The Evolution of Standards for Naturally Occurring Fluorides: An Example of Scientific Due Process

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SYNOPSIS

In three quarters of a century of observation and research, the effects of fluoride on dental caries and on general bodily health have been well documented. An expanding data base has allowed a firming up of the guidance and standards for appropriate and safe levels of naturally occurring fluorides for human consumption. Over time, through specific recommendations, the maximum fluoride concentrations deemed appropriate have been altered, but by a process of considered adjustment. Although the Public Health Service has been responsible for the formalization of many of the recommended standards, those recommendations have been based on research from many fronts.

In the most recent reconsideration of the standards for natural fluoride, the most exhaustive and thoroughly documented review to date was done, incorporating review by representatives from State, Federal, and private programs. Although the specific example of the development of standards for natural fluoride is used, it should be illustrative of similar processes that are constantly underway in regard to substances and factors with a potential impact on the public's health. Expansion of the data base through research and scientific inquiry will lay the foundation for future reconsideration of the standards for naturally occurring fluorides.

OUR EVERYDAY LIVES are touched directly or indirectly by a myriad of standards affecting the food we eat, the water we drink, and the fuel we burn in our cars. However, the origins for such standards and the processes by which they are updated or discarded are not immediately evident.

A cursory review of international, Federal, and State standards might lead one to believe that every possible physical or chemical moiety has had at least one standard created for it. In truth, this is not the case. For example, every year the number of new synthetic substances that come under the aegis of Federal review, but that lack specifications and agent-explicit exposure criteria, number in the thousands. The degree to which the guidance provided for the management of any substance or physical effect becomes a constraint depends on the weight of scientific evidence and the degree of government regulation applying to a particular substance or situation. Not until specific language is attached to standards through legal enactment do we reach the level of regulation. Until that point, the guidance or standards established by professional organizations or governmental entities are elective, and pressures for compliance come from the peer professional group. As an illustration, a single substance, naturally occurring inorganic fluoride, will be examined in the context of the historical and physiological significance of its presence in public drinking water supplies. By an examination of the evolution of standards for this substance, we hope to enhance the appreciation of "scientific due process" and administrative review.

Distribution and Physiological Effects

Fluorine and its compounds are widely distributed in the biosphere, being found in both water and earth (*1*). Great concentrations of fluoride, associated with volcanic eruptions, have also occasionally been found in the air. Surface waters such as lakes, rivers, and ponds generally contain only trace amounts of the element. Ground waters such as shallow or deep wells contain variable amounts, but generally greater concentrations than are found in surface waters. Geographic distribution is also a significant factor, as many areas of the Southwest and some areas in the Midwest have been shown to have up to 10 ppm of naturally occurring fluoride in ground water supplies (1 ppm is the concentration produced when 1 mg of fluoride is dissolved in 1 l of water).

Most of the fluoride ingested is absorbed quickly in the stomach and intestines, but a small portion is eliminated in the feces (*2,3*). The amount that is retained in the body depends on the person's age and overall fluoride intake, the fluoride concentration in drinking water, and the length of time the person has lived in a particular area. When significant amounts of fluoride are present in drinking water supplies (greater than, say, 0.1 ppm), the amount of fluoride eliminated in a 24-hour period is for long-term residents approximately equal to the amount consumed daily in the drinking water. Essentially all of the fluoride that is retained is deposited in the developing or remodeling bones, mostly the spine and vertebrae, or in developing teeth.

From an abundance of scientific evidence accumulated through decades of research, it is apparent that naturally occurring fluorides, in the concentrations found in the United States, will produce the following effects, based on a dose-response phenomenon.

1. Concentrations in drinking water of approximately 1.0 ppm reduce dental decay by about 65 percent compared with the decay rates found in similar populations consuming drinking water without significant amounts of fluoride (*4–6*).

2. At concentrations of about 2.0 ppm or above, dental fluorosis may be manifested. Changes in color and opacity may occur variably on the surfaces of the teeth, and in the more severe forms of fluorosis, the morphology of tooth surfaces may be affected by pronounced developmental hypoplasia (*7–9*). The predictability of dental fluorosis in individuals is unknown, but the frequency of distribution of the various degrees of fluorosis in a population can be predicted with some confidence and can be described by Dean's Community Fluorosis Index (*10*).

3. No untoward general physiological effects are to be anticipated (*10,11*).

Evolution of a Standard

Eighty years ago, a dental enamel defect termed "dental di chiae" was first described by Eager, a Public Health Service dental officer working in Naples, Italy. Although the cause of this enamel defect was not known at the time, Dr. Frederick McKay, a Colorado Springs dentist, noticed that many of his patients, particularly those who had lived in the area all their lives, had an apparently permanent stain on their teeth that came to be known locally as "Colorado stain." McKay continued to study the effect, unaware that fluoride, which was present in high concentrations in the drinking water, could be the cause. Then, in 1931, a chemist working for the Alcoa Aluminum Company performed a spectrographic analysis of water from Bauxite, Ark. (an area where endemic dental mottling like that in Colorado Springs had been reported), and discovered high concentrations of fluoride.

Later, H. Trendley Dean of the Public Health Service described the occurrence of dental mottling in many different localities and further demonstrated the direct relationship between naturally occurring fluoride and dental mottling (*12–14*). Of even greater significance was the clear relationship that he found between the levels of naturally occurring fluoride and the prevalence of dental caries. Clearly, the presence of fluoride in drinking water in greater than trace amounts was a good predictor of lower prevalence of caries.

In 1946, the Public Health Service adopted a standard establishing the upper limit for naturally occurring fluoride at 1.5 ppm for drinking water supplies (*15*). The basis for this limit is not clear, but the formulators of the 1946 standards had access to the 1925 Public Health Service Drinking Water Standards, in which the criterion for standard setting was that "from any evidence at hand . . . the danger, if any, is so small that it cannot be discovered by available means of observation" (*16*). It should be noted that compliance with the 1946 standards was voluntary.

Between 1946 and 1962, Arnold (*17*) and others came to recognize that the optimum concentration of fluoride in drinking water might not be the same for all areas and might require adjustments based on the mean annual temperature of an area. The basic thinking here was that people in warmer climates will consume more water, and thus more fluoride, than persons living in cooler climates, even when the natural fluoride concentrations are the same. Later studies substantiated the fact that as temperature increases, the body's demand for fluids also increases. In 1953, Galagan, of the Public Health Service's Division of Dental Public Health, and coworkers (*18,19*) completed significant studies on climate and endemic dental fluorosis. Using Dean's 1942 Community Fluorosis Index (*10*), Galagan found that in midwestern communities, no objectionable dental fluorosis was evidenced until the fluoride level reached 1.8 ppm, but in communities in Arizona, moderate to severe fluorosis was found at concentrations as low as 0.7 ppm. For the optimal prevention of dental caries, Galagan recommended that the fluoride concentration in a community's water supplies correspond with the locality's mean maximum temperature and offered the following guide.

Mean maximum temperature (° F)	*Recommended optimum fluoride concentration (ppm)*
50.0–53.7	1.2
53.8–58.3	1.1
58.4–63.8	1.0
63.9–70.6	.9
70.7–79.2	.8
79.3–90.5	.7

This guide closely approximates a standard for promoting caries inhibition while limiting dental fluorosis regardless of the source of fluoride. (Once fluoride is consumed—whether it occurs naturally, is added in fluoridation of a community's water supply, or originates in a combination of the two—it provides identical ionic fluoride, which at a given concentration produces identical effects.)

The 1962 Public Health Service Drinking Water Standards (*20*) raised the limit for naturally occurring fluoride to twice the optimum for caries prevention in a particular locality. Water supplies with fluoride concentrations higher than that were to be voluntarily rejected by individual communities to avoid objectionable dental fluorosis. These standards also addressed limits and optimums for adjusting fluoride concentrations in water systems deficient in naturally occurring fluoride, as shown in the following table.

Annual average maximum daily air temperature[1] *(° F)*	*Recommended control limits (fluoride concentrations in mg per l)*		
	Lower	*Optimum*	*Upper*
50.0–53.7	0.9	1.2	1.7
53.8–58.3	.8	1.1	1.5
58.4–63.8	.8	1.0	1.3
63.9–70.6	.7	.9	1.2
70.7–79.2	.7	.8	1.0
79.3–90.5	.6	.7	.8

[1] Based on temperature data obtained for a minimum of 5 years.

During the 1950s and 1960s, a "two-fold margin of safety" recommendation appeared frequently in the literature, although the original method of computation has been questioned. However, in 1967, the Division of Dentistry of the Public Health Service recommended that Section 5.23 of the 1962 Public Health Service Drinking Water Standards be dropped back from an upper limit of 2 times the optimum to 1.5 times the optimum. This recommendation was based on the results of earlier studies (*14,21,22*).

The debate continued when Dr. Lloyd Richards of the Division of Dental Health, California State Department of Health, made several recommendations regarding the 1962 Public Health Service Drinking Water Standards, based upon his 1967 study (*23*). One such recommendation was to reduce the allowable limits of fluoride to 1.5 times the optimum, which supported the recommendation of the Division of Dentistry of the Public Health Service. Apparently there was growing evidence that the upper limit for fluoride should be established at 1.5 times the optimum level.

In 1975, the Environmental Protection Agency (EPA), under the provisions of the Safe Drinking Water Act (42 U.S.C. 300), promulgated the National Interim Primary Drinking Water Regulations, which classified a great number of naturally occurring elements as contaminants and placed them under either the mandatory primary regulation or the elective secondary regulation. These regulations reinforced, and for the first time made mandatory, a concentration of 2 times the optimum for dental caries protection as the upper level of acceptable concentration for naturally occurring fluoride, as shown in the following table.

Annual average maximum daily air temperature (° F)	*Recommended control limits of fluoride concentration (mg per l)*			*Approval limit (mg per l)*
	Lower	*Optimum*	*Upper*	
50.0–53.7	1.1	1.2	1.3	2.4
53.8–58.3	1.0	1.1	1.2	2.2
58.4–63.8	.9	1.0	1.1	2.0
63.9–70.6	.8	.9	1.0	1.8
70.7–79.2	.7	.8	.9	1.6
79.3–90.5	.6	.7	.8	1.4

Shortly after promulgation of the National Interim Primary Drinking Water Regulations, the EPA issued guidelines for communities seeking variances that were intended to provide temporary exemptions and adequate time for them to address the issue of compliance. Objections to the fluoride limit and some of the language used in the law classifying fluoride, among other elements, as a contaminant were expressed by the American Dental Association, several States, and other national dental organizations. The date for final compliance was eventually shifted from January 1981 to January 1984.

Reactions against the proposed EPA fluoride regulation continued to swell, and in June 1981 were formalized in a petition from South Carolina to the EPA. This petition requested the EPA to exercise its rule-making authority to repeal that portion of the Primary Drinking Water Regulations establishing maximum contaminant levels for fluoride. The Environmental Protection Agency acknowledged receipt of the petition and promised an accelerated review of the fluoride limit. This review was carried out in cooperation with the Surgeon General of the Public Health Service and other interested parties as part of the process of revising the regulations.

Responding to a request of the Surgeon General for review of pertinent scientific findings on safe and appropriate limits for naturally occurring fluoride, in January 1982 the Chief Dental Officer of the Public Health Service appointed an ad hoc committee to review the scientific data base and prepare a set of findings, recommendations, and justifications. Proceeding with a thorough review of the literature, the committee, which was composed of experienced and respected Public Health Service officials, evaluated the previous criteria for establishing Public Health Service drinking water standards for naturally occurring fluoride in the light of research recently completed by the National Institute of Dental Research and the South Carolina Department of Health and Environmental Control, as well as research still underway at the University of Texas.

After several months of consideration, numerous meetings of the committee, and meetings with EPA representatives, a series of draft statements was formulated, upon which comments were solicited from dental public health experts and national dental organizations. A final position statement was issued over the Surgeon General's signature in August 1982. Although in the statement several findings are put forth about the safety of naturally occurring fluorides at the concentrations found in the United States and about the value of fluorides in preventing caries, the essence of the position statement is that to minimize the occurrence of undesirable cosmetic effects, it is most prudent to maintain the upper limit of fluoride in drinking water at two times the recommended optimum concentration. This is the recommendation that the Surgeon General has made to the Environmental Protection Agency for use in reconsidering its initial classification of fluoride in the National Interim Primary Drinking Water Regulations. At this writing, the EPA revision has not been completed.

References . . . .

1. Geology and ground water resources of the Baltimore area. Bulletin No. 4. Maryland Department of Geology, Mines and Water Resources. Annapolis, 1962.
2. Smith, F. A.: Safety of water fluoridation. JADA 65: 598–602 (1962).
3. Wallace-Durbin, P. J.: Metabolism of fluorine in the rat using F(18) as a tracer. J Dent Res 33: 789 (1954).
4. Ast, D. B., Smith, D. J., Wachs, B., and Cantwell, K. T.: Newburgh-Kingston caries-fluorine. XIV. Combined clinical and roentgenographic dental findings after ten years of fluoride experience. JADA 52: 314–325 (1956).
5. Arnold, F. A., Jr.: Effect of fluoridated public water supplies on dental caries prevalence. Public Health Rep 71: 652–658, July 1956.
6. Becker-Dirks, O.: The relation between the fluoridation of water and dental caries experience. Int Dent J 17: 582–604, September 1967.
7. Dean, H. T., Dixon, R. M., and Cohen, C.: Mottled enamel in Texas. Public Health Rep 50: 424–442, Mar. 20, 1935.
8. Akpata, E. S., and Jackson, D.: Mottled permanent incisors in 15-year-old Lagos children. Community Dent Oral Epidemiol 6: 36–39 (1978).
9. Hypomineralization and increased porosity in dental fluorosis. Nutr Rev 37: 348–350 (1979).
10. Department of Health, Education, and Welfare: Mottled enamel and fluoride water. *In* Water fluoridation—the search and the victory, edited by F. J. McClure. U.S. Government Printing Office, Washington, D.C., 1970, ch. 7, pp. 54–74.
11. Centers for Disease Control: Summary of studies and evaluations since 1976 refuting allegations of an association between cancer and water fluoridation. Atlanta, Ga., October 1981.
12. Dean, H. T., and Elvove, E.: Some epidemiological aspects of chronic endemic dental fluorosis. Am J Public Health 26: 567–575 (1936).
13. Dean, H. T.: Chronic endemic dental fluorosis (mottled enamel). JAMA 107: 1269–1272 (1936).
14. Dean, H. T., and Elvove, E.: Further studies on the minimal threshold of chronic endemic dental fluorosis. Public Health Rep 52: 1249–1264, Sept. 10, 1937.
15. Department of Health, Education, and Welfare: Public Health Service Drinking Water Standards. U.S. Government Printing Office, Washington, D.C., 1946.
16. Report of Advisory Committee on Official Water Standards. Public Health Rep 40: 693–721, Apr. 10, 1925.
17. Arnold, F. A.: The role of fluoride in preventive dentistry. JADA 30: 399–508 (1943).
18. Galagan, D. J., et al.: Climate and fluid intake. Public Health Rep 72: 484–490, June 1957.
19. Galagan, D. J.: Climate and controlled fluoridation. JADA 47: 159–170 (1943).
20. Department of Health, Education, and Welfare: Public Health Service Drinking Water Standards. U.S. Government Printing Office, Washington, D.C., 1962.
21. Dean, H. T., and Elvove, E.: Mottled enamel in South Dakota. Public Health Rep 54: 212–228, Feb. 10, 1939.
22. Arnold, F. A.: Grand Rapids fluoridation study—results pertaining to the 11th year of fluoridation. Am J Public Health 47: 539–545 (1957).
23. Richards, L. F., et al.: Determining optimum fluoride levels for community water supplies in relation to temperature. JADA 74: 389–397 (1967).