important, ensure that proper draining areas are serviced and maintained to prevent seepage, foot-borne filth, or provide breeding places for pests (CFR 2012). Though these measures sound like simple actions, they are often overlooked or their importance downplayed, however, if found out of compliance, a food firm can pay a costly price. For example, *Listeria Monocytogenes* can thrive in floor drains, wet or damp floors and walls, and within the grooves and on door handles of food manufacturing plants. According to Kozak, J., Balmer, T., Byrne, R., & Fisher, K. (1996), “It has become readily apparent that transmission of foodborne listeriosis to man is primarily the result of environmental contamination and the ease of transmission from the environment to animals and food contact surfaces. Therefore *L. monocytogenes* should be considered an environmental contaminant whose primary means of transmission to humans is through foods which become contaminated during production and processing”. Though not the only mode of contamination, science has shown this to be one of the more prevalent paths. Consider this example as a potential source of contamination. *L. monocytogenes* is currently living in the drain of a food firm. At the end of the production day, an employee using a spray hose to clean the floors. This action

aerosolizes and deposits the bacteria on and in surrounding structures like equipment, walls, door handles, as well as on the working tables. A study conducted by Shale, K. & Lues, J.F.R. (2007) discussed the following:

“In food processing, food may be contaminated as a result of bioaerosol pollution. Bioaerosols can exist (a) as “passengers” on solid dust particles, on skin, hair, clothing, or suspended in the air during frequent vigorous physical activities such as slaughtering, carcass dressing, and deboning; (b) within droplets formed by the aerosolization of water spraying/splashing during food processing or the cleaning process; or (c) as single organisms or micro-colonies remaining in suspension after dissipation or evaporation. Bioaerosol contamination of food products may have a serious impact on product quality and shelf life, and may pose a public health hazard especially where pathogens are involved”.

### **Why are you concerned with my plant’s construction and design?**

If any individual has ever witnessed or been inside a facility that is cluttered, full of rusted barrels, or rotting-molded pallets at the rear door, they have been subjected to improper facility construction and design. Sufficient space for equipment placement and storage, is a key component in maintaining sanitary food manufacturing. If any individual has ever walked inside a facility and wondered why an old swinging door is the only barrier separating the outside environment from the food prep and packaging floor, they are witnessing improper plant design. In the aforementioned, scenario the propensity for contamination is at an all time high, based on poor location and partition of work areas. Effective layout design of a firm, ensures proper sanitation measures can be established and expanded if needed, even monitoring how and where employee's are

entering, preparing for work, and exiting the facility, affects safe food preparation and packaging.

The CFR states that surfaces in a firm should be smooth and easily cleanable, and leaves the option of choosing the surface up to the individual firms. This is important as cracks, crevices, and grooves of any kind can spell disaster for a firm. Most individuals are unaware that a crack in a floor or wall can contribute to bacterial growth. They are also unaware that certain materials, like wood, can contribute to bacterial growth more so than others, like stainless steel. An article in the Food Safety Consortium newsletter (2009) discussed research from the Food Safety Consortium at Kansas State University that found that by washing floors and especially around floor drains in food manufacturing facilities that *L. monocytogenes* can easily travel from the drain to food contact and non-contact surfaces. This is accomplished by using high-pressure cleaning procedures to remove dirt and debris from the floor and drain surfaces. They further discovered that “aerosols generated by the washing can transfer the bacterial cells upward onto surfaces where food is being processed a few feet above the floor”.

De Wit, Brekhuizen, and Kampelmacher (1979); Humphrey, Martin, and Whitehead (1994); Humphrey, Martin, Slader, and Durham (2001); Y. Chen, Jackson, F. Chen, and Schaffner (2001); Gorman, Bloomfield, and Adley (2002); De Cesare, Sheldon, Smith, and Jaykus (2003); Kusumaningrum Riboldi, Hazelberger, and Beumer (2003); Moore, Sheldon, and Jaykus (2003); and Rayner, Veeh, and Flood (2004) discussed food contact surfaces have the potential to act as reservoirs for bacteria over extended time periods, and they have been shown to transfer pathogenic bacteria to food”. (as cited in Dawson, P., Han, I., Cox, M., Black, C., & Simmons, L. 2006).

**What role does ventilation and lighting play into my firm's compliance with the CFR?**

If an area is not properly ventilated it is not only harmful to the food product, but to the individual preparers. Seppanen and Fisk (2001) and Philomena, Bluysen, Seppanen, Clausen, Miller, and Roulet (2003), “indicate that IAQ (known as indoor air quality) has much relation to the ventilation and air-conditioning system of building (as cited in Li, A., Liu, Z., Liu, Y., Xu, X., & Pu, Y. 2011). Li et. al (2011) discussed how the HVAC system was used to supply fresh air and remove the pollutants caused by the activity of occupants, the equipment of furniture and the materials of decoration. However, the modern large building is so airtight on account of energy saving”. This leads to the HVAC system not being designed or maintained in a manner conducive to the space or building that it is servicing. As a result, it often can turn into the source of indoor pollution leading to adverse health issues. According to Li et al. (2011), “Air ducts have supplied hotbed for microorganisms. The reproduction of microorganism releases various metabolic products such as odors, toxin and allergic substance which can transmit to the whole building with wind and intensify the microbial contamination of indoor air”. Furthermore, Foarde, K. & Menetrez, M. (2002) stated, “Depending on the amount of dirt (particles of dust or powder food product, the material, and the environmental conditions, the HVAC system may become an active growth site for microorganisms and a source of biological contamination” (as cited by Othmane, M., Havet, M., Gehin, E., Sollicec, C., & Arroyo, G. 2011).

Enough emphasis cannot be placed on proper ventilation and cleaning of the ventilation system in order to reduce, if not eliminate, the spread of harmful bacteria.

Bacteria such as *Listeria monocytogenes* thrive in the water located in air conditioner condenser pans. As condensate builds on the pipes, equipment, and area around the unit, the bacteria can eventually be deposited or aerosolized directly on raw materials, in-process or finished food products and food contact surfaces. This poses a threat to any food product being manufactured or held in a facility.

The CGMPs mention proper lighting in hand-washing areas; dressing and locker rooms; bathroom facilities; all areas where food is examined, processed, or stored; and where equipment or utensils are stored and cleaned. For individuals who are wondering why such emphasis is placed on lighting in these areas, the answer is as follows: If one cannot properly see where contamination is or may occur, they will be unable to properly maintain the areas. In addition, the use of lighting assists in deterring certain pests such as, but not limited to, roaches and rodents from entering the facility. Eliminating hiding places eliminates the threat of contamination. Finally, the ideal lighting solution would consist of safety-type light bulbs, fixtures, skylights, or other structures that create a barrier between the light source and exposed food. This assists in eliminating the potential for glass from the light bulbs coming into contact with the food and food contact surfaces.

#### **What should I know about substances used for cleaning and sanitizing my firm?**

The focus of this part of the regulation that should be paid close attention to is the chemical agents used to properly clean the food facility environment, utensils, and equipment. Cleaning compounds and agents should always be stored in a clean place and kept safe for use according to each product's instructions. Over the years, numerous studies have been performed that evaluate the effectiveness on reducing bacterial loads.

Thormar, H. & Hilmarsson, H. (2010) discussed such studies in their research by stating, “cleaning with disinfectants such as hypochlorite was found to significantly reduce the number of viable bacteria on contaminated kitchen surfaces, whereas cleaning with detergent and hot water was much less effective”.

The code vaguely discusses the types of cleaning agents, which can be used or stored in a plant where food is processed or exposed. Instead, it lists categories of agents required to maintain clean and sanitary conditions, those necessary for laboratory testing procedures, those used for plant and equipment maintenance and plant operations. The ball is placed in the firm’s court to research which products would work best for their operation. With the use of the internet or through a company representative, a firm can determine what would be permissible in a food operation. Material Data Safety Sheets (MSDS) have become more accessible to the public. Enforcement agencies often ask firms to know what products they are using in their operation to ensure that they are safe.

It is a good idea to label and identify all toxic cleaning compounds and sanitizing agents and to store them in a location where they will not potentially contaminate food or food contact surfaces.

### **Why is pest control mentioned so frequently in the regulations?**

. The CGMPs focus on pest control in order to task firms to take proactive steps to prevent the introduction of pests in their firm. Blazar, J., Lienau, E. & Allard, M. (2011), stated “Foodborne pathogens survive for some time outside their environmental reservoir, insects can be physically infected upon contact with fecal matter or other poorly monitored biohazards teeming with foodborne pathogens and then physically carry these pathogens”.

Serving as a contributory factor in the spread of foodborne diseases, their presence around food has always been unacceptable. According to Blazar et al (2011), “The potential presence of foodborne, pathogenic bacteria, such as E. coli and Salmonella spp., in insects may be in part responsible for the public health issue that the United States currently faces”. Unfortunately, it is not uncommon for rodents and insects, to find their way into a food plant, especially if the facility is not kept in a clean, sanitary manner to prevent these unwanted visitors or if structural vulnerabilities exist. Pests are known to be vehicles of disease, cause destruction to property, contamination of work surfaces and food products, loss of reputation due to low public opinion, potential government enforcement like closure or fines, and poor employee relations.

To drive the idea home, take a glance back in time to the Bubonic Plague. According to history, one only has to remember the outbreak of the Bubonic Plague that sent Europe into the dark ages during the 1300's due to flea bites that were carried by infected rats that were transported in grain ships from China (Themiddleages.net 2007). The plague wiped out one-third of Europe's population at the time. Put that in real time numbers and imagine two billion of the Earth's six billion habitants falling ill and dying in a matter of hours. Now fast forward to present day and imagine an infected pest infiltrating a food plant food area. Distribution is above and beyond what it was during the plague. The infected products being distributed to the general public could result in an epidemic of mass proportions.

### **What Are Steps I Can Take in Effective Pest Prevention?**

While there are many actions a firm can take in pest prevention, here are some common actions a firm can utilize for effective pest control. Good hygiene, increases in

inventory management, and exclusion practices should be given utmost importance in pest prevention. This mirrors information presented in the CGMPs. Site personnel have the day to day responsibility of these actions being carried out, but the commitment takes initiative from executive management on down. Educational posters in multiple languages to address language barriers that disrupt communication, reporting and recordkeeping to track GMP compliance such as pest observation logs and pest control reports containing treatment dates, pests found, pesticides used, etc are just some ways that a firm can increase pest prevention. Yes, it may cost initially, but it pays off in the long run.

**What should I know about the sanitation of the various surfaces in my firm?**

The CGMPs state, "All food contact surfaces, including utensils and food-contact surfaces of equipment, shall be cleaned frequently as necessary to protect against contamination of food. (CFR 2012)

Non-food contact surfaces of equipment should be cleaned as frequently as necessary to prevent contamination. According to Verran, J (2002), "The tendency for a surface to facilitate the retention of micro-organisms is highly undesirable because the presence of the micro-organisms poses a biotransfer potential (as cited by Verran, J., Packer, A., Kelly, P., & Whitehead, K. 2010). The texture of the surface in question plays a role in bacteria proliferating in the food environment due to not being able to be thoroughly cleaned. According to Scheurman, T., Camper, A., & Hamilton, M. (1998), "Increased surface roughness will additionally provide features such as pits and scratches which will increase the area for attachment" (as cited by Verran, J., Packer, A., Kelly, P., & Whitehead, K. 2010) and further supported by Jullien, C., Benezech, T., Carpentier, B.,

Lebret, V., & Faille, C. (2003) and Taylor, R., Maryan, C., & Verran, J. (1998), “Surfaces with many defects of uneven dimension and distribution have poor cleanability and are more likely to remain more soiled than those with a more ‘designed’ topography, because of an increased number of retention sites for soiling components and micro-organisms” (as cited by Verran, J., Packer, A., Kelly, P., & Whitehead, K. 2010).

Food equipment's food contact and non-food contact surfaces have been researched and found to be documented as significant vehicles of cross-contamination throughout the food chain. Prior to one food coming into contact with remnants from another food, it is imperative that the total unit be thoroughly cleaned as contamination can exist throughout the equipment such as in grooves, bolts, trays, or blades. In a study performed by Papadopoulou, O., Chorianopoulos, N., Gkana, E., Grounta, A., Koutsoumanis, K., & Nychas, G. (2011), they found that foodborne pathogens from one meat product using in a meat mincing machine were deposited on a piece of meat that did not harbor pathogens prior. In addition research performed by, Tang, J., Nishibuchi, M., Nakaguchi, Y., Ghazli, F., Saleha, A., & Son, R. (2011), concluded that both rubberwood and polyethylene cutting boards remain a potential vehicle of contamination due to the transfer of their target bacteria, identified as *Campylobacter jejuni*, due to the transfer of bacteria from contaminated raw meat to board and from the cutting board to the cooked meat.

“The use of single service articles such as paper cups, paper towels, and utensils are often abused in the food industry. Many food establishments will touch the parts of the utensils that will enter the mouth with their bare hands. At Farmer’s Markets, we find that they also place the utensils in an upright position and patrons tend to touch more than one as they try to grab one. We also have the issue of insects contaminating the utensils”.

(Anonymous, personal communication, July 13, 2012). According to my source, who is a member of a local health department within the Commonwealth of Virginia, it is best to store single service items in a covered container and provide them to patrons upon request. Being that these products are created for single use and then trash, they should be viewed and treated in that manner in order to reduce contamination from occurring. Many people tend to reuse plastic ware and then end up contaminating community tables, etc.

### **How Important is My Water Supply and Plumbing?**

Close attention should always be paid to the water supply at a food firm. The food industry has long been a large consumer of water, utilizing it to meet their day-to-day needs. It is used for a multitude of functions such as, as an ingredient; a direct food contact source (i.e. blanching, steaming, soaking, rinsing, cleaning, conveying, and chilling); and as a primary agent in the cleaning and sanitizing of food contact and non-food contact surfaces, machinery, and utensils. As a result, it is essential that the water used be potable, tasteless, odorless, colorless, and free of contaminants such as metals and especially organisms. According to Arnone, R. & Walling, J. (2007), “The primary pathogens of concern in the US are bacteria, protozoa and viruses”. Budzinska, K., Wronski, G., & Szejnuik, B. (2012) stated, “Water can play an important role in transmission of the bacteria *Listeria monocytogenes*, which causes a disease dangerous for people and animals called listeriosis”.

Even though water is a major component of the food industry, it can also become a powerful source of contamination and illnesses. According to Arnone, R. & Walling, J. (2007), “The majority of large-scale waterborne disease outbreaks in the past have been attributed to human contamination or inadequacies at water treatment plants”. They go on

to state, “The sources of most waterborne pathogens are human and animal feces from infected individuals, and from human and animal carriers”.

Illnesses related to the water can be a result of lack of sanitation, increased water loving insect populations, chemical seepage, lack of hygiene, or a break down of the wastewater treatment systems. Even unused pipe ends, often called dead ends, can trap water and serve as a hotbed for the growth of harmful bacteria. According to Arnone, R. & Walling, J. (2007), “Exposure pathways for pathogens in drinking water include ingestion, dermal contact and inhalation. Failures in water treatment systems and the inability of disinfection procedures to inactivate all pathogens allow these microorganisms to remain in the finish water”.

The GMPs (CFR 2012) state, “The water supply shall be sufficient for the operations intended and shall be derived from an adequate source. Any water that contacts food or food-contact surfaces shall be safe and of adequate sanitary quality. Running water at a suitable temperature, and under pressure as needed, shall be provided in all areas where required for the processing of food, for the cleaning of equipment, utensils, and food-packaging materials, or for employee sanitary facilities.” The use of the term “adequate” is most often associated with “potable” water. This stems from joint efforts between federal, state, and local agencies and relates to municipal and well water supplies.

To this end, plumbing plays a vital role. Viewed as a closed system, care should be taken to prevent cross-connections between potable and non-potable water (or waste) systems thus further creating contamination of potable water. Cross-connections have been found to exist in such places as hard plumbing between potable and non-potable water lines, water hoses that do not have backflow prevention devices, and water hoses

left lying on the floor in a pool of water. All of these examples allow clean water to be compromised by exposing it to harmful bacteria.

Water and plumbing must also be monitored frequently to enable the food firm to quickly correct a potential issue of contamination. Municipal water systems generally check for a variety of chemicals, naturally occurring contaminants, physical characteristics, and microbial pathogens. The type of testing and the frequency may be dependent upon the population served, source water type, and the supply type. A number of households utilize private wells as their potable water source. What many people do not realize is that some food firms also have their own private well systems. This requires testing periodically to ensure that the supply remains safe. The CGMPs do not give a definite time frame as to how often monitoring and testing should occur. It is highly suggested by the federal government that the water be checked on a yearly basis. State and local governments have more stringent requirements. If plumbing issues are detected, it is highly advised that monitoring (i.e. testing) be performed on a monthly basis.

### **Why does my inspector focus on the restrooms?**

Think of an employee restroom as a high risk environment. This is the one room within the enclosed building where biological waste convey from humans to the waste/sewage system. This is where correct plumbing moves it away from the food plant, while never coming in contact with potable water, to a location where it can be disposed. Unfortunately, the movement of the waste product is not always as effective and sanitary as desired. Just by flushing the toilet, a flurry of aerosolized organisms from the waste are released into the air and land on the employee (i.e. hair, clothing, shoe soles, and jewelry), walls, floors, door handles, soap dispensers, and any other surface within the

restroom. The fecal transfer continues as they flush handles, touch soap dispensers and door knobs, rub their fingers through their hair, and even brush up against the building structures. Microorganisms are continuously transferred from one surface.

This is where employee hygiene practices, restroom proximity to the food manufacturing or holding areas (i.e. plant design), and sanitation play vital roles. As an employee leaves the restroom area, they continuously shed these organisms and allow them to deposit on food contact and non-food contact surfaces.

In addition, this room is connected to other rooms within the food plant through the air ventilation system. So odors and bacteria can also travel via the air and contaminate food products, multiple surfaces food contact and non-food contact surfaces, and employees.

### **Why Are You Focusing on My Trash Receptacle and Dumpster?**

When it comes to facilities and sanitary control, some important issues for firms to remember revolves around water, plumbing, drainage, and sewer and trash disposal. Focusing on the latter, trash receptacles and pest control feed off of each other. Think of the trash as an attractant for pests in that it can be a breeding and feeding site.

Do you remember the school age song “Shoo, Fly Don’t Bother Me!” Most people just sing the chorus over and over again. In it, the singer repeatedly asked the fly to get away from him. Known as a nuisance or pest, flies have habits closely linked to the spread of microorganisms. For example, science has shown that as flies land on their target surfaces, flies often feed and lay eggs on feces and garbage remains. They then travel from the trash site to the inside of firms where they come into contact with exposed food products and food contact surfaces. Immediately upon touching such surfaces, flies are able to throw-up the contents of their stomachs on the food. This enables them to turn

the food into liquid so they can easily eat. In addition to eating on the food and surfaces, flies also empty their bowels on them. These habits aid in the spread of organisms that could be potentially harmful to humans. For this reason, firms are encouraged to continuously monitor their work area both inside the facility and outside. The use of trash bags that close tightly and containers with a tight seal prevent pests from access and thus inhibit the activities such as the one above from occurring. Exterior sites where waste is stored, like dumpsters, should be kept as far away from the building as possible and frequently emptied to prevent various pests from feeding and living on the premises.

Man, beast, insect, and microbe inhabit Earth. With such a vast array of life forms constantly competing for land, food, and water resources, foodborne related diseases, among others, have had an opportunity to flourish. Due to this competition, diseases are appearing at an increasing rate thus increasing the need for public awareness of health and environmental concerns.

For years, the government has attempted to serve as security for public health by attempting to reduce, if not diminish, vulnerabilities and threats observed from farm to fork. While some goals have been met in time, a majority are met with resistance. Some will say that this is due to globalization creating language barriers, increased food industrialization, environmental degradation, and good old economics; while others will simply attribute it to mindsets. All and more have played a role in increasing foodborne illness vulnerabilities and continual decreasing of communication between government, academia, and the food industry. To set government and the food industry on the right path, they must meet each other half way. This means talking to each other in a way that each can understand what the other wants and needs. Public health is a collective goal

and a shared responsibility. Successful implementation of the CGMPs serves to better the relationships between government, academia, the food industry, and the end user. It must be done to stronghold foodborne diseases from becoming a domestic and possibly an international threat.

Anonymous, personal communication, July 13, 2012.

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