National Rural Water Association
www.nrwa.org

Water & Wastewater Equipment Manufacturers Association
www.wwema.org

August 11, 2008

The Honorable Nick Lampson
Chairman
Energy and Environment Subcommittee
Science and Technology Committee
U.S. House of Representatives
Washington, DC 20515

The Honorable Gene Green
Chairman
Environment and Hazardous Materials Subcommittee
Energy and Commerce Committee
U.S. House of Representatives
Washington, DC 20515

The Honorable Barbara Boxer
Chairwoman
Environment and Public Works Committee
U.S. Senate
Washington, DC 20510

The Honorable Jim Inhofe
Ranking Senator
Environment and Public Works Committee
U.S. Senate
Washington, DC 20510

Dear Chairman Lampson, Chairman Green, Chairwoman Boxer and Ranking Member Inhofe:

We are writing to ask you to review the EPA and private-sector programs to determine their effectiveness in ensuring that the most innovative, effective and economical drinking water treatment is available to small and rural communities which are required to install treatment to comply with federal standards.

The Safe Drinking Water Act (SDWA) requires that EPA identify affordable technologies for small and rural communities to meet the federal standards. However, it appears that the currently available EPA and private-sector programs for approving technologies may be limiting use of the most efficient and economical compliance technologies to the small communities, which need it most due to their limited economies of scale.

This issue was recently brought to our attention by a small community in Kansas (attachment #1) that is interested in an innovative technology to comply with EPA's total organic carbon and disinfection by-products standards (the so-called Enhanced Biological Filtration – EBF - produced by ClearValue, Inc., a drinking water technology corporation in Texas).

It appears that in order for any technology to be practically available for use by communities, large and small, it must receive NSF/ANSI Drinking Water Additives Standards 60/61 approval to ensure its health effects safety for use in potable water applications – as most states request such approval (attachment #2). The technology's designer did apply for NSF/ANSI approval through NSF International; however, NSF International was not able to approve the technology under its protocol (attachment #3). NSF International did not conclude

that the technology was unsafe; but, that the designer could not prove future safety given unknown variables.

Ironically, numerous experts from the EPA, the state agencies, and the scientific community have commented that the technology is promising, and should be available for compliance purposes (attachment #2). Much of this substantive commenting was provided to NSF International (attachment #4). However, without NSF/ANSI approval, these experts' compelling findings can't overcome the current structural reality that only NSF/ANSI approved technologies can be used for compliance purposes.

It is inconsistent with the intent of the Safe Drinking Water Act that EPA would enact costly standards on many small communities, and then be able to remain silent on the effectiveness and safety of a promising and cost-effective technology that may allow for economical compliance with federal standards.

EPA requires thousands of communities to add drinking water treatment in order to comply. Additionally, the SDWA requires that EPA identify affordable technologies for small and rural communities to meet the standards. However, the program for approving affordable and innovative technology exists outside of EPA's authority, governmental oversight and review. NSF International is a private company that operates outside the auspices of the EPA – even though its decisions are critical to determining the federal government's obligation to provide affordable technology to allow communities to reasonably comply with enforceable federal drinking water standards.

EPA officials sit on NSF International panels in official EPA capacity, where NSF International can make unilateral policy decisions on the safety of innovative technologies (attachment #3) and not be held publicly accountable for its decisions in the same manner as if the policy decisions where made within the EPA auspices. This dynamic creates a situation where one EPA official comments favorably on the same technology that another EPA official on the NSF International panel raises concerns about. Only the EPA official on the NSF International panel has a binding impact on approval and availability of the technology (attachment #2 & #3).

This is all while the EPA Environmental Technology Verification (ETV) program is apparently not a workable alternative, as ETV does not assure the safety of any direct and indirect additives from a health effects standpoint – and as one EPA Region commented, *"drinking water programs do not have the resources to conduct special studies on EBF."* (attachment #2).

Currently, small and rural communities are having a very difficult time complying with EPA's drinking water regulations for disinfection by-products (DBPs) – the regulation that the EBF technology claims to be most effective in addressing.

Experts have commented that EBF would provide treatment for DPBs that would not necessitate the lowering of residual chlorine levels. An adequate residual chlorine level is required to protect the public from exposure to microbial pathogens. EBF would further reduce

the need for coagulants and the health concerns associated with their use, especially that of aluminum-based chemical additives. This could mean less aluminum being added to the public's drinking water, which may be on the increase with water systems increasing their aluminum-based coagulants in order to comply with EPA's rules.

All of the above is happening under the structure of the federal drinking water regulatory program. This federal program's requirement for compliance technologies has resulted in a situation where small community water systems' compliance options come under the control of corporations, which operate outside of federal authority and oversight.

We appreciate your attention and consideration of issues explained in this letter, and would be eager to work with you on solutions.

Sincerely,

Mike Keegan
NRWA

Dawn Kristof Champney
WWEMA

Public Utilities
Department

Kurt Bookout
390 E. Central
El Dorado, KS 67042
wildcat@eldoks.com

October 10, 2007

Mike Keegan
National Rural Water Association

Dear Mr. Keegan :

The City of El Dorado has been struggling with TOC compliance for several years. Our high quality source water, that drains largely from the Flint Hills Tallgrass Prairie, has relatively low TOC levels in the range of 3-4 mg/l. Due to the way that TOC is regulated, based on percent removal, as opposed to most contaminants that have an MCL, it is very difficult for El Dorado to achieve the percent removal requirements. Compounding that problem is a source water alkalinity that due to zebra mussels, has shown wide variations from 70 mg/l to 125 mg/l. If alkalinity is under 120 mg/l, TOC removal requirements increase. The City of El Dorado would be interested in looking at EBF technology, if approved, as a means of TOC compliance. This technology would also significantly reduce the opportunity for disinfection by-product formation, another real concern for most surface water treatment facilities.

Sincerely,

Kurt Bookout
Director of Public Utilities

Attachment #1

Mike Keegan, National Rural Water Association
Original Question

Mike Keegan <keegan@bookcase.com> 8/22/2006 11:12 AM

Dear: Mr. Thomas Grubbs, Dr. Paul Berger, Mr. Blake Atkins, Mr. Toney Bennett, Mr. Kurt Bookout, Mr. Mike Matheney, and Mr. Tom Bowman:

I work for the rural water association (small communities who have to comply with the DBPs rules) and which has about 25,000 members. I would be grateful for any comments or advice on an issue, that you are familiar with, and that is important to our membership. It is my understanding that Enhanced Biological Filtration (EBF, like the one developed by Clear Value), could provide very economical DBP compliance; however, EBF has not been certified or listed within either NSF/ANSI Standard (e.g. 60 & 61) and is therefore not available to any drinking water system/community.

The issue I am trying to understand is: should the NSF/ANSI Standards be used to certify EBF (especially since biofilters are in use today using ubiquitous micro-organisms).

It is my understanding that NSF International has told some interested U.S. Congressional staff that the certifying standards (e.g. NSF/ANSI Standards 60 and 61) don't apply to bio-filters (i.e. that NSF just can't certify the technology within either NSF/ANSI Standard 60 or 61 and that and there are no alternative standards for biological technology that would allow NSF International to certify the technology so that the technology could be accepted by the states). Clear Value disagrees with the NSF assertion and believes NSF could certify the technology. Also, Clear Value believes that the previous work performed by or for NSF (see attachment from Clear Value) represents the necessary analysis/finding for certification). Can you comment on the merits of these claims?

Also, I would be interested to know if you think there is the necessary institutions, standards, and processes to certify drinking water compliance technology so that ALL innovative technology (like EBF if appropriate) are available and accessible to be used in small communities' drinking water supplies. If what the NSF International is saying is accurate, then it appears that there would be a need for an additional certifying institution or process?

Thank you for any assistance. My membership is very interested in access to economical compliance technology and we appreciate your help and expertise. Please let me know if I can answer any questions or be of any assistance.

Mike Keegan, Analyst
National Rural Water Association &
Law Offices of John H. Montgomery
101 Constitution Ave., NW Suite 900
Washington, DC 20001
[c & IM] 202-294-4785 [f] 866-385-3160
keegan@ruralwater.org

Attachment (provided by Clear Value)

Attachment #2

Thomas Grubbs, Manager, Office of Water, US EPA, Washington, DC

From: Grubbs.Thomas@epamail.epa.gov [mailto:Grubbs.Thomas@epamail.epa.gov]
Sent: Monday, August 28, 2006 2:13 PM
To: Mike Keegan
Cc: atkins.blake@epamail.epa.gov; kgolemon@mailbmc.com; Mike Matheny; Paul Berger; Richard Haase; Toney Bennett; 'Tom Bowman; Kurt Bookout
Subject: Re: Advice on should the NSF/ANSI Standards be used to certify biofilters for EPA drinking water compliance

Mr. Keegan - EBF appears to be a feasible technology for systems to use for organic precursor removal, which would facilitate compliance with DBP standards. EPA is interested in making all appropriate technologies available to systems through acceptable certification processes. I will try to meet with my office director when she returns from vacation after Labor Day to determine what steps EPA should take.

Tom Grubbs, PE
Environmental Engineer
Office of Ground Water and Drinking Water
202-564-5262

Blake Atkins, Manager, Drinking Water Programs, US EPA, Region VI, Dallas, TX

Date: Fri, 25 Aug 2006 08:17:59 -0500
From: Atkins.Blake@epamail.epa.gov
Subject: Re: Advice on should the NSF/ANSI Standards be used to certify biofilters for EPA drinking water compliance
To: Mike Keegan <keegan@bookcase.com>

Mr. Keegan,

Having helped promulgate the Disinfection Byproducts Rule (DBPR), and recognizing the difficulty that many public water systems in EPA Region 6 would experience in complying with this new regulation, I was very excited to learn of the prospect of enhanced biological filtration (EBF) addressing this drinking water regulatory compliance issue in an economical fashion. While the notion of biological filtration is not new (used in slow sand filtration and deep-bed biological filters), applying the technology systematically to public water systems to address DBPR compliance is a new concept.

I had hoped that EBF could be piloted in Oklahoma, Texas, and Louisiana, as these states have high levels of naturally occurring organic matter in drinking water sources that react with disinfectants, forming high levels of disinfection byproducts. These states are now experiencing higher rates of DBPR noncompliance than elsewhere in the country. For this reason, I continue to hold hope that an affordable means of addressing DBPR compliance is identified. Likewise, I hold hope that EBF is given the chance to prove itself as a viable technology for reducing disinfection byproduct levels in public water systems.

The Region 6 state drinking water programs do not have the resources to conduct special studies on EBF, and must have some form of verification that any direct or indirect additive to drinking water will not cause harm to the public. Since Region 6 states rely upon NSF/ANSI approval of direct and indirect additives, this approval process would appear to be the most expeditious means of approving EBF, where a biological matrix is added directly to drinking water supplies.

_____

Blake Atkins, Chief
Drinking Water Section
EPA Region 6 â€“ Dallas
214-665-2297

Kurt Bookout, Director, City of Eldorado, KS (microbiologist)

From: "Kurt Bookout" <wildcat@eldoks.com>
To: "'Tony Bennett'" <TBENNETT@tceq.state.tx.us>,
"'Paul Berger'" <rainchoir@aol.com>,
"'Mike Keegan'" <keegan@bookcase.com>,
"'Mike Matheny'" <mlmatheny@earthlink.net>,
"'Blake Atkins'" <atkins.blake@epa.gov>,
"'Thomas Grubbs'" <grubbs.thomas@epa.gov>,
"'Tom Bowman'" <thomas.a.bowman@us.ul.com>
Cc: "'Richard Haase'" <richard@clearvalue.com>, <kgolemon@mailbmc.com>
Subject: RE: Advice on should the NSF/ANSI Standards be used to certify biofilters for EPA drinking water compliance
Date: Wed, 23 Aug 2006 08:35:34 -0500

I have not heard a valid reason why NSF will not look at certifying EBF. That's what they get paid to do. It appears they don't have the expertise to look at this technology, so they are brushing it off. I agree with Tony, EPA Labs need to tackle this one if NSF can't.

Mike Matheny, President, Evera Biologicals (accomplished microbiologist)

From: "Michael Matheny" <mmatheny@enverallc.com>
To: <Grubbs.Thomas@epamail.epa.gov>, "'Mike Keegan'" <keegan@bookcase.com>
Cc: <atkins.blake@epamail.epa.gov>, <kgolemon@mailbmc.com>,
"'Mike Matheny'" <mlmatheny@earthlink.net>,
"'Paul Berger'" <rainchoir@aol.com>,
"'Richard Haase'" <richard@clearvalue.com>,
"'Toney Bennett'" <tbennett@tceq.state.tx.us>,
"'Tom Bowman'" <thomas.a.bowman@us.ul.com>,
"'Kurt Bookout'" <wildcat@eldoks.com>

Subject: RE: Advice on should the NSF/ANSI Standards be used to certify biofilters for EPA drinking water compliance
Date: Mon, 28 Aug 2006 21:03:48 -0400

Mr. Keegan,

I am not an expert on the regulations associated with drinking water. I am the owner, and principal scientist, for Envera, LLC. We manufacture a variety of microbial cultures, including those that would be of use in the EBF. Regulations aside, it seems very logical to me that one would seed filtration systems with naturally occurring, carefully identified, scientifically selected, non-pathogenic bacteria rather than letting any type of organism colonize the filter. EBF utilizes this approach of "selective colonization" to put the correct type of organisms in the system. In addition to doing a better job cleaning the water, these organisms will help to reduce, or eliminate, the disease causing organisms often found associated with these filtration systems.

Please feel free to contact me if you need any assistance with the microbial portion of this project.

Sincerely,

Mike Matheny
610-384-8069
www.enverallc.com

Mr. Tony Bennett
Manager and Assistant to the Director
Drinking Water Programs, TCEQ (Texas)
(The entire staff of the TCEQ reviewed EBF prior to submission of the standard)

From: Tony Bennett [mailto:TBENNETT@tceq.state.tx.us]
Sent: **Tuesday, August 22, 2006 4:14 PM**
To: **Paul Berger; Mike Keegan; Mike Matheny; Kurt Bookout; Blake Atkins; Thomas Grubbs; 'Tom Bowman**
Cc: **Richard Haase; kgolemon@mailbmc.com**
Subject: **Re: Advice on should the NSF/ANSI Standards be used to certify biofilters for EPA drinking water compliance**

This EBF mixture of organisms is clearly an additive to water systems. As such, states (at least Texas) would require some type of certification that no harmful microorganisms are added in the process. Texas relies on ANSI/NSF standards and approval of products to those standards by organizations accredited by ANSI. That said, Texas also has a method to grant exceptions. Since there is no ANSI/NSF standard for such a product, this would be eligible to be reviewed for an exception to the rules. However, I do not think that any of the parties, the state, the water system, the customers, or Clearvalue would look favorably upon taking on an opened end liability of adding this to a public drinking water systems without some health based certification. Maybe this something that the EPA lab should take on directly.
Tony

NSF International

July 28, 2005

Mr. Richard Haase
ClearValue, Inc.
P.O. Box 18856
Sugar Land, TX 77496-8856

Dear Mr. Haase,

The following response was developed by a sub-group of the drinking water experts serving on the Council of Public Health Consultants after review of the May 14, 2005 Enhanced Biological Filtration (EBT) Task Team submittal. The submittal is the EBT Task Team's response to the seven questions posed by the Council during their October 2004 annual meeting.

The Council of Public Health Consultants sub-group determined that the presumption that non-pathogenic organisms are not capable of causing waterborne disease is inadequate to support the inclusion of the proposed screening protocol in NSF/ANSI 61 Drinking water system components – Health effects. This screening protocol does not address potential exposure to the EBT organisms through other water uses such as showering and bathing, during which the user could be exposed to the organisms through inhalation, dermal, or eye exposure.

While the EBT organisms may be susceptible to downstream disinfection, no data have been provided to demonstrate the effective log reductions of the organisms by final filtration and disinfection. Similarly, it is recognized that filtration and disinfection operations occasionally fail for short periods of time. No data are presented to indicate what might happen if some EBT organisms escaped into the distribution system at a time when human or mechanical error might result in inadequate removal of the organisms before they reached the distribution system. Insufficient data have been presented that would indicate the EBT organisms can be sufficiently controlled once introduced into the intended environment such that unintended side effects or contamination would not occur.

The need for a full risk assessment of the technology was requested during the October 2004 CPHC meeting by the U.S. EPA Office of Drinking Water representative serving on the Council. The response provided by the Task Team was not considered adequate.

It is the Council of Public Health Consultants sub-group on drinking water's recommendation to NSF International that no further development of this proposal be supported.

Regards,

Ernest Julian, Ph.D.
Chair, Council of Public Health Consultants

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NSF Council Of Public Health Consultants – Biofiltration Review Sub-Group

Mr. T. Duncan Ellison, Executive Director, Canadian Water & Wastewater Association

Dr. Ernest Julian, Chief, Office of Food Protection, Rhode Island Dept. of Health - Chair of NSF Council of Public Health Consultants, 2005

Dr. Dennis Juranek, Associate Director, Division of Infectious Diseases, CDC

Dr. Jerome Nriagu, Professor, University of Michigan School of Public Health

Dr. Edward V. Ohanian, Director, Health & Ecological Criteria Division, USEPA

Dr. Robert W. Powitz, Forensic Sanitarian, R.W. Powitz & Assoc., P.C.

Mr. Gayle Smith, Utah Department of Environmental Quality (retired) – Chair of NSF Drinking Water Additives Joint Committee

Mr. Gary Yamamoto, Chief, Drinking Water Technical Programs, State of California

Mr. Brian Zamora, Director, Public Health and Environmental Protection Division, County of San Mateo, California

Richard A. Haase
President & CEO
richard@clearvalue.com

ClearValue®
clearvalue.com

The Earth is mostly water.
Our bodies are mostly water.
ClearValue's Innovations improve
our water, our air, our health and our world.

February 5, 2007

c/o	Delivery Means
Hon. Barbara Boxer, U.S. Senator - via	
Mr. Eric Olsen US Senate EPW Committee	Eric_Olson@epw.senate.gove
Hon. Senator Barbara Boxer, U.S. Senator – via	
Ms. Michelle Nellenbach US Senate EPW Committee	Michelle_Nellenbach@epw.senate.gov
Mr. Mike Keegan, President,	
National Rural Water Association	keegan@ruralwater.org

To: Mr. Dennis Lawlor, President
Ernest Julian, Ph.D., Chair, Council of Public Health Consultants

NSF International
P.O. Box 130140
Ann Arbor, MI 48113-0140

Subject: Enhanced Biological Filtration (EBF) Task Team Response to CPHC Letter Dated 07/28/05 Received 10/18/06

Mr. Lawlor and Dr. Julian:

The EBF Task Team, chartered by the NSF/ANSI Standard 60/61 Joint Committee, received the attached unsigned communication dated 07/28/05, Exhibit A, on or about 10/18/06 from the US Senate Environment and Public Works Committee. It is the understanding of the EBF Task Team, as communicated by the representative of NSF International to the U.S. Senate Environment and Public Works Committee, that NSF International and NSF International's CPHC seek a response from the EBF Task Team to said unsigned communication.

Substantive Responses

Exhibit A states in the second paragraph:

> "The Council of Public Health Consultants sub-group determined that the presumption that non-pathogenic organisms are not capable of causing waterborne disease is inadequate to support the inclusion of the proposed screening protocol in NSF/ANSI 61 Drinking water system components – Health effects."

In response, the EBF Task Team would like to state to NSF International and NSF International's CPHC:

1. There has been to date no proposal by the EBF Task Team to NSF International or to NSF International's CPHC wherein the inoculum cultures for EBF are selected solely by pathogenicity.

2. The specific cultures selected by the EBF Task Team, as listed in detail within Tab 4 of the May 14, 2005 response to the CPHC by the EBF Task Team are all identified by the American Type Culture Collection (ATTC). Specifically:

Telephone: 281.261.9543
ClearValue, Inc.
P.O. Box 128561
Sugar Land, Texas 77496-8856
Facsimile: 281.261.6505

Attachment #4

"Bacillus anyloliquefaciens – strain 3002 (ATCC #700385)
Bacillus laevolacticus – strain 3003 (ATCC #700387)
Bacillus licheniformis – strain DA3 (ATTC #55406)
Corynebacterium nitrophilus – strain MFK
Pseudomonas putida – strain HC (ATTC #770369)
Pseudomonas putida – strain 3012 (ATTC #700412)
Pseudomonas putida – strain 3PMN (ATTC #31482)"

These cultures are all known and identified. These cultures were all reviewed by The Toxicology Group, a division of NSF International. The Toxicology Group, a division of NSF International, reported on April 9, 2001 that the above list of cultures "[w]ere reviewed and considered acceptable for the application", ref. Exhibit B.

3. Tab 8 of the May 14, 2005 response to the CPHC by the EBF Task Team identifies most of the organisms, including common organisms, identified as waterborne disease-causing organisms in the USA. This list was prepared by Dr. Paul Berger of the US EPA as an informal document in response to the CPHC. The EBF Task Team was and is in full agreement that any and all organisms listed by the US EPA as waterborne disease-causing should be excluded as inoculum for EBF, ref. Exhibit C.

4. Tab 9 of the May 14, 2005 response to the CPHC by the EBF Task Team is an article published by Taylor, et al. "Risk Factors for human disease emergence" which identifies known organisms identified as pathogenic. As this list and similar lists are updated by the US CDC, the EBF Task Team was and is in full agreement that all organisms so listed by the US CDC should be excluded as inoculum for EBF, ref. Exhibit D.

5. In strong contrast to the assertion within Exhibit A from NSF International's CPHC, which states a concern relating to waterborne disease, the Toxicology Group, a division of NSF International, has screened EBF inoculum for pathogenicity, opportunistic behavior and virulence factors, as well as the potential for waterborne disease, again ref. Exhibits B, C and D.

6. This asserted concern by NSF International's CPHC was not previously put forth to the EBF Task Team; therefore, the EBF Task Team was not here-to-fore provided an ability to respond.

Exhibit A further states in the second paragraph:

> "The screening protocol does not address potential exposure to the EBT organisms through other water uses such as showering and bathing, during which the user could be exposed to the organisms through inhalation, dermal, or eye exposure."

In response, the EBF Task Team would like to state to NSF International and NSF International's CPHC:

1. It is the responsibility of the US EPA to regulate this concern via the US EPA Drinking Water Regulations. "Inhalation, dermal, or eye exposure", as well as ingestion of organisms within drinking water is the responsibility of the local operator and enforced by the State Regulators with regulations promulgated by the US EPA, e.g. US EPA Drinking Water Regulations. (For example Legionella is regulated by the Surface Water Treatment Rules and causes disease by inhalation.)

2. As stated in the May 14, 2005 response to the CPHC by the EBF Task Team on page 5 item 4 a:
   "The only environment into which said organisms are to be introduced is the structure of EBF. This is while the only potential environments outside of the EBFT [EBF] for the organisms is either backwash water or to pass final filtration."

3. As detailed in the proposed EBF NSF/ANSI Standard 61 insertion, EBF is to operate upstream of final filtration in a drinking water plant, ref. Tab 3 of the May 14, 2005 response to the CPHC by the EBF Task Team, Exhibit E, attached; therefore any and all organisms within EBF are to be removed from and/or disinfected within a drinking water according to the US EPA Drinking Water Regulations. EBF is not to operate except within and according to the protocols of the US EPA Drinking Water Regulations, as stated in Exhibit E. EBF is not to operate except upstream of final filtration, as stated in Exhibit E. EBF is not to be used in a drinking water which does not contain a final disinfectant, as stated in Exhibit E.

4. As stated in the May 14, 2005 response to the CPHC by the EBF Task Team on page 4 item 3 a:

   "There are five (5) improvements to said downstream systems because of EBFT [EBF]:

   1. As the process of natural selection reveals a competition for survival and nutrients, then the removal of TOC (substrate) from the water by the microorganisms of EBFT [EBF] will, therefore, reduce the concentration of indigenous bacteria in the drinking water by reducing the concentration of available TOC (food - this is wherein EPA studies reveal nearly all raw water sources to contain pathogenic species of microorganisms, as compared to the species of enhanced biological filtration which are non-pathogenic).
   2. [EBF inoculated microorganisms are upstream of final filtration, which is required in drinking water surface water plants, and disinfection, which is required for any drinking water distributed from a municipal source.] Distribution disinfectants commonly used are chlorine and/or chloramines (both of which are listed in NSF/ANSI Standard 60).] [Original edited by Dr. Paul Berger]
   3. [An effect of "natural disinfection" was demonstrated in a field evaluation of Enhanced Biological Filtration in Beaumont, Texas. Beaumont was chosen as Beaumont was, at that time, operating with an indigenous biological filter out of necessity; as, the kinetics of anthracite/sand filtration in combination with the water's TOC placed Beaumont out of permit on monitored DBPs, specifically trihalomethanes (THM(s)) and haloacetic acids (HAA(s)) when the disinfectant (chlorine or chloramines) was added prior to final filtration. Operation in Beaumont, at that time, with disinfectant addition after filtration kept the concentration of THM(s) and HAA(s) below US EPA permit requirements. During the EBF field test demonstration, while the resultant TOC in the 3-inch test column was reduced to near 2 mg/L and that of plant operations was near or over 4 mg/L, the plate count in the filtered water after said column was under 100 organisms/ml while the plate count in the filtered water after final filtration in the plant was in excess of 3,000 organisms per mil. This significant difference in plate count > 30:1 demonstrates a "natural disinfection capability" of EBF.] [Original edited by Dr. Paul Berger]
   4. Removal of TOC downstream reduces both the disinfectant demand and the development of drinking water DBPs, which have been shown to be toxic, carcinogenic and teratogenic. This result is the operating goal of EBFT [EBF].
   5. Operation of a drinking water plant with EBFT [EBF] improves operating risk by reducing potential health impacts to the citizenry. A Failure Mode and Effect Analysis (FMEA) of operating a drinking water plant with EBFT [EBF] is attached." (FMEA is attached as Exhibit F.)"

Attachment #4

5. This asserted concern by NSF International's CPHC was not previously put forth to the EBF Task Team; therefore, the EBF Task Team was not here-to-fore provided an ability to respond.

Exhibit A states in the third paragraph:

> "While the EBT organisms may be susceptible to downstream disinfection, no data have been provided to demonstrate the effective log reduction of the organisms by final filtration and disinfection. Similarly, it is recognized that filtration and disinfection operation occasionally fail for short periods of time. No data are presented to indicate what might happen if some EBT organisms escaped into the distribution system at a time when human or mechanical error might results in inadequate removal of the organisms before they reached the distribution system."

In response the EBF Task Team would like to state to NSF International and NSF International's CPHC:

1. The log reduction of organisms within a final filter in a Drinking Water Plant is the responsibility of the US EPA and is promulgated in the US EPA Drinking Water Regulations.
2. The log reduction of organisms due to a disinfectant concentration in downstream distribution piping is the responsibility of the US EPA and is promulgated in the US EPA Drinking Water Regulations.
3. The operation of a Drinking Water Plant is the responsibility of the system in conjunction with the state for which the Drinking Water Plant operates; this is while operating protocols for drinking water plants are promulgated in the US EPA Drinking Water Regulations.
4. A Failure Mode and Effect Analysis (FMEA) for EBF previously provided within Tab 7 of the May 14, 2005 response to the CPHC by the EBF Task Team. Said FMEA is attached herein as Exhibit F.
5. Log reduction for bacteria in filtration and in disinfection have been researched by the US EPA and reported via The US EPA Drinking Water Regulations as evidenced in The Long Term 2 Enhanced Surface Water Treatment Rule, ref. Exhibit K.
6. Slow sand filtration, e.g. filtration with ubiquitous (unknown) biological cultures, has been practiced for decades and is an approved method of drinking water purification as evidenced in the US EPA Drinking Water Regulations in the Long Term 2 Enhanced Surface Water Treatment Rule, ref. Exhibit K.
7. The US EPA has recognized the efficacy of biological filtration with the use of unknown ubiquitous cultures in the removal of the TOC precursors to the formation of DBPs, ref. Exhibit L.
8. It is important to note the inherent safety of EBF as compared to items 6 and 7 herein, as the biological cultures for EBF are screened for pathogenicity, opportunistic behavior, virulence factors and waterborne disease as presented above.

Exhibit A further states in the third paragraph:

> "Insufficient data have been presented that would indicate the EBT organisms can be sufficiently controlled once introduced into the intended environment such that unintended side effects or contamination would not occur."

In response, the EBF Task Team would like to state to NSF International and NSF International's CPHC:

1. As stated in the May 14, 2005 response to the CPHC by the EBF Task Team on page 3 item 2 a:

"Change in nature is a constant. Organisms in the water are continually incorporating new genetic material by various mechanisms (e.g., conjugation, transduction, transformation) and altering their own genetic makeup (e.g., transposition). Thus, one cannot assume that the bacteria introduced into the filter will not change. However, any change should be toward greater competitiveness in its ecological niche; the survival of the introduced bacteria depends upon its competitiveness. It would be exceedingly unlikely that such change will result in an introduced organism becoming pathogenic. The reason is the following: a microbe in a particular ecological niche (e.g., water, filter) must be able to compete successfully for nutrients against the microbial flora already adapted to that niche and resist antagonistic forces present (toxin production by other organisms, predation, bacteriophage, natural water stresses, disinfection, etc.). Any genetic change that does not serve this purpose is a liability and the organism will probably die. Any organism has a defined level of energy (i.e., ATP) for growth and replication, and a gene change that would make the organism pathogenic for humans would place the organism at a disadvantage in its normal ecological niche. This is why gastrointestinal pathogens typically do not survive for long periods outside the gut. This issue is explained in greater detail in a review article by M.McGloughlin and R. Doi of the University of California-Davis (*Genetically Engineered Microorganisms, Environmental Introduction*, Encyclopedia of Microbiology 2:259-279 (1992)).

Some bacteria natural to the water environment and soil can cause disease in some individuals whose immune system is deficient or have another underlying health condition. These bacteria, known as opportunistic pathogens, include *Legionella pneumophila*, the *Mycobacterium avium* complex, and *Pseudomonas aeruginosa.* Some of these organisms grow in water filters. It is no more likely, and probably less likely (depending on how the introduced organisms are selected), for the introduced bacteria to cause disease than the existing microbial flora.

With regard to data on the survival of organisms introduced into a particular natural environment, one published study involved introduction of several species of bacteria and one of yeast into sewage, lake water, and soil. The organisms included *Salmonella typhimurium* (a fecal pathogen), *Staphylococcus aureus* (a nonfecal pathogen), *Klebsiella pneumoniae* (an opportunistic pathogen common in some waters), *Bacillus subtilis* (common soil bacterium), *Agrobacterium tumefaciens* (common soil bacterium), *Rhizobium meliloti* (common in soil near and in roots of legumes), and *Saccharomyces cerevisiae* (a common yeast). In nonsterile environments, every introduced organism declined by several magnitudes over a few days. Even in sterile environments, most introduced organisms declined, although several were able to grow. The authors concluded that some species persist in environments in which they are not native if they tolerate abiotic stresses, withstand starvation conditions, and coexist with antagonistic organisms. If an introduced organism fails in even one of these three factors, it fails to survive. (Liang, L., J. Sinclair, L. Mallory, and M. Alexander, 1982.
Fate in model ecosystems of microbial species of potential use in genetic engineering. Appl. Environ. Microbiol. 44(3):708-714.)."

2. As previously provided within Tab 5 of the May 14, 2005 response to the CPHC by the EBF Task Team, such a concern can only be the responsibility of either the US EPA or the Office of Science and Technology Policy (OSTP), ref. Exhibit G. Specifically, within the referenced Tab 7 on page 261 is stated:

> "The Office of Science and Technology Policy (OSTP) has established overall policy regarding how biotechnology will be regulated and coordinated in the United States. This policy has been outlined in formal notices published in the *Federal Register.* "

Further, page 262 states:

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> "Three agencies share primary responsibility for regulating the organisms, products, and processes for recombinant DNA technology, whether they be designed for closed systems or for environmental release. They are the Food and Drug Administration (FDA), the United States Department of Agriculture (USDA), and the Environmental Protection Agency (EPA)."

Further still, page 262 states:

> "Because biotechnology cuts across so many government agencies, interagency coordination is vital for the development of consistent policies and resolving jurisdictional mattes. A certain degree of consensual oversight has been achieved through the auspices of the BSCC, a committee of the Federal Coordinating Council for Science, Engineering and Technology, which reports to the OSTP, Executive Office of the President. The BSCC was formed as a result of the first OSTP publication of a Coordinated Framework for Bio technology Regulation. The BSCC is composed of senior policy officials from the USDA, EPA, FDA, NIH, and the National Science Foundation (NSF)."

Exhibit A states in the fourth paragraph:

> "The need for a full risk assessment of the technology was requested during the October 2004 CPHC meeting the US EPA Office of Drinking Water representative serving on the Council. The response provided by the Task Team was not considered adequate."

The EBF Task Team would like to respectfully state to NSF International and NSF International's CPHC that NSF International and NSF International's CPHC are operating against the guidelines established for NSF/ANSI Standards 60 and 61 by demanding a Risk Assessment of EBF, as:

1. The US EPA Drinking Water Regulations govern the operating protocols for EBF while neither NSF International nor NSF International's CPHC have any authority or responsibility over the US EPA Drinking Water Regulations, as stated in Annex A of NSF/ANSI Standards 60 and 61.

2. Stated in the May 14, 2005 response to the CPHC by the EBF Task Team on pages 8, 9 and 10:

> "The EBFT [EBF] Task Team and previously the Biological Filtration Task Team have reviewed this request on numerous occasions. (This request is always presented by an employee of NSF International. This request has continually been voted down in both the Biological Filtration Task Team and in the NSF/ANSI Standard 60/61 Committee. There is no doubt that another or the same NSF employee is trying to force this request on the EBFT [EBF] Task Team, again.)
>
> As previously reviewed and reported many times, a risk assessment for EBFT [EBF] is not required because of: (1) Common sense in combination with a microbiological background and a working knowledge of the US EPA Drinking Water Regulations, (2) Annex A of NSF/ANSI Standards 60 and 61 (attached) in combination with the US EPA Drinking Water Regulations; and (3) The chosen strains for inoculation have already been reviewed by The Toxicology Group, a division of NSF International, for pathogenicity, opportunistic behavior and virulence factors. Specifically:

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(1) The US EPA Drinking Water Regulations define regulatory protocols for the operation of a drinking water purification plant to physically separate and chemically disinfect raw water for microorganism contamination. The US EPA Drinking Water Regulations define a required amount of physical removal, along with an allowable amount of physical contamination (measured as turbidity and analytically measured as nephelometic units (NTU)), in combination with a required amount of disinfection to control pathogenic microorganisms. The final filter in a drinking water plant is the final physical removal of physical contamination, which in the context of this discussion may be the inoculum of EBFT [EBF]. The physical protocols placed in use today by the US EPA are for removal/control of pathogens. This is in stark contrast to control of the proposed non-pathogenic inoculum of EBFT [EBF]. And, as stated previously, the proposed inoculum of EBFT [EBF] is limited to heterotrophs, which are easily disinfected should any pass final filtration. This is also in stark contrast to the indigenous microorganisms (bacteria, viruses and animals) in the raw water, many of which are not easily disinfected should any pass final filtration. Common sense in combination with a microbiological background and knowledge of the US EPA Drinking Water Regulations dictate that the EBFT [EBF] is a significant reduction in health risk as compared to procedures which are currently in place and which are currently supported by ANSI/NSF Standards 60 and 61.

(2) ANSI/NSF Standards 60 and 61 state in Annex "A" on page A1:
"The following general procedure shall be used to evaluate drinking water substances under this Standard:

1) A determination shall be made as to whether a published (publicly available in printed or electronic format) and peer reviewed quantitative risk assessment for the substance is available.
2) When a quantitative risk assessment is available, the reviewer shall determine whether the assessment is currently used in the promulgation of a drinking water regulation or published health advisory for the substance (see the requirements of annex A, section A.3.).
   - If the assessment is used in the promulgation of a drinking water regulation, the Single Product Allowable Concentration (SPAC) shall be derived from the regulatory value(s); or
   - If the assessment is not the basis of a drinking water regulation, the assessment and its corresponding reference dose shall be reviewed for its appropriateness in evaluating the human health risk of the drinking water substance;

   NOTE – When reviewing as assessment used in the promulgation of a drinking water regulation, it is recommended that the regulatory authority be contacted to verify the currency of the assessment under consideration."

As has been communicated to NSF International on many occasions over the past 3 years:

1) Publicly available peer reviewed documents were evaluated by The Toxicology Group, a division of NSF International for the proposed substances (biological cultures). A final report by The Toxicology Group, a division of NSF International affirmed use of the substances in 2000. Further, The Toxicology Group, a division of NSF International, reviewed

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the substances for pathogenicity, opportunistic behavior and virulence factors. This is when the US EPA Drinking Water Regulations (Regulating Authority) require the removal of pathogens.

2) As the proposed Standard incorporates protocols from and is governed by the US EPA Drinking Water Regulations, there are defined SPACs incorporated within the Proposed Standard from the operating protocols of the US EPA Drinking Water Regulations.

3) Therefore, for NSF International to perform a risk assessment on EBFT [EBF] would mean that NSF International would have to perform a risk assessment on the US EPA Drinking Water Regulations. Such a decision making process is beyond the scope and control of NSF International.

4) Should there be a decision for a risk assessment, such a decision can only be made by the US EPA, as such a decision authority is legislated by the US Congress and controlled by the Office of the President.

(3) The chosen strains for inoculation have already been reviewed by The Toxicology Group, a division of NSF International, for pathogenicity, opportunistic behavior and virulence factors. This is in stark contrast to the requirements of the US EPA to remove pathogenic microorganisms from drinking water. Therefore, the proposed heterotrophic microorganisms have already been reviewed past any reasonable requirement, as promulgated by Annex of ANSI/NSF Standards 60 and 61, as well as the US EPA Drinking Water Regulations.

In conclusion, a risk assessment is unwarranted given: knowledge of the proposed technology in combination with common sense and a knowledge of the US EPA Drinking Water Regulations; the operating guidelines of NSF International as defined within Annex A of Standards 60 and 61 in combination with the US EPA Drinking Water Regulations; and work completed 4 years ago by The Toxicology Group, a division of NSF International."

As is known from the US EPA Disinfection By-Product (DBP) Regulations, the disinfection of drinking water includes, unfortunately, the formation of disinfection by-products. This fact is presented in layman's terms within Tab 10 of the May 14, 2005 response to the CPHC by the EBF Task Team, ref. Exhibit H, and is referenced in Exhibit E. Research has shown individual DBPs or mixtures of DBPs to be toxic, carcinogenic and teratogenic, ref. Exhibit H (as well as the US EPA Disinfection By-Product Regulations). This is while many of the known DBPs are not yet regulated, most notably those from ozone and chlorine dioxide disinfection, ref. Exhibits H and I. NSF International lists within NSF/ANSI Standard 60 disinfectants used in drinking water; this is while NSF International has refused to provide any SPAC to the DBPs formed in drinking water during disinfection and has not performed a risk assessment of the DBPs formed in drinking water disinfection or of the NSF/ANSI Standard 60 chemicals which form said DBPs in drinking water during disinfection. As the US EPA regulates DBP formation in drinking water and the US EPA regulates microbial removal and microbial disinfection in drinking water while NSF International has not performed a risk assessment of DBP formation or of the NSF/ANSI Standard 60 Listed Chemicals which form DBPs, it is not reasonable that NSF International would insist to perform a risk assessment on EBF; this is especially when the operating protocol for EBF are the US EPA Drinking Water Regulations, ref. Exhibit F.

As generally practiced in the industry, drinking water plants which operating with ozone disinfection prior to filtration often develop a biological filter loaded with organisms indigenous to the raw water in order to reduce Assimulatable Organic Content (AOC), wherein the indigenous organisms tend to reduce TOC to an

extent (limitted to the AOC component) while the EBF organisms would be chosen and thereby much more effective to reduce TOC. (AOC molecules are defined as those molecules which can be reduced by a Biofilter inoculated with indigenous micro-organisms; AOC is a subset of TOC and does not include most of the toxic, carcinogenic and teratogenic molecules created in ozonation. In strong contrast, EBF inoculation organisms have been chosen so as to be effect with all TOC molecules, not just AOC molecules.) Ozone disinfection of drinking water is presented in layman's terms within Tab 11 of the May 14, 2005 response to the CPHC by the EBF Task Team, ref. Exhibit I. This is while NSF International lists within NSF/ANSI Standard 60 the chemicals used to manufacture ozone at a drinking water plant, e.g. oxygen. This is while it is well known that disinfection of drinking water with ozone forms DBP molecules, which are at least one of: alcohols, glycols (including ethylene glycol), aldehydes (including formaldehyde), ketones (including methyl ethyl ketone), and organic acids (including oxacyllic acid), ref. Singer, Philip C., *Formation and Control of Disinfection By-Products in Drinking Water,* AWWA, 1999, excerpts attached as Exhibit J and referenced in Exhibit E. These DBP molecules are at least one of: toxic, carcinogenic and teratogenic while NSF International has refused to provide any SPAC to these DBPs and has not performed a risk assessment of these DBPs or of ozone or of oxygen. As the US EPA regulates DBP formation in drinking water and the US EPA regulates microbial removal and microbial disinfection in drinking water while NSF International has not performed a risk assessment of DBP formation or of the NSF/ANSI Standard 60 Chemicals which are known to cause DBP formation, it is rather irrational that NSF International would insist to perform a risk assessment on EBF; this is especially when the operating protocol for EBF are the US EPA Drinking Water Regulations, ref. Exhibit F.

Conclusions

From the above, it can be concluded that:

- The concerns and issues posed by NSF International and NSF International's CPHC within Exhibit A are not warranted with many having been previously addressed by the EBF Task Team.
- As guided within Annex A of NSF/ANSI Standards 60 and 61, NSF International is not to perform a risk assessment against a US EPA protocol. This guidance would certainly include the US EPA Drinking Water Regulations.
- As NSF International **does not regulate** the concentration of DBPs in drinking water from the use of NSF/ANSI Standard 60 Listed Chemicals, specifically:
  - o chlorine,
  - o bleach,
  - o ozone from oxygen,
  - o chlorine dioxide from at least one of sodium chlorite, bleach and hydrochloric acid,

  while NSF International **does not perform a risk assessment** against the known DBPs of these chemicals, most notably: alcohols, glycols (including ethylene glycol), aldehydes (including formaldehyde), ketones (including methyl ethyl ketone) and organic acids (including oxacyllic acid) **or of the aforementioned chemicals listed within NSF/ANSI Standard 60 which form said DBPs**, then NSF International and NSF International's CPHC appear to be improper in asserting themselves against the US EPA Drinking Water Regulations in relation to EBF.
- EBF has precedence in drinking water purification via slow sand filtration, ref. Exhibit K.
- Log removal of bacteria and disinfection of bacteria has been studied and is regulated via the US EPA Drinking Water Regulations, ref. Exhibit K.
- Biological filtration is recognized by the US EPA as a method of TOC removal, ref. Exhibit L.

Finally, NSF International has created a required industry approval mechanism via NSF/ANSI Standards 60 and 61 by lobbying all 50 States of the United States of America to require use of NSF/ANSI Standards 60 and 61; therefore, and in the case of drinking water chemicals and equipment, e.g. NSF/ANSI Standards 60 and 61, respectively, it is a challenge for any site within any state to implement a chemical or biochemical program within drinking water purification without a listing in at least one of NSF/ANSI Standards 60 and 61. With the creation of said approval mechanism, NSF International has created for itself a mechanism to control the products used within the drinking water industry. Owning and operating such an industry controlling mechanism, NSF International and the members of the CPHC should operate according to the authority promulgated to NSF International from: Congress, the NSF International contract with the US EPA and guidelines as established and written within Annex A of NSF/ANSI Standards 60 and 61.

Sincerely yours,

Richard A. Haase, President

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Attachment: Exhibits A – L.

Attachment #4