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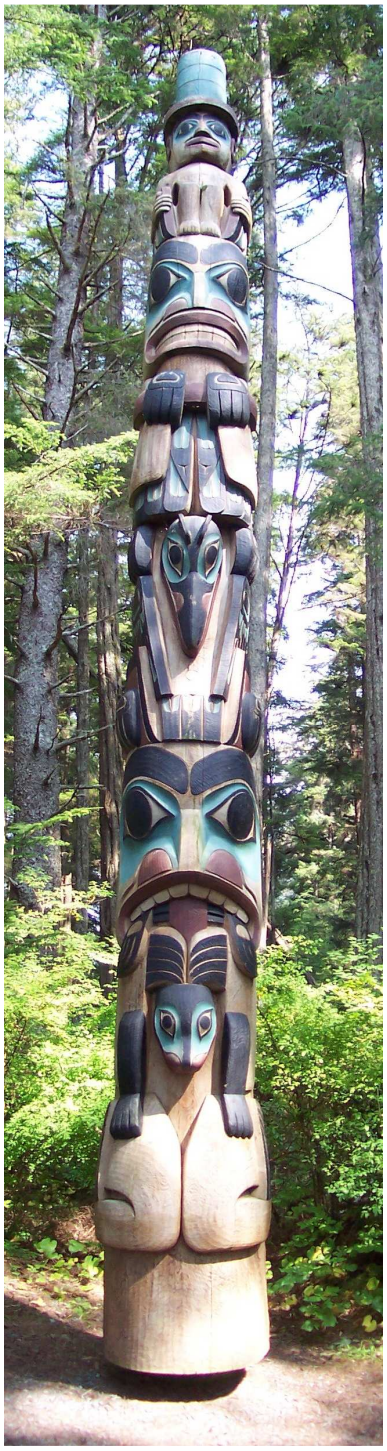
Disinfection versus Sterilization



The Indigenous peoples of the Pacific Northwest Coast in North America are widely credited with creation of the totem pole. The totem pole is a large sculpture carved from trees and the meanings of such poles range from notable events, familiar legends, or clan lineages. The wide belief that the vertical order of the images corresponded to importance has led to the common phrase "low man on the totem pole." With the most important figure being situated on top of the pole, one would prefer to not find themselves associated with the previous colloquialism. Regardless, the phrase and its connotation are not entirely accurate as examples of poles exist with important figures located on top, bottom, and even in the middle. For the purpose of this Spore News, however, we'll draw from this notion of vertical hierarchy orientation as we discuss the progression from cleaning through sterilization. Let us start with the lowest "man" on our sterilization totem pole.

If one desires to achieve a condition of sterile, we must start at the beginning…cleaning. The act of cleaning refers to physical removal of soil, debris and any particulate matter from surfaces.

Moving up one notch on the sterilization totem pole we arrive at sanitization which refers to significantly reducing or eliminating vegetative bacterial cells. An example of a sanitizer would be isopropyl alcohol which is sprayed on an operator's gloves. If the product is used directly on the body (such as soaps containing an active chemical agent) the term antiseptic is used instead. Such products are registered in the US by the FDA because their intended use is on people.

If we turn to the food industry, pasteurization and sanitization might be found at somewhat equal levels on our totem pole. Pasteurization is a method of heat treating food to kill disease causing organisms without harming the flavor. Developed by the French chemist and biologist Louis Pasteur, milk is typically heated to 63°C for 30 minutes or "flashed" to 71°C for 15 seconds to achieve pasteurization. Following the exposure to heat, the milk is rapidly cooled to refrigeration temperatures (~8°C). This level of heat insult will be effective at killing the harmful vegetative organisms but would have virtually no impact on a bacillus in its spore state.

Disinfection moves one step closer to the top and has three levels of classification. A low level disinfectant kills most vegetative bacteria and lipid or medium sized viruses. Intermediate level disinfectants kill all microbial pathogens except bacterial endospores. High level disinfectants kill all microbial pathogens and some bacterial endospores but will not be completely effective on large numbers of resistant bacterial endospores. Whereas antiseptics are used on the body and thus are registered with US FDA; sterilants, disinfectants and sanitizers are registered by the US Environmental Protection Agency as they are used on hard surfaces.

Now let us consider the term decontamination, which is defined as any activity that reduces the microbial burden to prevent contamination or infection. Thus, it is a general term that encompasses all of the previously discussed terms. One should note that the definition of decontamination is so broad that it also encompasses "sterilization". However, it seems that when industry actually arrives at a condition that can be defined as "sterile" we revert to using the more descriptive, less-broad term. The "level" of decontamination needed is situation dependent. For example, surgical instruments would need to be decontaminated to a level of sterility whereas that level of microbial killing may not be necessary for environmental surfaces such as floors and walls.

For some, the top of the totem pole would be sterilization, which can be defined as an act or process, either physical or chemical, which destroys or eliminates all forms of life. When used in an industrial application, sterilization is a validated process used to render a product free of all forms of viable microorganisms, including all bacterial endospores. The ability to demonstrate at least a six-log reduction of bacterial endospores is often required with sterilization.

Others may have one additional level which would be depyrogenation. As the name suggests, depyrogenation involves the destruction of pyrogens (i.e. fever producing substances). Bacterial endotoxins are examples of pyrogens and they are not inactivated by the thermal insult typically associated with a sterilization process. Pyrogens require temperatures well in excess of normal sterilization process temperatures. When using dry heat as a sterilizing agent, temperatures of 150°C to 190°C are typically employed. When depyrogenation is the goal, dry heat temperatures may exceed 250°C.

How does all of the above impact the world of biological indicators? Let us look at some text that appears in USP 32 about vapor phase hydrogen peroxide (VPHP). Specifically,

USP 32, chapter <1035> states, "This process has been shown to be an effective surface sterilant or decontaminant. VPHP is capable of achieving sterilization…however it is also commonly used as a surface decontaminating agent in the treatment of sterility testing, biological and chemical containment, manufacturing isolators, and clean rooms. Surface decontamination…is a process designed to render an environment free of detectable or recoverable microorganisms. Biological indicators are widely used to verify the efficacy of the decontamination process. However, in the case of decontamination, a spore log reduction value of three to four is adequate because the goal is decontamination rather than sterilization." For additional discussion on decontamination validation, refer to USP 32, chapter <1208>, STERILITY TESTING – VALIDATION OF ISOLATOR SYSTEMS.

Thus, we can see that according to USP, a three to four log reduction of bacterial endospores is required to demonstrate successful decontamination whereas a six log reduction is appropriate for sterilization applications. The SGM biological indicator (BI) HPVD/6 consists of 10^6 *Geobacillus stearothermophilus* spores inoculated onto a stainless steel disc, packaged into a Tyvek®/mylar envelope. If one were to use this product where decontamination was the goal, recovery assays would need to be performed on the exposed discs to accurately document the spore log reduction delivered by the decontaminating agent. An alternative is to use the HPVD/3 product. With only 10^3 spores per disc, these BIs can be cultured into liquid broth and incubated for a growth/no-growth response. Attainment of at least the three to four log reduction recommended in USP 32 would be evidenced if none of the HPVD/3 BIs showed growth.

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