HETEROTROPHIC BACTERIA IN DRINKING WATER FROM POU & POE DEVICES

Executive Summary

Many kinds of bacteria thrive in all aspects of our personal environment such as the air around us, our skin, and our food. For example, tens of thousands such microorganisms per milliliter are commonly found in pasteurized milk. Fruits, vegetables, frozen dinners, and meats may contain millions of heterotrophic bacteria per gram and still be fresh, pleasing, and healthful to eat. One may inhale thousands of heterotrophic organisms per breath from normal air. Healthy skin hosts hundreds of thousands per square inch; and in the healthy human mouth itself, each milliliter of saliva contains as many as 150 million heterotrophic microorganisms.

These organisms are in abundance almost everywhere, but they are not to be confused with disease-causing bacteria, which generally do not effectively compete and grow in water treatment equipment where normal amounts of heterotrophic bacteria are present. The point remains that while inspection and testing of our water supplies to ensure the absence of disease-causing bacteria is necessary, the ingestion of general bacteria that typically colonize in drinking water, plumbing, and treatment units does not have significant health effects.

The Yale University School of Medicine Study [6 & 7] found that, while bacteria levels increased in water treated by faucet-mounted and under-the-sink granular activated carbon filters, there was no significant health risk associated with this increase. A second study by the same research group in the same community involving larger point-of-entry units, resulted in the same finding: no associated health risk.

Health and Welfare Canada funded a large study at the University of Quebec[8] in 1988-1989 in which 308 homes using tap water were compared with 299 homes supplied with POU reverse osmosis units. The results showed 34 percent fewer gastrointestinal illness among the POU water users. In all bases of comparison, users of POU treated water with higher HPC levels had lower incidences of illnesses compared to those using tap water.

Six studies[13-18] cite evidence whereby scientists have tried to "contaminate" POU carbon filters with live pathogens. In all cases, the pathogens failed to thrive. In all cases, all of the pathogens died out entirely. This "biocompetitive exclusion" benefit is due to the overwhelming hardiness of harmless HPC organisms in the water treatment environment. Dr. Stephen Edberg of Yale University explained at the 1993 American Water Works Association (AWWA) Water Quality Technology Conference[19] that enteric organisms represent a fundamentally different branch of life from the indigenous bacteria found in natural water and soil environments. Enteric pathogens are not suited to survive in the face of competition in a water treatment environment. They must operate at different temperatures and salinity

levels, their food sources are entirely different, they require attachment to substrate materials with completely different properties, their defense needs are different, and enteric organisms require a new and different set of molecular "armaments" to facilitate tissue invasion and degradation, than do the ubiquitous natural soil and water HPC bacteria.

Dr. Joan B. Rose of the University of South Florida, Drs. Charles P. Gerba and Patricia Rusin of the University of Arizona, and Dr. Charles N. Haas of Drexel University collaborated on a comprehensive literature survey and analysis of risks due to HPC bacteria that was completed in 1998 and, likewise has, concluded a low risk of disease.[23]

The World Health Organization[22] concludes from the NSF International/World Health Organization Symposium on HPC Bacteria in Drinking Water Public Health Implications that was held April 22-24, 2002 in Geneva, Switzerland that increases of HPC (due to growth) in domestic water devices "do not indicate the existence of a health risk." The United States Environmental Protection Agency explains in the Agency's descriptions of potential health effects regarding the National Primary Drinking Water Standards that "HPC has no health effects." A preponderance of modern scientific studies and facts prove this to be true.

Conclusion: Thus scientific evidence supports the conclusion reached by both the World Health Organization (WHO) and the United States Federal Government that the heterotrophic organisms found in water from home water treatment equipment have no health effects. All waters contain bacteria, and these ubiquitous organisms can multiply when water, in the absence of a disinfectant, is retained in any container such as pipes, plumbing fittings, water heaters, bottles, or treatment equipment. Enteric, pathogenic, or disease-causing microbes, even when present in drinking water, do not compete effectively with the naturally occurring and harmless heterotrophic organisms and do not grow disproportionately in water treatment units. Potable drinking water that is further treated with point-of-use (POU) and point-of-entry (POE) home water treatment equipment remains microbiologically safe.

Introduction

Bacteria are the most numerous and variable organisms on Earth. Bacteria-like organisms were the first life forms to develop, and all life that has evolved since has had to contend with them. The number of types of bacteria is so great and they are so diverse that it is difficult even to know how to categorize them. They are so varied and the requirements of each species or strain are so specific that common analytical methods routinely miss more than 99% of them in some environments.[1]

Nutritional requirements are one basis of classification, and the first division is between "autotrophs" – those that make their own food by photosynthesis or oxidation/reduction of minerals, and "heterotrophs" – those that must consume organic (carbon-based) compounds from the environment to live. Most bacteria are heterotrophs, and that includes all human pathogens and most of the bacteria associated with drinking water systems. The population of heterotrophic bacteria in water is estimated with a "plate count" technique, in which a portion of a sample is mixed into or spread onto a plate of nutrient agar and incubated until colonies grow large enough to be seen and counted. In the old "Standard Plate Count" (SPC) procedure, one milliliter of sample was mixed into molten Plate Count Agar and allowed to solidify. SPC plates were incubated at 35°C for two days and counted. Most water laboratories today use the newer Heterotrophic Plate Count (HPC) procedure, in which one milliliter of sample is spread onto the surface of R2A Agar, a "lighter", less nutritious medium than SPC Agar and incubated at cooler temperatures, 18-25°C for up to a week or more. These differences produce a more sensitive assay, with values at least ten times greater than the old SPC, but still more than 99% of the organisms known to be present do not form countable colonies.[2] Why 99% fail to grow is unknown; most are believed to be dormant, many colonies are known to arise from particles harboring more than one cell, and the rest must simply have dietary requirements that are too varied and exotic to satisfy with a single formula. In any case, the result of any plate count procedure is <u>not</u> a completely accurate counting of the number of bacteria in the sample; it is an estimate of the population of "colony forming units" (CFUs) in the sample.

The presence of HPC bacteria is not restricted to drinking water. HPC organisms can be found virtually everywhere in our environment – in the air we breathe, in the food we eat, and even on inanimate surfaces such as the plates and glasses we use for eating and drinking. Total numbers and varieties of HPC organisms found in air, food, or on inanimate surfaces commonly surpass those found in water. HPC bacteria can be recovered from many water sources, including wells, springs, lakes and rivers, public water distribution systems, well water pressure tanks, hot water heaters, standing water in household plumbing, on-the-shelf bottled water, and household drinking water treatment systems.

Most potable water distribution systems are often found coated with sediment and tubercles of corrosion products inhabited by many kinds of macro- and microorganisms including simple bacteria. Once established, they grow until the

colony gets big enough to be affected by the turbulence and shear of water flow and begin to slough off. Unattached bacteria of each species reach maximum levels in the circulating water and then decline in waves of dominance.[3] Usually only a few types can be detected at any one time.

Essentially, all of the bacteria that inhabit drinking water systems came originally from the soil or surrounding environment of the region. Ordinary soil bacteria are not pathogenic. They are so common and so numerous that everyone would be ill constantly if not for the innocuous nature of HPC organisms and the most basic physiologic resistance common to all of us. Our skin, saliva, and stomach acidity are just three examples of our many effective barriers against these organisms being able to cause enteric infections.

It is well established that the HPC organisms, likewise, grow in and on the media and other surfaces inside POU & POE home water treatment products, often producing plate counts that significantly exceed influent values by ten times or more. Such products may include activated carbon filters, POE water softeners, mechanical filters of all types and sizes from small cartridge filters to large sand or multimedia filters, membrane systems, and treated water accumulation vessels. Such growths in these units occur largely due to stagnation (as a result of periods on nonuse), large surface area of the media within the unit, and availability of nutrients by adsorption from the untreated water onto the media or elution of organic substances from the media. The significance of such growths of HPC organisms in these products is the main subject of this paper.

Background

Concern about the SPC or HPC levels in water originally centered on its potential for interference with the Total Coliform analysis in water. The Total Coliform and the subsequent *E. coli* analyses indicate the potential presence of fecal contamination of the water. If SPC or HPC organisms interfere in the effort to find such contamination, then it would be of public health interest and may have to be controlled for this purpose alone. Such a level of interference has been proposed at 500 CFU per milliliter (ml). Even though this level was originally in relation to SPC, the same level without any discussion or justification was later extended to HPC, which generally counts about ten times more organisms than the SPC procedure. Such concerns led to the Total Coliform Rule promulgated in 1991, where the EPA stated that if a tap water sample had 500 or more HPC per milliliter of water, then there could be a suppression of the recovery of total coliforms by multiple tube fermentation and membrane filtration coliform analytical methods. Other methods such as the presence-absence (MMO-MUG) test do not suffer by such interference problems, but they were not approved until recently.

The need to measure and maintain SPC levels in public water systems has been explained well by Edwin Geldreich, formerly with US EPA[4]. He concluded that an SPC limit is needed for the following reasons:

1. Provide a method of monitoring for changes in quality,
2. Limit the secondary pathogens that can be of health risk in hospitals,
3. Reduce problems of interference with coliform analysis,
4. Indirectly monitor the effectiveness of chlorine residuals, and
5. Indicate the possible presence of sediments in the distribution system.

These reasons are germane and useful in relation to a public water supply treated centrally and distributed to the entire community through a network of pipes and valves to reach the end users. Obviously, any change, especially a substantial increase in the levels of background organisms, would indicate either a failure of the treatment process or potential cross-connection or intrusion in the distribution system. However, when we consider a POU unit used in an already disinfected water supply connected to the system inside the home under the sink or even at the point of entry, Geldreich's five points do not automatically apply. Concerns regarding chlorine residuals and sediments are not appropriate here. While it is acknowledged that there is an increase in HPC levels in the effluent waters from these units, in this case, it does not provide a method for monitoring water quality in a broad sense. Geldreich's concern about the secondary pathogens in hospital environments does not readily apply in normal household applications for drinking water treatment. Higher HPC levels may interfere with some coliform testing methodologies as discussed earlier, however, newer coliform test methods do not experience this interference, and this is not an issue in the water coming out of home water treatment units that have been applied only on a microbiologically-safe water supply because these units would not, normally, be the monitoring point for indication of fecal contamination Accordingly, an increase in the numbers in the treated water from POU and POE devices cannot be viewed in the same manner as one would when elevated HPC is found in a distribution system or after a central treatment process.

More recently, different people in the regulatory and academic fields are expressing other types of concerns, such as the presence of frank and opportunistic pathogens among the HPC group of organisms and their possible effect on infants, the elderly, and immunocompromised people in the population. The organisms of concern include *Legionella, Mycobacterium* complex, *Aeromonas hydrophila*, and *Pseudomonas auroginosa* along with well-known frank pathogens. Even though *Legionella* and *Mycobacterium* cannot be analyzed by the HPC procedure and require very different environmental conditions for growth than other normal species, because they do fit the definition of heterotrophs, some speculate they believe that there is cause for concern about these two also when elevated HPC levels come out of treatment devices. While there is not a large amount of data about the effect of HPC on children and the elderly, there are a few studies that can provide some information in this regard which will be discussed later.

Because of these researchers' concerns about HPC, there have been attempts to restrict the use of POU/POE products in the USA, Canada, and other countries. In 1978, both the U.S. Environmental Protection Agency and the Consumer Product Safety Commission proposed restrictions to the use of point-of-use carbon filters

because of concern about high HPC levels. The EPA action proposed to impose costly laboratory tests on interstate passenger carriers if those carriers chose to use water treatment filters. The CPSC was petitioned to ban the sale of all carbon filters. Both actions were rescinded after new data from Gulf South Research Institute studies[5] were examined which showed an increase in HPC levels from the POU devices tested, but with no fecal or total coliforms being detected in any of the effluent samples during the entire study. The researchers concluded that there is no health hazard due to the use of these devices. In 1981, Health and Welfare Canada proposed to ban the sale of all carbon filters in Canada. That action was stopped by fresh examination of the data and an agreement by the industry to limit carbon filter sales to water supplies known in advance to be microbiologically safe, and also to participate in epidemiological studies to be conducted at Yale University.

Health Effects

Allegations of adverse health effects attributable to the consumption of water containing heterotrophic bacteria coming out of all kinds of water treatment units has troubled the POU and POE industry over a long time. This has been so in spite of the presence of such bacteria in all aspects of our personal environment (See Figure 1). We now have good data to refute the presumption of hazard (e.g., the Gulf South Research Institute studies, the epidemiological studies by Yale School of Medicine, in addition to the past experience of the industry as a whole over more than half a century). Moreover, recent analyses of data are confirming old reports that soil bacteria are not merely harmless; their presence in POU and POE products can have a beneficial effect. Soil bacteria are so hardy and grow so well, and enteric organisms are so delicate and disadvantaged when away from the enteric environment, that any pathogens, which may occasionally and accidentally get into a unit, are overwhelmed. Ordinary HPC-type of bacterial growth in carbon filters, resin beds, bladder tanks, etc. appears to actively combat the spread of illness by stopping a plume of contamination, diluting it, and spreading it out at reduced levels, and eventually disposing of it altogether through competition and predation inside the unit.

There are four general areas of studies and/or general evidence that support conclusions that the HPC organisms exiting POU & POE units are not of health concern to the users of such devices when they use them to supplementally treat drinking water that is already microbiologically safe. These areas are covered individually below:

History

The first line of evidence is historical, referring to one of the seminal studies in water treatment and epidemiology from the 19th century, in which Robert Koch, the great German bacteriologist, showed that water filtration protected the citizens of Altona from cholera while neighboring Hamburg suffered greatly during an 1892 epidemic. Altona's filtration was done with slow sand filters, which develop a mat-like layer of microorganisms in the top inch or so of sand, called a *schmutzdecke*. It is a diverse community, which consumes the nutrients in sewage-laden waters at prodigious rates, apparently both starving out and grazing on enteric pathogens struggling to survive the shock of being expelled from the warm, rich intestinal environment. POU and POE products receive better quality water than that, so nothing so dramatic as a schmutzdecke forms, but the more moderate biofilm may also be able to counter the occasional incident of low-level contamination that sometimes can occur in drinking water supplies.

(After the epidemic in Hamburg was over, engineers studied the filtration plant and adjusted the flow rate for maximum production with minimum breakthrough of any turbidity that could carry pathogens. The plate count of water from slow sand filters that were fine-tuned to the ideal flow rate was about 100/ml, and that is the basis of the present German and EC recommended level for heterotrophic bacteria. Actually, it is merely an artifact of the hydraulics of the slow sand filters as operated and tested 100 years ago.) So the historical basis for the plate count test was for specific process control and not an indication of the presence of pathogens due to regrowth of bacteria downstream from the treatment plant.

Epidemiology

The second line of evidence is with epidemiological studies, and several have been done. The U.S. EPA funded two major projects at Yale University—one for point-of-use[6] and one for point-of-entry[7].

The POU study involved 250 families at a U.S. Naval base who used either tap water, faucet filters, or under-sink filters while maintaining a log of all illnesses and visits to the clinic. Filter effluents had more than ten times the plate counts of the regular tap water, but the families with filters did not have more illness. The POE study involved 176 homes with about 1,000 people, all in the university "family" with access to the Yale medical clinic. 80 homes had whole-house filters with two cubic feet of granular activated carbon (GAC) each, and 87 homes used regular tap water. Water samples were analyzed and illnesses logged for 21 months. The HPC levels were 2-3 logs (100 to 1000 times) higher in the homes with filters, but they, even the children and elderly, had no more illnesses of any kind. The conclusion from both POU and POE studies was that carbon filters did produce higher bacteria levels, but that they exerted no measurable adverse health effects.

Meanwhile, Health and Welfare Canada funded a large study at the University of Quebec[8] in which 308 homes using tap water were compared with 299 homes

supplied with POU reverse osmosis units. The results showed 34 percent fewer gastrointestinal illness among the RO water users. In all bases of comparison, users of RO treated water with higher HPC levels had lower incidences of illnesses compared to those using tap water. In addition, there was good correlation between the amount of water consumed and illness rates for those using tap water, but no such correlation for the RO group. This suggests that the tap water group's illnesses were waterborne, but the RO group's illnesses may not have been.

(Nonetheless, the authors reviewed the data and published another paper[9] reporting a dose-response relationship between plate counts at 35ºC and illness rates among the RO users only. That would suggest that the RO water caused gastrointestinal illnesses of one kind while simultaneously preventing some one-third of potential waterborne disease of another kind. The Water Quality Association has examined the raw data from this study and noted that it was in two parts: from March to June 1988 and from September 1988 to June 1989. Our complete analysis of the raw data showed that the rate of illness showed a negative association with HPC levels at 35ºC during Period 1, while it showed a positive association with the same during Period 2 as reported by the authors. The complete data set, when plotted together, shows the trend—the more bacteria the less disease. It is not clear why the authors did not use all the data, considering the small amount to start with.)

The most plausible explanation of the overall complete study is that the RO units removed pathogens that may cause low level gastrointestinal infections, which may have infiltrated into the mains through cracks and regrew in the distribution system after the water had left the treatment plant, and any that may have penetrated the membrane barrier were overwhelmed by competition from the more numerous non-pathogenic HPC organisms.

The same researchers conducted a more ambitious epidemiological study[10] over 16 months in 1993-1994 where they compared the gastrointestinal illness rate of people using plain tap water with that of people using three alternate water sources: tap water with a "bleeder valve" at the point of use (which prevented stagnation and loss of chlorine over night), bottled water (purified by reverse osmosis and ozonation), and tap water bottled at the filtration plant and supplied to users, all the while monitoring for several bacteria and viruses. The water from the alternate approaches often contained many times the HPC level of the regular tap water. After a couple of weeks of storage, the tap water bottled at the filtration plant had plate counts even higher than the reverse osmosis purified/stored water, but again, those two produced the best (lowest) illness profile. Distribution system based tap water (bleeder valve) alternatives had 14 to 19 percent more illnesses. The researchers concluded, contrary to their earlier hypothesis, that regrowth of bacterial contaminants in household pipes could be a health risk, this has shown that it might, in fact, have a protective effect.

There have been concerns about the effect of HPC organisms when children or the elderly are exposed. It is interesting to note that in all four epidemiological studies both groups were well represented and, in the Canadian studies, it was shown that

the children gained the most by having an RO system in place in the first study or when they consumed bottled plant or RO purified water in the second study.

There are no direct studies involving immunocompromised people mainly because of legal problems of doing such a study. One very indirect piece of evidence is that none of those who died as a result of the 1993 cryptosporidiosis outbreak in Milwaukee used any type of fine filtration device, and a survey study[11] in Milwaukee conducted during and after the outbreak showed that those who used home filtration devices with cyst reduction capability reported significantly lower incidences of diarrhea compared to those who did not use such devices. Another study[12] that has been recently conducted and reported is not with people, but with chemically immunocompromised female mice that were tested by peritoneal injection of HPC organisms of the type that were isolated from colonized POU devices incorporated into treated distribution systems in the earlier Payment study[8]. In this present study, no difference was found between the test subjects and the control subjects in spite of the rigorous nature of testing using immunocompromised mice and bypassing ingestion immunity mechanisms by the injection of the HPC organisms directly into the peritoneal cavity of the mice.

"Biocompetitive Exclusion"

The third line of evidence comes from research studies where scientists have tried to "contaminate" carbon filters with live pathogens. In all cases, the pathogens failed to thrive, although they were sometimes able to survive for extended periods inside the filters. In all cases, all of the pathogens eventually died out entirely. This section has been titled Biocompetitive Exclusion because it is believed that this is in fact the mechanism. Bicompetitive exclusion is not unusual or restricted only to water. Similar phenomena also benefit many other related fields. Several of the water related studies are summarized below:

- **Rollinger and Dott of the Technical University of Berlin inoculated sterile and nonsterile carbon filters with 1-10 million each of *E. coli, Pseudomonas aeruginosa, Pseudomonas putida, Klebsiella pneumoniae*, and *Streptococcus faecalis* bacteria. The first three colonized the sterile filters but not the nonsterile ones. The last two did not colonize under either condition. Failure to colonize was attributed to competition from a biofilm of naturally occurring organisms, which was demonstrated with scanning electron microscopy[13].**

- **Anne Camper et al. from Gordon McFeters' laboratory at Montana State University circulated the pathogens *Yersinia enterocolitica, Salmonella typhimuruim* and enterotoxigenic *E. coli* through one-inch GAC columns with and without the addition of natural or autoclaved river water to the system. All three species colonized sterile carbon, but the presence of the river organisms caused the pathogens to decline and die off. This was true regardless of whether the pathogens were introduced before, during, or after introducing the naturally occurring organisms[14].**

- **Edwin Geldreich et al. from the EPA's Drinking Water Research Division in Cincinnati, Ohio operated POU GAC filters on dechlorinated tap water and then inoculated them with *Enterobacter aerogenes, Enterobacter cloacae, Serratia marcescens*, and *Salmonella typhimurium*. None successfully colonized the filters and produced vigorous growth, although some were able to persist at low levels for some months. The highest individual plate count of any inoculated organism throughout the entire test was 8.5 *P. aeruginosa* per ml, in the initial sample after inoculation.[15]**

- **Donald Reasoner et al. from the same EPA-Cincinnati laboratory conducted another, similar inoculation with *Klebsiella pneumoniae, Yersinia enterocolitica* and *Aeromonas hydrophila*. As in the earlier study, none produced vigorous growth, and eventually all died off, although all were able to survive in the filters for several days or weeks.[16]**

- **Two studies on the effects of ion exchange water softeners on the microbiological quality of drinking water were completed in the United Kingdom in 1998. The *Water Softener Testing Study*[17] conducted by Cranfield University, School of Water Sciences evaluated water softeners over four months of normal use in a domestic house, and under microbial shock loading conditions in the laboratories of Cranfield University. The Thames Water-Kinetico Tests[18] examined hard and soft water microbial levels from eight households. Both studies analyzed total HPC counts at 22^0C and 37^0C, and also total coliforms and *Echerichia Coli* (*E.coli*). Both studies did show that the ion exchange water softener increases the total HPC counts, but on average by less than one order of magnitude (10x). The increases were always of environmental bacteria and not of enteric or pathogenic organisms, even under periods of 20-day stagnation and shock loadings of 90-liter batch solutions containing 190,000 *E. coli* per milliliter concentrations.**

All these studies have shown that such home water treatment products can be considered beneficial in limiting the effects of incidental contamination of a water system due to minor intrusions of contaminated water into a water supply. Such a benefit appears to be mostly due to the"biocompetitive exclusion" of HPC organisms present in these units. The industry, however, does label its products to not be used with water that is microbiologically unsafe. Even though HPC organisms accumulating in home water filters and reverse osmosis systems are not harmful and are likely of some benefit, industry understands and advises it is not appropriate to use these products with water of unknown microbiological quality.

Virulence Studies

True pathogens and even opportunistic pathogens seem to be effectively neutralized by indigenous heterotrophs growing in POU and POE products, nevertheless, there is still an apprehensiveness among some people that these naturally occurring soil organisms may cause disease themselves if they are sufficiently numerous or if individuals are sufficiently immunocompromised. Stephen Edberg of Yale University addressed this issue at the 1993 AWWA Water Quality Technology Conference[19]. He noted that enteric organisms represent a fundamentally different branch of life from the indigenous soil bacteria. They must operate at different temperatures and salinity levels, their food sources are entirely different, they require attachment to substrate materials with completely different properties, their defense needs are different, and enteric organisms require a new and different set of molecular "armaments" to facilitate tissue invasion and degradation.

Regarding natural immunity, the human immune response is a combination of many different modes of action. Only the most profound and general immune system failure, such as is produced to allow bone marrow transplantation, could affect the fate of waterborne bacteria in the body. Even AIDS victims suffer only one type of immune deficit, and with the exception of parasitic protozoan cysts, they are no more subject to gastroenteritis than the general population. And, of course, bone marrow, cancer, AIDS, and other patients still retain their ability to produce stomach acid.

Edberg sampled tap waters, bottled waters, and water in water coolers from all over the United States and Canada. All contained heterotrophic bacteria, which were isolated, cultured, identified, and tested for virulence factors and the ability to cause tissue damage. He found that 95% of the water bacteria could not grow at all under conditions analogous to the human host, and the remaining 5% were completely innocuous. There was a very low incidence in both the presence of virulence factors and in cytotoxicity. Not a single organism was found with multiple defense and attack mechanisms that might permit a real illness to develop. In addition, not a single organism derived from water was able to survive stomach acid. He concluded: "The human health threat from bacteria present in water consumed in the United States that has been subject to multiple barrier protection is insignificant."

Earlier Lye and Dufour of EPA conducted a survey of the ability of bacterial isolates from tap water to cause cell culture toxicity[20]. They found less than 2% of isolates, including *P.aeuruginosa*, possess cytotoxic activity. Payment et al. showed in a study[21] where they used blood agar that a small fraction of bacteria could be considered opportunistic pathogens due to their exhibition of multiple virulence factors. But use of the risk analysis approach has shown that an opportunistic pathogen such as P. *aeuruginosa* needs to be ingested at the rate of 5,000 to 10,000 per milliliter in two liters of daily intake to have even a 1:10000 chance of colonization (not infection). Monitoring of POU units does not show such high of levels of these organisms.

World Health Organization Expert Committee Report

A group of microbiology and public health experts including regulatory and medical expertise was convened in Geneva, Switzerland, 25-26 April 2002 to consider the utility of Heterotrophic Plate Count (HPC) measurements in addressing drinking water quality and safety. The group was convened following the NSF International/World Health Organization Symposium on HPC Bacteria in Drinking Water Public Health Implications. The meeting of the expert group was attended by 31 participants from Australia, Canada, France, Germany, Italy, Japan, the Netherlands, South Africa, Switzerland, UK, and USA (see attachment A). Their report can be reviewed in WHO web site[22]. Following is a summary of their conclusions:

- **The control of faecal (fecal) contamination in drinking water systems and sources where it occurs, is of primary importance. Faecal-specific indicator bacteria, such as *E. coli,* are the parameters of first importance in monitoring faecal pollution.**

- **There is no universal 'HPC measurement'. The test itself does not specify the organisms that are detected. Microorganisms recovered through HPC tests generally include those that are part of the natural (typically nonhazardous) microbiota of water; in some instances they may also include organisms derived from diverse pollutant sources'.**

- **Microorganisms will normally grow in water and on surfaces in contact with water as biofilms. Elevated HPC levels occur especially in stagnant parts of piped distribution systems, in domestic plumbing, in bottled water, and in plumbed-in devices such as softeners, carbon filters, and vending machines.**

- **HPC measurements are used as a measure of possible interference with coliform measurements in lactose-based culture methods. This latter application is of declining value as lactose-based culture media are being replaced by alternative methods that are lactose-free.**

- **There is a small number of studies that have examined possible links between HPC and nonintestinal outcomes in general populations. The conclusions of these studies do not support a relationship.**

- **There is no evidence that HPC values alone directly relate to health risk either from epidemiological studies or from correlation with occurrence of waterborne pathogens. They are, therefore, unsuitable for public health target setting, or as sole justification for issuing "boil water" advisories.**

- **There is no evidence that HPC levels *per se,* as measured by established procedures, have a direct relationship to the likely presence of, or act as indices for the numbers or presence of regrowth organisms such as legionellae*,* *P. aeruginosa* and nontuberculous mycobacteria.**

- **Exposure to general HPC microbiota is far greater through foodstuffs than through drinking water. Levels of exposure regarded as acceptable from foods are much greater than those regarded as acceptable from drinking water. Exposure to HPC microbiota also occurs through air and other environmental sources.**

- **Where the drinking water supply meets international norms such as WHO Guidelines for Drinking Water Quality, only those people with severe changes from normal as determined by their physicians or medical agencies (e.g. an absolute neutrophil count $<500/\mu l$) are considered immunosuppressed to the extent that they may require specially processed drinking water.**

Most pertinent to the subject of this report is their conclusion regarding HPC growth in POU/POE devices, which they referred to as "Plumbed in Devices":

<u>Bacterial growth occurs in plumbed-in domestic water devices (including water softeners, carbon filters etc.) and plumbed-in commercial devices such as beverage vending machines. HPC values in water samples typically increase in such devices. Increases of HPC (due to growth) in these devices, therefore, do not indicate the existence of a health risk, so long as the entry water meets acceptable water microbial quality norms (e.g. WHO Guidelines for Drinking-Water Quality). Appropriate maintenance of these devices is required for aesthetic reasons per manufacturers' recommendations</u>.

It is clear that this expert group's recommendations are generally in agreement with the content of this position paper and only strengthen its conclusions.

Conclusions

These findings in scientific fact echo the observed facts: there is no record of even a single confirmed case of gastrointestinal disease attributed to HPC bacteria growing in any of the millions of home water treatment products sold all over the world. At the same time, unfortunately, there exists an erroneous and contrary perception both within some parts of the regulatory community and also, thereby, with some consumers that bacteria of any type and/or source may be harmful. It is important to understand that neither the U.S. Environmental Protection Agency nor the World Health Organization has set any mandatory health limit for HPC organisms. Advisory or guide levels for HPC organisms are sometimes recommended, but only on the basis of aesthetics, or an indirect indicator of municipal disinfection effects,

not because of any health significance. In their 2002 Expert Committee Report, the World Health Organization (WHO) concluded that HPC due to growth in point-of-use (POU) and point-of-entry (POE) domestic water devices "do not indicate the existence of a health risk." This is consistent with the United States Environmental Protection Agency's (USEPA's) continuing statement that "HPC has no health effects." The extensive scientific evidence developed throughout history proves this to be true.

The correlation in the other direction (use of POU/POE water treatment products associated with lower illness levels) is much more striking. Regarding HPC bacteria, education and clarification are essential. Available scientific studies and experience have objectively and consistently verified that HPC growths in POU and POE products and the drinking water coming out of these systems are not harmful.

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