



DATE: October 9, 2015

TO: Washington State Board of Health Members

FROM: David DeLong, Board Staff

SUBJECT: PETITION FOR RULEMAKING: NSF CERTIFICATION OF FLUORIDATION ADDITIVES

Background and Summary:

On September 8, 2015, the Board received a rule making petition from James Deal, requesting that WAC 246-290-460 Fluoridation of Drinking Water, be amended to include a new paragraph. The petition asserts:

1. NSF/ANSI standard 60 requires that a number of toxicological studies must be conducted for each certified water additive.
2. NSF does not do the toxicological testing that their standard requires.
3. Fluoridation additives do not comply with the standard due to this lack of testing.

The petition requests a new subsection be added to WAC 246-290-460 to:

1. Require the Department of Health (DOH) to review toxicological data to determine that fluoridation additives comply with NSF/ANSI Standard 60.
2. Prohibit the use of fluoridation additives for use in Washington State until DOH has completed the review of toxicological data and verified compliance with the standard.

NSF is a trusted public health and safety organization that provides third party product testing and certification services, and develops national product standards to protect and promote public health. NSF is an independent and internationally accredited body, and its certification is a common requirement in many Board rules.

NSF/ANSI Standard 60 is the standard applied to drinking water treatment chemicals. This standard was "...developed to establish minimum requirements for the control of potential adverse human health effects from products added to water for its treatment." The standard was developed by the NSF joint Committee on Drinking Water Additives which has diverse membership from both public agencies and private industry.

NSF/ANSI standard 60 establishes a protocol for determining a "safe level" of an additive in drinking water supplies. This "safe level" is referred to in the standard as a "Single Product Allowable Concentration (SPAC)".

There are two distinct pathways in the standard to determine the SPAC. The first pathway is for chemicals that have an EPA regulated level (such as a Maximum Concentration Limit, or MCL) or another published risk estimation. The second pathway is for chemicals that do not have an EPA

Washington State Board of Health Members

October 14, 2015

Page 2

regulated level or other published risk estimation. In the second pathway, a certifying organization must conduct the tests and studies as outlined in Mr. Deal's petition in paragraph (c). However, because fluoride has an established MCL, the SPAC for fluoridation additives is set following the first pathway and (as stated in Annex A, section A.3.2 in the standard) requires no additional toxicological data.

The SPAC for products with an established MCL is determined using the following formula:

$$\text{SPAC} = \text{MCL} / \text{estimated number of drinking water sources}$$

The denominator in the equation recognizes that there may be other sources of the product of interest and is used to create a margin of safety to ensure that an additive does not result in levels exceeding the SPAC. The denominator in this equation is not a constant. It may be determined by data submitted to NSF for evaluation and inclusion in the standard. If no data on sources is available the default value is set at 10.

In the case of fluoridation additives, CDC provided source data which is documented in the standard in table C-1. The SPAC for fluoride as a direct additive is set at 1.2 mg/l and documented in table C-1. This level has been set in compliance with published requirements of NSF/ANSI Standard 60. Fluoridation additives that are NSF tested and certified do comply with this standard.

Based on our review of the NSF/ANSI Standard 60, we found that NSF International applied its established protocol for fluoridation additives and recommend that the Board retain it as the standard for WAC 246-290-460.