

## On the Standard Setting of Fluoride in Water: From Cookbook to Bible

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**SUMMARY:** The harm caused by overdose of fluoride intake is not in dispute. The contending issue lies in disagreement over at what level should it be regarded as overdose. There are different "guidelines" and "standards" from different organizations differently applied in different countries. These "guidelines" are said to have some kind of scientific backing. However, there are some serious questions as to how those so-called "scientific" guidelines have come about. On what grounds those figures are based, why one figure is preferred over the others. And while laboratory-based research is applied, many factors in people's way of life are also at work. This paper discusses these questions and gives an account of certain attempts to change the legal level of fluoride in commercial water from the experiences in Thailand. Although the attempts have been unsuccessful, some causes and lessons of failure could be of value. The paper is written with an aim to propose some ways out of the "standard" problems. Additionally it touches upon the problems of the roles of scientists and the WHO in fighting fluorosis, so that unintentional detrimental effects could be avoided.

**Key words:** Fluoride, drinking water, water consumption, WHO guidelines, water quality standards, standard setting, fluorosis index, oral health, Thailand, defluoridation, Thai experiences.

### A call for science with commitment

It is a truism in public health policy that its success hinges upon people's awareness and cooperation. The case of fighting fluorosis in Northern Thailand is particularly striking in terms of people's roles. They have done as much as the policy planners could hope for. Once the communities suffering from fluorosis have come to realize the cause of it, they put utmost efforts to solve the problems, which are their own. The willingness and capacities of the communities under study are both potential and actual. Actually the communities have been able to accomplish many necessary tasks such as making their own defluoridators and their own bone char. Potentially they are eager to learn, for example, as to what is fluoride really about, how to make improvements on existing defluoridator materials/equipment, how to collect water samples for fluoride testing, etc. Some, on their own initiatives, have opted to tap new sources of water with low fluoride concentration. That is to say, the people can reach these steps as far as their means permit.

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However, there are problems beyond the efforts of people themselves. One essential among them is the question: "how do we know what is the safe limit of fluoride intake? Or, to put it in another manner, what is the maximum permissible level of fluoride concentration beyond which is overdose? This is a very perplexing question for both the people as well as the professionals. If the unsafe level remains (at 1.5 mg/L<sup>1</sup> in Thailand, in Tanzania even at 8<sup>2</sup>), it naturally preempts all other needful preventive measures. If it could be adjusted, it would raise public awareness to a new level. The prospect of action will bring out health organizations and personnel. Their concerns will directly affect the awareness of the people. The more compatible they are, the more forceful development efforts from the people will be.

From the people's standpoint, naturally, the communities which are exposed to the danger of fluoride are not in a position to engage in a debate of a highly scientific nature. This role is a challenge to the professionals representing them. In this regard people's health largely depend upon professional assistance. On the path of development the people need fellow-travellers, be they professionals, state agents, or even politicians, as their allies.

Although there are two camps of thinking on the effects of fluoride among professionals, be they dentists, chemists, orthopedists, etc., one common ground of communication among them is what should be the maximum level of fluoride in water. It is known as the maximum level question. As to another question known as the optimal level question is rather contentious. The question specifically comes from those who see the benefits of water fluoridation that ask: "what is the optimal level of fluoride in water? Whereas those who are against water fluoridation see it as non-question. Given the absence of general consensus regarding the usefulness and harmfulness of systemic fluoride intake<sup>+</sup>, the question of the optimal level lies outside the scope of this paper.

### **THE PLURALITY AND UNRELIABILITY OF "THE STANDARDS" IN THAILAND**

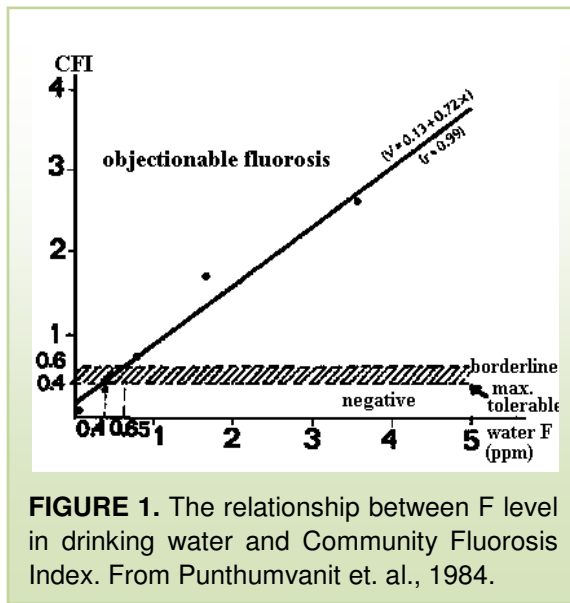
Results from research carried out by the ICOH during 1981 - 1983 (P. Punthumvanit et. al.1984 )<sup>2</sup> indicate that the narrow range between 0.4-0.65 mg/L is the borderline above which community dental fluorosis occurs. However it does not mean that the dental fluorosis is absent under the borderline. It still does occur, but among limited number of individuals. Hence, as far as the community fluorosis is concerned, the research team is of the opinion that 0.5 mg/L should be set as the maximum tolerable level of fluoride.

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<sup>+</sup> The authors agree absolutely with those who find water fluoridation, which results in systemic absorption in the whole body, could bring more harm than gain. More effective and safe usage of fluoride for dental health could be better achieved by means of topical application.

The findings were based on the samples of water from wells, which was the principle source of supply in the communities. That means the range "0.4-0.65 mg/L" is assumed to designate total water consumption (water used for cooking, and taken in by other methods), not merely drinking water.

The maximum fluoride level, tolerable according to ICOH, differs quite significantly from other organizations. There are several maximum fluoride levels, understood as *guidelines* for some authorities and *standards* for others. Different authorities have their own figures as follow.



**FIGURE 1.** The relationship between F level in drinking water and Community Fluorosis Index. From Punthumvanit et. al., 1984.

**TABLE 1** Standards of Fluoride in Drinking water in Thailand<sup>3</sup>

Organization	Year	Standard (mg/Litre)
WHO	1984	1.5
	1993	1.5
Thai FDA.	1991	1.5
Thai Industrial	1978	0.7-1
Dept of Mineral Resources	1978	1-1.5
Dept of Health	1988	1
	2000	0.7

The variety of standards apparently means that there is no "standard" to speak of. All these figures have questionable origins and dubious rationale. As a scientific adage would have it, it is up to a particular country to find its own particular figure. But it is embarrassing to say that the legal limit at 1.5 mg/L<sup>4</sup>, which is the Thai FDA's standard<sup>5</sup>, set for bottled water sold in Thailand is not based on any scientific evidence from our own country. In other words, the level of fluoride is disreputably not measured nor adjusted in accordance with local conditions. The consequences could be exacerbated in high fluoride areas where people are already more exposed to fluoride<sup>5</sup>. As has frequently happened, people in increasing numbers have turned to bottled water with Food and Drug Administration (FDA) approval labels, believing it a safety guarantee. Unfortunately not all these fashionable bottles with FDA label filled with seemingly hygienic water are that safe.

Since around 1977 due to growing health consciousness of the middle class and growing demand from tourists, bottled water has increasingly become a common item in the market. To avoid fluoride-containing water in the backyard, bottled water, for some, is the remedy. The changed consumers' behaviour makes *WHO guidelines for drinking-water quality*, (1996)<sup>6</sup> relevant and problematic at the same time. Its relevance springs from the industrial regulation of standard setting. The WHO publication provides a certain amount of fluoride to be referred to as a guideline, or often understood as a standard. The problematic side is related to two points ensued from this new consuming practice. First, a distinction is made between drinking water and water consumed by other means, and the amounts of fluoride therein. Secondly, the level of fluoride, meant as *guidelines* for some authorities and *standards* for others, is generally understood to be concerned with drinking water, and not water consumed by non-drinking methods. As a result attention is paid exclusively to drinking water consumption, in spite of the fact that, for some people's way of life, non-drinking water consumption exceeds it.

Statistically put, around 90% of bottled drinking water of various attractive brands lucratively marketed, have a fluoride concentration not exceeding 0.5 mg/L which is, we strongly believe, the tolerable level of fluoride in drinking water for Thailand. The rest (around 10%) has a higher level. And around 1.5%<sup>7</sup> of this latter group has a fluoride content even higher than the legal limit. Thus a percentage of the bottled water in the market, some of which are officially approved, could well be a misleading health alternative measure.

The 10% portion does not seem to be very high. But things are not what they seem. This portion has its water resources and is usually manufactured in high fluoride areas. The story takes a tragico-comedy mode. High fluoride-containing water is bottled and sold to customers who must be spared from fluoride<sup>5</sup>. This is especially acute for those who already suffer from fluorosis. A common Thai saying "Escaping from a tiger, but running into a crocodile" - analogous to the English "Out of the frying pan into the fire" - is appropriate for this context.

#### **ATTEMPTS TO STANDARDIZE THE "STANDARDS"**

Against this background the ICOH published *Fluoride in Bottled Water and Consumers' Protection*, (1997) based on research results from high fluoride areas. A seminar on the same theme was organized in July 1997 to discuss the danger of fluoride and the need to reset the tolerable level of fluoride in bottled water. For this is particularly pressing for people in northern Thailand which the fluoride belts cross. The publication and the seminar were expected to sensitize the authorities and to bring the necessary change in the tolerable levels. The objectives were half realized. The Department of Health issued a new figure of tolerable fluoride quantity in bottled water (from 1 to 0.7 mg/L), but the FDA has not so far been persuadable.

Additionally the Dental Health Division, Department of Health held another seminar in March 2000. However, no subsequent outcome has been promising. In spite of a

formal submission to reconsider the figure, there has been no indication that the FDA will change it.

### THE MYSTERIOUS FIGURE "1.5"

It is customary in many countries that the value 1.5 mg/L is set as the maximum level for drinking water. For good or bad those countries have adopted the figure from *WHO guidelines for drinking-water quality*, (1996). It is a useful role for WHO, performing a function taking the benefit of the economy of scale, to provide a certain guideline figure for countries bereft of sufficient research capacities of their own. The WHO publication in question is well aware of the importance of the specificity in each locality and a particular context. It is explicit that the figure (1.5 mg/L) is in essence a guideline, and not a recommendation, nor a standard. The publication also gives an additional explanation of the level 1.5 mg/L:

*“ In setting national standards for fluoride, it is particularly important to consider climatic conditions, water intake, and intake of fluoride from other sources (e.g. from food and air)”.(p236 )*

The addendum is nicely stated as a precaution. In effect, however, the figure "1.5" mg/L has been prominent, and the caveat marginal in the general understanding. Over years, the former has become an *idée reçue* if not *idée fixe*, and the latter 'lost and not found'. It is understandable why they have turned into what they are now. The countries that have adopted the WHO guideline are, by and large, underdeveloped countries. Their inadequate resources for research have compelled them to accept the guideline in the first place. To advise them to find their own figures according to their own circumstances is to urge them to conduct their own research. That is not a realistic assumption. The situation is something of paradox. By way of analogy, a teacher of mathematics gave a ready-made, albeit incomplete, answer to a student who is not quite capable of a calculation. Later the same teacher still insists that the student should come up with his own calculation. One perhaps cannot but ask why the answer of that nature is given in the first place?

Being not sufficiently well equipped right at the beginning, hence following the guideline is naturally the easy way out for the developing countries. There should be no surprise why no research to find their own levels has really been carried out. In retrospect one can clearly see the process of metamorphosis of a hypothetical number from being simple proposition to being sacred principle. The guideline is not simply a guideline, but it has attained the status of standard. It has even become "the international standard", as the Thai FDA has put it. Their reasoning is that since it is the WHO, as an international organization, that has issued the figure. Therefore the figure should be regarded as the international standard. The WHO, in the eyes of many in the underdeveloped world, denotes a high degree of authority. Unfortunately or otherwise their publications, though titled as guidelines, carry the weight of credentials. "The international standard" could then even eventually become orthodoxy.

With a prior knowledge of the consequences, should the WHO not then be more thoughtful about its publications? Admittedly, the WHO cannot be held responsible for the actions and rules of its member countries. Certainly the WHO could justifiably affirm that *Guidelines* are merely guidelines, and not laws to be religiously followed. Nevertheless, once it is known that developing countries have their own misguided ways of making sense of the *Guidelines*, and the resulting detrimental effects are alarming, an international organization with noble aims such as the WHO may have second thoughts.

Granted the figure "1.5" mg/L is subject to local modification, the followers of the guidelines could argue that the figure certainly does not come from thin air, but must have been well thought out. It should therefore be normatively acceptable. A response can be in the form of question, i.e., from where does the figure come? What is the logic behind it? Not being a research institution as such, the WHO usually makes studies of and disseminates available data and information. That is to say the figure was derived from a study somewhere. But since no reference was made, the origin remains a mystery. Hence the adoptive countries have not firm grounds to stand on. It is highly probable that they might just follow the footsteps trailed along by feet of clay.

Nevertheless to give credit where it is due, the WHO has also stated the occurrence of fluorosis even at a point lower than 1.5 mg/L.

*"Fluoride may give rise to mild dental fluorosis (prevalence: 12-33%) at drinking-water concentrations between 0.9 and 1.2 mg/litre. This has been confirmed in numerous studies, including a recent large-scale survey carried out in China, which showed that, with drinking-water containing 1 mg of fluoride per litre, dental fluorosis was detectable in 46% of the population examined." (p. 235)*

This point in fact repeats earlier findings raised in another WHO document (1994)<sup>8</sup>. To let it see the light of day, it is opportune here to quote it at length:

*"Hong Kong, for example, has adjusted the fluoride concentration in its drinking-water several times since water fluoridation began there in 1961, using different levels in the hot and cooler seasons and the endeavouring to find an appropriate year-long concentration. According the United States Public Health Service guidelines, the most appropriate concentration for Hong Kong would be around 0.8 mg/l. However, fluorosis in children was found to be still unacceptably high at that level. The concentration was reduced in several stages to 0.5 mg/l in 1988.*

*It can be stated that –the recommended levels of fluoride in drinking water according to annual temperature, as listed in the United States Public Health Service guidelines of 1962, are not appropriate for use in tropical and subtropical areas of the world. Because higher-than-expected levels of fluorosis have followed their application, it seems that the recommended range is too high for these areas, the level of 1.0 mg/l*

should be seen as and absolute upper limit, even in a cold climate, and 0.5 mg/l, now used in Hong Kong and recommended in the Gulf States, may be an appropriate lower limit.) “p18)

Even with all these qualifications the Thai FDA just adhere to the high figure (1.5 mg/L). The figure, as the Thai FDA see it, comes from the book *WHO guidelines for drinking-water quality*, (1996). The book runs to almost 1,000 pages, a careful study of it (and other related WHO publications) would be extremely useful. It could save the FDA and other organizations time-consuming and hair-splitting debates.

To emphasize the earlier points once more, there can be no such thing as one-size-fit-all formula. No organization, and certainly not the WHO, has ever proclaimed a standard. If there were to be a standard, it needs to be a local standard, not an international one. But the process of changing the standard, legally stipulated by the FDA, is scientifically and bureaucratically very complicated. It requires a risk assessment according to Codex Guidelines (a joint FAO/WHO expert consultation). That means a great amount of an expensive endeavour and of a specific kind of research, the span of which takes not less than five consecutive years, to propose a new one.

The value of this high-sounding goal, complex and expensive in its execution, could be justifiable or even beyond reasonable doubt. But what can be questioned is the easy way in which the *status quo* was established in the first place. It is very simple to adopt the simplistic notion, but extremely complicated to change it. We all know that Thailand has limited resources to carry out her research to meet the Codex requirements. This is, however, not the worse case. There are many more developing countries that are in an even more difficult situation than Thailand.

It seems, for a bureaucratic authority, that apparent evidence in anthropological terms do not carry as much weight as results carried out in the name of science. At this juncture perhaps it is useful to remind ourselves that one of the criteria for public health policy is the promotion of people's self-care. Since the policy wants people to find their own practical ways to advance their self-regulated well-being, it is imperative for the authorities to care about the standard.

To reiterate, in solving the fluorosis problem, a group of terminologies - standard, guideline, and tolerable, optimal, maximum, recommended level - need to be made intelligible more widely. Oftentimes they are used interchangeably, and occasionally loosely. But they have far reaching implications. It is very necessary, for both the professionals and the general public alike, to make distinction among them. And since each country must find its own tolerable fluoride level, in addition to ample available data, one practical and realistic way is to seriously take people's experiences into consideration. This alternative to the "bureaucratic-scientific method" can be achieved by means of anthropological field research. From this standpoint the professionals in alliance with the people can better identify the magnitude of the problems together with the ways and the means of solving them.

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