

**Conference for Food Protection
2016 Issue Form**

Issue: 2016 I-041

Council Recommendation: Accepted as Submitted _____ Accepted as Amended _____ No Action _____

Delegate Action: Accepted _____ Rejected _____

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Issue History:

This is a brand new Issue.

Title:

Food equipment cleanability and design

Issue you would like the Conference to consider:

Contaminated food contact surfaces of food equipment are known to be a contributing factor to food borne disease transmission. At a minimum, food contact surfaces should be designed and formed of materials conducive to their effective cleaning and sanitation across their entire service life, not just the first day they were placed into service. At a minimum, these surfaces should have recommended cleaning and sanitizing protocols that include frequency, methods and means.

American National Standards Institute (ANSI) performance certification standardized tests are only performed on brand new (virgin) equipment, the surfaces of which are free of any wear and/or food residue/biofilm accumulation at the time of certification testing. There are no current ANSI Sanitation performance certification test methods to ensure that equipment food contact surfaces can be effectively cleaned and sanitized beyond the food equipment's first use.

Matrices of soils, including inorganic and organic matter accumulates on food contact surfaces, if not cleaned and sanitized with a specific frequency using effective methods can harbor opportunistic microorganisms of many species. These include the spoilers along with pathogenic bacteria and virus. A discipline of focused and continuous effort to clean and then sanitize these surfaces is needed to ensure a reasonable standard of care, especially in those operations that serve highly susceptible persons. The artifact definition of CLEAN (*to sight and touch*) is not sufficient for food contact surfaces that are inaccessible to sight or touch.

Equipment that requires clean and sanitize in place (CIP, or CSIP) processes to clean and sanitize food contact surfaces that are not readily accessible for inspection present the greatest risk from this gap in ANSI sanitation performance certification testing. Examples include internal food contact surfaces in ice machines such as its harvest plates, sumps and the potable lines interconnecting them. Risk is amplified when a carbon filter is placed upstream from the ice machine, which is often the case. The reference link #3 below

presents a table showing growth rates for biofilms in drinking water lines where there is no residual chlorine. Since carbon filters remove chlorine, this chart has direct correlation to wetted surfaces leading into and within an icemaker. Other reference links below provide evidence of growth and propagation of biofilms even in ice waters.

Other examples of food equipment that are dependent upon CIP processes that are ill defined in the code and within ANSI sanitation standards include the interior surfaces of product lines used to deliver jumpable Time Temperature for Safety Food 9TCS0 products from a walk-in refrigerator (for example) to a dispenser (or dispensing freezer); or condiments from a bag-in-the-box to the point of application, along with soda and juice dispensers.

Section 4-205.10 of the FDA Food Code states that equipment listed to an ANSI sanitation standard is deemed to comply with chapters 4-1 and 4-2. Such a listing *does not* however relieve the operator of their duty to comply with everything else in chapter 4 beyond 4-2, such as section 4-6 and 4-7 and the remainder of the code. It is unfortunate that Section 4-602.11 (E) (4) (a) and (b) introduce an arbitration in the science based safety of the code. Here is the current text:

(4) In EQUIPMENT such as ice bins and BEVERAGE dispensing nozzles and enclosed components of EQUIPMENT such as ice makers, cooking oil storage tanks and distribution lines, BEVERAGE and syrup dispensing lines or tubes, coffee bean grinders, and water vending EQUIPMENT:

(a) At a frequency specified by the manufacturer, or

(b) Absent manufacturer specifications, at a frequency necessary to preclude accumulation of soil or mold.

Coffee bean grinders, and cooking oil storage tanks have little in common with the other examples listed in this food codes criteria section as they do not relate to equipment designed to prepare, hold or convey liquid food products. This inconsistency creates an arbitrary circumstance that obfuscates hazards associated with food equipment with internal or external liquid food plumbing lines that otherwise lack inspection ports or access openings for all or most of the equipment's wetted food contact surfaces.

Section 4-205.10 (4) (a) (above) infers that following a manufacturers instruction for use of their equipment will ensure a reasonable standard of care. This is inaccurate. Though it is true that the manufacturer is strictly liable for their equipment design, this liability does not ensure food-safe equipment design. Few manufacturers of food equipment have conducted any kind of professional risk analysis, whether internally or a third party of the potential hazards to foods prepared or processed using their equipment across the life of their equipment.

Generally speaking, the industry pursues product certification to a large extent because it is the shortest well-traveled path to obtaining local approvals, nationwide. Their overall goal is compliance with local interpretations of adopted rules and regulations, and they rely upon the codes and standards development organizations to have their acts together to ensure reasonable minimum safety. We have let them down with this issue.

It is well known today that though a surface may appear "clean" to sight and touch it can still be contaminated with fats, oils and other invisible organic matter that both inactivates sanitizers and shields pathogens. In food equipment dependent upon clean and sanitize in

place (CSIP/CIP), surfaces can be coated with *Pseudomonas spp* (biofilms) and with them myriad other microorganisms. *Pseudomonas aeruginosa* is a gram negative, rod shaped pathogen common in almost all biofilms and is particularly dangerous to highly susceptible persons with diminished immune systems. *Pseudomonas fluorescens*, though less common and considered less virulent is known to continue to grow in waterlines and other fluid food lines at temperatures as low as 4 degrees Celsius (4°C/39.2°F).

Because the internal surfaces of small bore water lines and tubing common in liquid foodservice and beverage equipment (which includes foods such as potable water, ice, coffee, tea, juice, beer, wine, soda, etc) are inaccessible, there is no way of visually determining if biofilms are present. Without competent risk analysis as is now required in the Food Safety Modernization Act (FSMA) as described in the hazard analysis risk based preventative control (HARPC) regimes, there is no reasonable way to ensure that the manufacturers recommended cleaning and sanitizing protocols and frequency are adequate to ensure continuously sanitary food contact surfaces.

Hazard analysis critical control point (HACCP) regimes with their prerequisite programs (PRP's) and the new Hazard Analysis and Risk-based Preventive Controls (HARPC) programs with their Sanitation Standard Operation Procedures (SSOPs) provide a method by which reasonable interventions are put in place to mitigate risks to food. The fact that there are food contact surfaces that cannot be accessed for inspection, cleaning and sanitation by itself should be enough for any reasonable person concerned about public health and safety, to seek answers to the questions of risk, and to pursue improvement in poorly designed equipment with food contact surfaces that cannot be effectively inspected, cleaned and sanitized, or verified to be clean and sanitary. What is needed for equipment with inaccessible food contact surfaces is a risk based preventative control approach to ensure food safety.

Public Health Significance:

Failure to properly clean and sanitize food contact surfaces has been identified as a significant contributing factor to food borne disease transmission. Because the ANSI sanitation standards do not exist for testing food contact surfaces across their service life for continuous cleanability and sanitation suitability, the FDA Food Code needs to add new minimum safety criteria to fill the gap.

Section 4-602.11 has been used as a kind of catch-all waste basket for criteria that did not fit well in other sections of the code, or for things that are or were considered to be of lesser importance. For example, this section not only covers equipment used with liquid foods, some of which are TCS, but also coffee grinders and other equipment systems that lack similar microbiological risks. For these reasons we recommend that coffee grinders and the (hot) cooking oil systems be removed from this section entirely and replaced with examples of food service equipment with liquid food plumbing lines that depend upon a clean and sanitize in place (CSIP or CIP) capabilities to ensure clean and sanitary food contact surfaces. From a risk analysis, categorization and prioritization perspective, it is more appropriate that coffee grinders, meat saws, large cutting boards and other food equipment food contact surface too large to be cleaned out of place (COP) in a sink or dish washer should be subjected to in place cleaning (IPC) protocols, pursuant to their listings and the manufacturers instructions.

Reference links -

1. Control of Biofilm Growth in Drinking Water Distribution Systems
<http://infohouse.p2ric.org/ref/15/14291.pdf>
2. Phylogenetic and Functional Heterogeneity of Sediment Biofilms along Environmental Gradients in a Glacial Stream <http://aem.asm.org/content/67/2/799.full>
3. Water Contamination Emergencies Managing the Threats (see last page discussion) - <http://tinyurl.com/ntah4mg>
4. Spread of *Pseudomonas fluorescens* Due to Contaminated Drinking Water in a Bone Marrow Transplant Unit: <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3122780/>
5. Contaminated feeding bottles: the source of an outbreak of *Pseudomonas aeruginosa* infections in a neonatal intensive care unit: <http://www.ncbi.nlm.nih.gov/pubmed/19059675>
6. Other peer reviewed publications:
<https://www.yousendit.com/download/ZWJWR0IVNXZtNEs1eDhUQw>

Recommended Solution: The Conference recommends....:

a letter be sent to the FDA requesting the 2013 Food Code be amended as follows (language to be added is underlined; language to be deleted is in strike through format):

Section 4-602.11

(A) through (D) remain unchanged.

(E) Except when dry cleaning methods are used as specified under § 4-603.11, surfaces of UTENSILS and EQUIPMENT contacting FOOD that is not TIME/TEMPERATURE CONTROL FOR SAFETY FOOD shall be cleaned and sanitized:

(1) At any time when contamination may have occurred;

(2) At least every 24 hours for iced tea dispensers and CONSUMER self-service UTENSILS such as tongs, scoops, or ladles;

(3) Before restocking CONSUMER self-service EQUIPMENT and UTENSILS such as condiment dispensers ~~and~~, display containers, ice bins; and

~~(E)(4) In EQUIPMENT such as ice bins and BEVERAGE dispensing~~

~~nozzles and with enclosed with enclosed liquid food plumbing line components of EQUIPMENT such as dispensing freezers ice makers and dispensers, cooking oil storage tanks and distribution lines, BEVERAGE, syrup and condiment dispensing lines or tubes, coffee bean grinders and water vending EQUIPMENT and similar enclosed liquid food contact surfaces that depend upon CSIP processes for safety:~~

1. At a frequency of once a week or more frequently as may be necessary to preclude accumulation of soil or mold prevent accumulation of soils or the formation of biofilms, molds and other foreign contaminants.
2. Or at a frequency as recommended by the manufacturer when publicly available third party process validation test data supports their recommended cleaning and sanitizing frequency and protocols given their equipment's intended use and expected service life.

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It is the policy of the Conference for Food Protection to not accept Issues that would endorse a brand name or a commercial proprietary process.