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July 7, 2000

The Honorable Ken Calvert
Chairman Subcommittee on Energy and the Environment
Committee on Science
U. S. House of Representatives
Suite 232O, Rayburn House Office Building
Washington, DC 20515-6301

Dear Mr. Chairman:

Thank you for your letter of May 8, 2000 to Dr. Joseph Cotruvo wherein you request information from NSF International (NSF) on fluoride containing compounds. We appreciate having received an extension in order to allow NSF staff sufficient time to provide a comprehensive response to your request.

This response is comprised of a general information section entitled *Background on NSF and the Drinking Water Additives Program* and a section that answers the 8 questions in your letter. I have attached additional documents that will also assist in answering your questions.

It is important to note that your questions relate to two separate issues, and departments, within NSF – standards and product certification. First, ANSI/NSF Standard 60 – the American National Standard developed by NSF and a consortium of major stakeholders consisting of the American Water Works Association (AWWA), the AWWA Research Foundation (AWWARF), the Association of State Drinking Water Administrators (ASDWA), and the now inactive Conference of State Health and Environmental Managers (COSHEM) was developed from 1985 to 1987. Second, NSF operates a separate product testing, certification and listing program based on the requirements of the standard.

The health based principles of Standard 60 were originally developed by the NSF Health Advisory Board (HAB) which is a panel of non-NSF health science experts. This group continues its role in an advisory and oversight function to NSF and its Toxicology staff to assure that ANSI/NSF Standards are consistent with current public health principles.

The standard and the certification program are recognized and utilized by AWWA and its member utilities, and adopted in most state regulations. More than 43 states have regulations in place requiring product compliance with ANSI/NSF Standard 60. (See Attachment 14). The program provides a product quality and safety assurance that aims to prevent addition of harmful levels of contaminants from treatment chemicals.

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Fluorosilicate products are comprised of a fluoride entity as well as a silicate entity. Based on previously published studies, there is virtually complete dissociation of the fluoride and silicate entities in dilute solutions. As such, the toxicological evaluation of fluorosilicate products is conducted through the evaluation of each entity separately.

ANSI/NSF Standard 60 requires, when available, that the U.S. EPA regulated Maximum Contaminant Level (MCL) be used to determine the acceptable level for a contaminant. The MCL for fluoride is 4 mg/L of drinking water. As such, NSF has not independently developed toxicology data to support this level of human exposure. The Maximum Allowable Level (MAL) for fluoride ion in drinking water from NSF Certified treatment chemicals is 1.2 mg/L, or less than one-third the EPA's MCL. The product Maximum Use Level (MUL) certified by NSF ranges from 4 - 6.6 mg/L.

There is no EPA MCL for silicate in drinking water. When an MCL does not exist for a contaminant, ANS/NSF Standard 60 provides criteria to conduct a toxicological risk assessment of the contaminant and the development of a Maximum Drinking Water Level (MDWL). NSF has established a Maximum Drinking Water Level of silicate at 16 mg/L. A fluorosilicate product MUL of 4-6.6 mg/L results in silicate drinking water levels substantially below the 16 mg/L MAL established by NSF for silicates. Attachment 15 outlines the derivation of the NSF MAL for silicates.

In general, NSF Certified fluoridation products have been tested and found to comply with the requirements of ANSI/NSF Standard 60 for 12 additional inorganic chemicals. Additional testing of these products for radionuclides has resulted in no measurements above the detection limits. The specific answers below provide additional detail.

If there is any more information that you need, please do not hesitate to contact me.

Sincerely.

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cc: Dr. Joe Cotruvo, NSF
Dr. Lori Bestervelt, NSF

List of Attachments

Attachment	Description
1	FR Notice 5/17/84 - Disposition of the Federal DWA Advisory Program
2	FR Notice 7/7/88 - Termination of the Federal DWA Program, Notice
3	ANSI/NSF Standard 60 - DW Treatment Chemicals- Health Effects
4	ANSI/NSF Standard 61 - DW System Components- Health Effects
5	NSF Standards Development and Maintenance Policies
6	Standards Update - Flowchart of the Standards Development Process
7	1987 NSF DWA Joint Committee Membership List
8	1987 NSF Council of Public Health Consultants List
9	NSF Certification Policies for DW Treatment Chemicals - Standard 60
10	Toxicology Data Review Submission Form - Part A
11	Toxicology Data Review Submission Form - Part B
12	NSF DWA Listings Book
13	NSF DWA Certification Process - 7 Steps
14	ASDWA State Survey of Adoption of ANSI/NSF Standards 60 and 61
15	NSF MAL Derivation for Silicates in Drinking Water

Background on NSF and the Drinking Water Additives Program.

NSF International was established in 1944, as an independent, not-for-profit, third party organization dedicated to the protection of public health and safety. NSF has more than 300 employees consisting of engineers, chemists and toxicologists who develop U.S. national standards and provide independent product testing and certification services for products that impact food, air, water and the environment. NSF is a World Health Organization (WHO) Collaborating Center on Drinking Water Safety and Treatment, as well as for Food Safety.

NSF involvement in the evaluation of drinking water chemicals, including fluoride-based chemicals, began in 1985, when the U.S. EPA granted an NSF-led consortium of stakeholders the responsibility to develop consensus, health-based, quality specifications for drinking water treatment chemicals and drinking water system components (Attachment 1). EPA also requested development of a product testing and certification program that would allow for independent product evaluations for use by states, cities, and water utilities, as a basis for product acceptance and use.

The original goal of the standard and certification program was to develop a preventative mechanism for selecting treatment chemicals that would not contribute harmful levels of contaminants to drinking water. The standards and the certification program were designed to be dynamic, to change as regulations change, and to constantly be tied to the requirements of the Safe Drinking Water Act and its drinking water quality regulations. In 1988, EPA terminated its informal chemical additives advisory program upon completion of the NSF standards and successful launch of the NSF product certification program (Attachment 2). We believe that the NSF standards and certification program have succeeded in achieving the goals of the original mandate.

The NSF Certification program consists of seven steps for initial product certification, and 4 steps on an annual basis. (See Attachment 13).

Today, NSF provides testing and certification services for thousands of products from more than 30 countries. NSF publishes its listings on its web site at www.nsf:org as well as in hardcopy (Attachment 12). In addition, attached is a copy of the NSF Certification Policies for Drinking Water Treatment Chemicals (Attachment 9). This document outlines the rules that govern the product certification program, over and above the requirements of the standard.

This section provides responses to the 8 questions in your letter.

Question 1. Please provide the identification and affiliation of each member of the committee or committees contributing to the policies established for each of the fluorine-bearing additives destined for the public water supplies, both current committee members and those responsible for establishing product standards for fluoride.

In response to an identified need for health-based standards dealing with drinking water contact products, a consortium led by the National Sanitation Foundation (now NSF) worked to develop voluntary third-party consensus standards for all direct and indirect drinking water additives. Other consortium members were the American Water Works Association (AWWA), the American Water Works Association Research Foundation (AWWARF), the Association of State Drinking Water Administrators (ASDWA) and the Conference of State Health and Environmental Managers (COSHEM, now inactive).

ANSI/NSF 60 *Drinking water treatment chemicals – Health effects* was initially adopted in December 1987, and was last revised in May 2000. It establishes minimum human health effects requirements for the chemicals that are added directly to drinking water for its treatment or other purposes. The standard was developed using a consensus standards development process with representation of the major stakeholder interests, including product manufacturers, product users such as consultants and water utilities, and representatives from the regulatory/public health sectors. As an American National Standard, each revision to ANSI/NSF 60 also undergoes a public comment review. This public comment process allows for any interested party to obtain a copy of the proposed revision and to submit comments or objections to NSF. All comments received are handled in accordance with the due-process requirements set forth in the ANSI procedures and NSF policies.

Each edition of ANSI/NSF 60 contains a list of the committee members who oversee the development and review of that edition of the standard. These committees consist of the NSF Joint Committee for Drinking Water Additives, the balanced group of approximately 36 representatives from the user, regulatory and manufacturing sectors, and the NSF Council of Public Health Consultants, which is a group of approximately 45 independent, public health experts from government, academia and the environmental health community. The current version of ANSI/NSF 60 (2000) is enclosed for your review (Attachment 3), as well as a list of the membership of these committees when the Standard was first adopted in 1987 (Attachments 7 and 8). Copies of the NSF *Standards Development and Maintenance Policies* (Attachment 5) and “Standards Update” (Attachment 6) are also enclosed to provide further detail on the standards development process.

Question 2. Under General Requirements 3.2.1, formulation submission and review, ANSI/NSF 60 -1999, are manufacturers of hydrofluosilicic acid and silicofluorides required to "submit for each product, when available, a list of published and unpublished toxicological studies relevant to the treatment chemical and the chemicals and impurities present in the treatment chemical?"
The standard requires that the manufacturer of a product submitted for certification provide toxicological information, if available. NSF requires that manufacturers seeking certification to the standard submit this information as part of their formulation or ingredient supplier submission.

Has your document, General Requirements 3.2.1, Formulation submission and review, ANSI/NSF 60 - 1999. been peer reviewed for accuracy? If so, please provide the names, affiliations and contact information for the peer reviewers.
The document (ANSI/NSF Standard 60) has been peer reviewed for accuracy. Joint Committee and CPHC members and contact information are contained in Attachments 3, 7, and 8.

Please provide:
All lists complying with the above requirement submitted by manufacturers of hydrofluosilicic acid and silicofluorides.
NSF has based its certification on the product use not exceeding the EPA's MCL for fluoride. Separately, NSF has developed an MAL for silicates of 16 mg/L that supports the silicate portion of the products in question. In addition, potential contaminants are also limited by the standard. The supporting rationale for the silicate MAL is enclosed in Attachment 15.

The complete record of all tests of each fluorine-bearing additive using ion chromatography, atomic absorption spectroscopy, and scintillation counting.
NSF toxicology review and testing of fluorosilicate compounds looks for potential trace contaminants such as heavy metals and radionuclides. The formulation review step examines not only the product formulation, but also considers potential contaminants from the ingredients, processing aids, and any other factors impacting contaminants in the finished drinking water. Contaminants in the finished drinking water are not permitted to exceed one-tenth of the EPA's regulated MCL (Maximum Contaminant Level) when the product is added to drinking water at its Maximum Use Level, unless it can be documented that a limited number of sources of the contaminant occur in drinking water.

NSF has reviewed its files and has compiled a summary of our findings (Table 1) in lieu of complete test reports. Individual test reports, as well as formulation information are protected by nondisclosure agreements with certification clients.

NSF searched its files to determine the level of contaminants found in these fluoridation products, when the product is dosed to water at the Maximum Use Level (MUL). The exact number of laboratory tests performed is not readily available

because we maintain records only on those tests where a contaminant was detected. The results in Table 1 include initial product tests as well as annual product monitoring tests. In total, these products have been tested more than 100 times in our laboratories. Table 1 indicates that metals contamination of drinking water as a result of fluoride chemical use is not an issue. There has not been a single fluoride product tested with a metal concentration in excess of its corresponding MAL.

Silica and silicates, which make up a portion of the fluoridation chemicals mentioned above, are addressed by the certification of sodium silicates to a level of 16 mg/L under ANSI/NSF Standard 60. (See Attachment 15).

Beginning in early 1998, NSF went beyond Standard 60 requirements and voluntarily began testing fluoridation chemicals for the presence of radionuclides (alpha and beta emitters) utilizing EPA Test Method 900.0, as specified in Annex B of ANSUNSF Standard 60. To date, we have not found any sample with a positive (detected) result, with detection limits of 4 pCi/liter and 3 pCi/liter for gross alpha and gross beta, respectively.
Table 1

	Number of Fluoride Samples with Positive Test Results	Average Contaminant Concentration in Samples with Positive Test Results* (ppb)	Maximum Contaminant Concentration in Samples with Positive Test Results (ppb)	ANSI/NSF Standard 60 Maximum Allowable Level (MAL) (ppb)	US EPA Maximum Contaminant Level (MCL) (ppb)
Antimony	0	NA	NA	0.6	6
Arsenic	39	0.43	1.66	2.5**	50
Barium	1	0. 19	0.17	200	2000
Beryllium	5	0.21	0.3	0.4	4
Cadmium	3	0.06	0.1	0.5	5
Chromium	3	0.14	0.2	10	100
Copper	8	0.49	0.55	130	1300
Lead	7	0.4	1.1	1.5	15
Mercury	5	0.013	0.015	0.2	2
Nickel	0	NA	NA	NA	NA
Selenium	I	0.60	0.6	5	50
Thallium	6	0.03	0.05	0.2	2
Radionuclides	0	NA	NA	-	-

**Only those samples where a contaminant was detected contribute to the average. The average contaminant concentration for all samples tested is significantly lower, and is affected by detection limits and number of detections.*
*** ANSI/NSF Std 60 utilizes Canadian MACs and EPA MCLs in determination of MALs.*

A true and complete copy of all tests that identify the full composition of each fluorine-bearing additive, including all attendant organic substances, radionuclides and other chemicals.

Compositional analyses are not required by the NSF standard. The verification of composition is performed during the annual unannounced plant inspection by NSF auditors who verify sources and ratios of labeled ingredients. Separately, there are industry standards from AWWA (American Water Works Association) (ANSI/AWWA B702-99 for Sodium Fluorosilicate and ANSI/AWWA B703a-97 for Fluosilicic Acid) that provide for compositional requirements.

Copies of any and all tests or studies of each of the fluorine-bearing additives that consider or indicate degree of dissociation.

The standard requires testing for contaminants that are likely to be present in the product. A study by N.T. Crosby, published in 1969 in the Journal of Applied Chemistry (Volume 19), establishes dissociation of fluorosilicates at 99% for 1ppm fluoride concentrations in drinking water.

Copies of any and all studies that have been performed on laboratory animals using hydrofluosilicic acid or silicofluorides.

NSF does not perform animal testing, although these may be required under Standard 60 if hazard/risk based action levels are exceeded. NSF toxicologists may review animal studies during the toxicology evaluation step of the product certification process.

Copies of any risk assessment documents in NSF International files that pertain to fluorine-bearing pesticides, such as cryolite.

Fluorine-containing pesticides such as cryolite are not required analyses under the standard, unless it is determined to be part of the formulation, or a potential contaminant. NSF would test for this or any other contaminants if indicated during the formulation review step.

Question 3. Have any studies on hydrofluosilicic acid or silicofluorides been submitted to NSF under claimed Confidential Business Information protection?

There have not been any studies on hydrofluosilicic acid or silicofluorides submitted to NSF under claimed Confidential Business Information protection.

Question 4. What are the Maximum Contaminant Levels, or any other regulatory standards, established for the following contaminants (either singularly, in combination with another substance, or in the elements' various forms) or any other contaminants reported as present in the fluorine-bearing substances hydrofluosilicic acid and other silicofluorides used in fluoridation programs?

Maximum Contaminant Levels (MCLs) can be found in Annex E of the enclosed copy of ANSI/NSF 60. Annex E of Standard 60 lists the federally regulated MCLs. Of the contaminants listed in your letter, MCLs exist for arsenic, barium, beryllium, cadmium, chromium, fluoride, lead, mercury, selenium, and dioxin (as 2,3,7,8-TCDD). Federal regulatory standards have not been established for the remaining contaminants listed in your letter.

Question 5. What tests are performed to identify the full and exact consistency of the fluorine-bearing product and determine the concentrations of each of the contaminants or combination of contaminants in a sample? Upon what occasion or frequency are these tests performed? Are Certificates of Analysis provided with each shipment of such products from the manufacturer?

NSF tests certified products at least annually for prospective contaminants (See response to Question 2). An NSF Certified company may produce many shipments during the course of the year, but the company is contractually bound to not change the formulation ratios, ingredients or add unauthorized sources of supply. Certificates of Analyses are typically provided by the vendor to the utility on a per shipment basis. There are industry standards from AWWA (American Water Works Association) (ANSI/AWWA B702-99 for Sodium Fluorosilicate and ANSI/AWWA B703a-97 for Fluosilicic Acid) that provide for affidavits and Certificates of Analyses.

Question 6. What is the purpose of establishing a maximum allowable level (MAL) for additives, restricting the contribution to drinking water of any one product to 10% of the Maximum Contaminant Level (MCL)?

The purpose of establishing a maximum allowable level (MAL) for individual drinking water additives products at 10% of the MCL is to recognize that contaminants may enter drinking water from other points throughout the system, including the source water, during the treatment and distribution process, and either through direct addition or surface contact. Limiting individual products to a contribution of 10% of the MCL for a given contaminant provides an extra margin of safety so that it is unlikely that the summation of the contributions from all potential sources will exceed the MCL at the tap.

Question 7. Under what circumstances or authority is an additive certified when the MAL of 10% of the established MCL is exceeded?

An MAL of greater than 10% of the MCL can be established by the certification body in limited cases if it can be reasonably documented that there are no other significant sources of the same contaminant, that together, would result in the finished drinking water contaminant concentration exceeding the MCL. Fluoride has an MAL of 1.2 mg / liter, which is 30% of the MCL. This is justified on the basis of the limited number of other potential sources of fluoride ion to drinking water. For example, water that naturally contains sufficient fluoride is not additionally fluoridated, and fluoride is seldom present in other additives.

Question 8. What tests and how often are they performed by NSF International to determine the exact consistency and concentrations of all contaminants in hydrofluosilicic acid, silicofluorides and sodium fluoride products? What is the ratio of NSF International tests to shipments by manufacturers of the additives? Are NSF International test results compared with Certificates of Analyses as a quality assurance measure?

As indicated in question 2, the testing required by the standard is for regulated metals. NSF additionally performs radionuclides analysis. Contaminant testing is performed initially upon application, and at least annually thereafter. Samples are collected during unannounced inspections by NSF auditors.

As mentioned previously, NSF tests products at least once per year. A contract signed by the NSF Certified manufacturer precludes production or process changes without written consent from NSF.

NSF test results are not routinely compared to Certificate of Analyses results. Certificates of Analyses often report on parameters not required under ANSVNSF Standard 60. For example, the AWWA standards mentioned previously require testing for fluoride content, moisture, impurities, etc. The AWWA standards also incorporate the option of additional purchaser specifications.

Please provide the committee with copies of any NSF International publications, studies, and reports relating to fluoride.

As mentioned earlier, NSF relies on the U.S. EPA MCL and its supporting documentation, as specified in the standard. See attachments listed in the cover letter.