FOODSAFE "CLEAN"

A position paper calling for development of validated international standardized test method for measuring hygiene relative to food operations

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There exist many methods of assay for determining the cleanliness of surfaces in preparation for sanitization, disinfection and sterilization. The fact that none of these have been validated may be due to our past inability to use a cross disciplinary approach to define CLEAN thereby providing quantifiable criteria for a surfaces availability to be sanitized.

It is a matter of reasonable thresholds given same or similar circumstance to mitigate risk associated with contamination. Risk assessment, communication and management are couched in statistics, whereby the probability of contamination to the level that a health safety hazard exists is on a curve based upon observation and measurement. Our collective failure to have any validated test methods for determining CLEAN is testament to the frustration experienced in many diverse industries and market segments. With recent advancements in detection and measurement technologies, we have before us the opportunity to develop practical standardized test methods capable of validation for specific applications of intended use.

The efficacy of sanitizers is reported in terms of specific log reductions for specific target organisms given their assay environments and factors of time, concentration and energy transfers. But all of this is relative to presumed organic loads or their absence. Many AOAC, JIS or other validated international standardized test methods presume specific organic loads, such as the 5% bovine serum common for testing solutions intended to be used as pesticides pursuant to registrations for FIFRA compliance. We talk about "residuals" in the context of a solutions efficacy given a specific level of organic load challenge, yet we have no validated measure of these specific organic loads on various contact surfaces which reduces the likelihood of a successful sanitizing step.

HACCP program success can not be achieved without effective prerequisite programs and verification regimes to constantly reassess risks of contamination to our foods and beverages. The very act of identifying a hazard to foods and beverages presumes quantifiable measure for reasonable threshold limits, as ZERO risk is known to not exist. It is important to have clear definitions for the various categories of safety we conceive. In the vernacular of hygiene we use such words as decontaminated and clean as synonyms, or are they? After all, it is well known that you cannot expect to be effective in sanitizing surfaces that are not first clean.

For purposes of infection control and hygienic safety, CLEANING is a separate and prerequisite step to sanitizing which is precursor to sterilization. The current state of the art is to perform cleaning checks using simple "soil" detection swabs, such as the Pro-Tect M made by VWR or BCATM Protein Assay's as made by Pierce. APC and TPC plating methodologies have been available for decades but their convenience, cost and speed have been limiting factors to their commercial acceptance as audit or QC tools. Then there are the photo-metric measurement assays such as OPA made by

Miele, and a range of competitors in the field of chemiluminessence and bioluminescence, all of which may be accurate enough, but each is expensive and all lack practicality for field audit and or QC inspection.

The measure of a given organic loads reasonability is a function of both the bio-burdens characteristics and those of the interfacial surface for any particular intended use. It is therefore necessary to present a matrix of risk categories based upon multi-dimensional axis; e.g. intended food/beverages characteristics, along with those of food contact surfaces/stainless steel, the use environment, vitrified china or glass stem ware, anodized aluminum, cast iron, ceramic tile, quarry tile, tile grout, schedule 80 black iron pipe, PE, PET, PTFE, PVC, etc. Other surfaces must have their own reasonably clean characteristics, such as the epidermis of the hands, or green leafy produce, a wooden pizza peel, cutting board, door pull on a freezer or a front door, the keys on a cash register, the surface of a gloved hand, the surface of meats, nuts, egg's, film food wraps, the coil of a refrigerator, etc. In infection control circles, the surface of an endoscope, a stent or surgical implement must be sterile to reduce probability of cross contamination, just as the air itself is purified and its characteristics controlled to reduce airborne transmissible agents that may provide infective dose upon contact with an open wound of a healthy or immuno compromised person or animal.

The first step is to categorize FOODSAFE cleans' applicability and one logical place to start is hard surfaces intended for food/beverage contacts. These surfaces and materials compatibility are spelled out in NSF ANSI Std 2, with reference to Std 51. If this first category is defined, then reasonable thresholds for organic load can be determined based upon target organisms and their expected environments given their food/beverage processes. Such methodology would also take into account biofilms which have plagued process piping and drains throughout recorded history.

In recent years ATP assay instruments have found their way into the QC market as convenient, fast and relatively inexpensive means of quantifying the presence of adenosine triphosphate. It is well known that the presence of ATP is a reliable indicator of organics, alive or otherwise. There are a number of competitors in the field and together they have simplified and dramatically improved the ability of field audit/inspection personnel to quickly determine with relative accuracy the "cleanliness", e.g. reasonable lack of organic load on a given surface.

The National Sanitation Foundation International (NSF) is sponsor to the Joint Committee for Food Equipment (JC), which is an ANSI standards development organization. I have been a voting member of the JC representing the North American Food Equipment Manufacturers (NAFEM) association since 2001, and serve on many task groups. The NSF JC complies with ISO65/IEC criteria for industry consensus standards development and is thus comprised of three distinct groups. Regulatory has representation from Federal, State and local levels, and a few representatives from Canadian Health agencies too. Industry is represented by persons employed by the manufacturers, some of food products and others of food equipment along with representatives of affected trade associations. Consumers are represented to the NSF JC by academia and by consultants and other ANSI certifying body personnel, together

NSF's JC is a likely candidate for consideration as the developer of a standard to define CLEAN, from a FOODSAFE perspective, ie., what quantifiable level of organics on a food contact surface is reasonably defined as FOODSAFE CLEAN in preparation for a separate sanitizing step.

The "Association of Analytical Communities," e.g., AOAC International is committed to be a proactive, worldwide provider and facilitator in the development, use, and harmonization of validated analytical methods and laboratory quality assurance programs and services. AOAC's "Official Methods of Analysis" have been defined as "official" by regulations promulgated for enforcement of the Food, Drug, and Cosmetic Act (21 CFR 2.19), recognized in Title 9 of USDA-FSIS Code of Federal Regulations, and in many cases by the US Environmental Protection Agency (EPA). US EPA is the authority having jurisdiction for the maintenance and enforcement of FIFRA, and act of Congress containing all pesticide regulations; all sanitizers, disinfectants and sterilants being categorized as pesticides.

The timing of this initiative coincides with a brand new AOAC project working towards validating ATP instrumentation and regimes. If and when ATP becomes validated in this manner we will then have the speed, convenience, accuracy and reasonably priced and validated tool we need to do field audit and inspection to Quantify cleaning processes to further improve our food handler training programs and cleaning and sanitizing regimes. So too will we have the tool needed to reexamine other performance standards whose criteria were developed without such tools and may be found to lack correlation limiting innovation and optimization.

I invite you and other interested stakeholders, public and private, NGO or GO to collaborate in the pursuit for reliable, replicable and reasonable test methods for determining "FOODSAFE" food contact surface cleanliness.

Please send you enquiries to:

tomj@jdpinc.com or call, 651-203-2462, or contact Mike Kohler at NSF International.