

Review Article

Fluoride concentration in bottled water: a systematic review

Concentração de fluoreto na água engarrafada: uma revisão sistemática

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Abstract

This study aimed to summarize major methodological features and main findings described in the studies on fluoride concentration monitoring in bottled water, published in specialized journals between 2008 and 2012, highlighting their implications for public health surveillance. A systematic review was conducted searching scientific articles in the databases: Lilacs, PubMed and Scopus. Twenty-two articles from the world's main continents were included: 68.2% informed both the number of samples and brands collected; 81.8% examined products collected in only a city or metropolitan area; 77.3% assessed the outcomes using a sound criterion; 45.5% compared the values of fluoride measured in the sample and those informed in the label, being noted significant discrepancies. In conclusion, the discrepancy between the found amount and the informed concentration in the label was quite common reinforcing the warnings raised by several researchers. The parameters that define hazard to health and instruct the content of labelling should be revised. There is an important room for improvement of the methodological procedures in further studies.

Keywords: fluoride; fluoridation; surveillance; bottled water.

Resumo

O objetivo foi sumarizar as principais características metodológicas e os principais achados descritos em estudos sobre monitoramento da concentração de fluoreto em água engarrafada publicados em revistas científicas especializadas entre 2008 e 2012, examinando suas implicações para a vigilância em saúde pública. Uma revisão sistemática foi realizada buscando artigos nas bases de dados: Lilacs, PubMed e Scopus. Vinte e dois artigos dos principais continentes do mundo foram incluídos: 68,2% informaram tanto o número de amostras como de marcas recolhidas; 81,8% examinaram produtos coletados em somente uma cidade ou área metropolitana; 77,3% avaliaram os achados usando critério lícito; 45,5% compararam os valores observados na amostra com aqueles informados no rótulo, sendo notadas discrepâncias significativas. A discrepância entre o valor observado e o divulgado no rótulo do produto foi bastante comum, reforçando as advertências reclamadas por vários pesquisadores. Os parâmetros que definem risco para saúde e instruem o conteúdo da rotulagem deveriam ser revisados. Observou-se importante espaço para melhorar os procedimentos metodológicos em futuros estudos.

Palavras-chave: fluoreto; fluoretação; vigilância; água engarrafada.

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INTRODUCTION

Bottled water can be defined as water obtained directly from a natural source, ground or not, that undergoes process of packing into an appropriated vessel for its distribution in the market, and consumption by individuals and families in households and also public spaces such as kindergarten, schools, workplaces, health units, restaurants and areas of high circulation of people, such as bus stations, airports etc. According to the amount of mineral salts, trace elements and other constituents and parameters, the water can be considered only natural or natural and mineral, both classified as bottled water¹.

The consumption of bottled water has increased in the last years worldwide. Between 2006 and 2011, the global consumption changed from 178 billion to more than 231 billion of liters. China, Indonesia and Thailand are examples of countries where the consumption in the period grew more than 10%. In Brazil, the increase was also above of global average and the consumption surpassed from 12.5 billion to more than 17 billion of liters during the same time².

The reasons for utilizing of bottled water vary. Evidence from different studies summarized by Ward et al.³ showed that smell, appearance, taste and convenience are more important factors to explain the consumers' preference than health features related.

An investigation on water consumption patterns among US children showed that tap water represented 60% of drinking water volume whereas bottled water reached 40%. Non-Hispanic white children mostly consumed tap water, whereas Mexican-American children mostly consumed bottled water⁴. Among Brazilian adolescents that declared daily intake of water, 30 percent pointed bottled water as main source⁵.

The replacement of tap water consumption by bottled water can represent a risk for child dentition according to the fluoride concentration^{6,7}. Bottled water surveillance can be defined as the continuous and vigilant public health assessment and review of its safety and acceptability. This kind of assessment does not exclude or replace the bottled water supplier's responsibility. Therefore, it is essential to monitor the water quality regarding fluoride amount and to assess the needed of surveillance measures directed to protection of population health.

Several studies have been published with that purpose, however, no critical balance was produced on the knowledge released in the recent years across scientific articles. In addition, a systematic review could provide knowledge on research gaps in the existing literature to aid planning future research.

The aim was to summarize major methodological features and main findings described in the studies on fluoride concentration monitoring in bottled water published in specialized journals between 2008 and 2012 highlighting their implications for public health surveillance.

METHODS

A systematic review was undertaken to assess the studies on fluoride concentration in bottled water. Systematic reviews are a method of knowledge synthesis that require a clearly formulated question and use systematic and explicit methods to identify, select, critically appraise, and extract and analyze data from relevant research. They can be used to address diverse research questions such as what are the benefits and harms of a determined treatment in pregnant women or what is the prevalence of a determined condition in 5-6-year-old children. Tricco et al.⁸ describe different types of systematic reviews according to the research questions selected and methods utilized. This review systematic consisted of a narrative synthesis involving a structured interrogation and a summary of the findings of included studies. The review included observational studies and scientific articles in English, Portuguese and Spanish that were identified by electronic search at SCOPUS, a database of peer-reviewed scientific literature, and also health sciences bibliographic information databases such as LILACS and PUBMED. The syntaxes of searching strategies were adapted for each database.

Two search keys were used for SCOPUS: 1- "*Bottled Water*" and "*Fluorides*", both as keywords; 2- "*Fluorides*" as keyword and "*Bottled Water*" and "*Surveillance*" as terms in any field. Six syntaxes were used for LILACS: 1- "*Fluorides*" as subject descriptor and "*Bottled Water*" as word in any field; 2- "*Fluorides*" as subject descriptor and "*Water*" as word in any field; 3- "*Fluoridation*" as subject descriptor and "*Bottled Water*" as word in any field; 4- "*Fluoridation*" as subject descriptor; 5- "*Fluorides*" and "*Surveillance*" and "*Bottled Water*" as words in any field; 6- "*Fluorides*" and "*Surveillance*" as words in any field. Two search strategies were utilized for PUBMED: 1- "*Fluorides*" as keyword and "*Drinking Water*" and "*Surveillance*" as terms in any field; 2- "*Fluorides*" as keyword and "*Bottled Water*" as term in any field.

A calibration exercise was conducted to ensure reliability in correctly selecting articles for inclusion before the screening process. In case of any element of doubt, a second screener revised the records. Published articles in specialized journals between 2008 and 2012 were included. This timeframe was established considering the objective directed to identify the main implications for public health surveillance. Moreover, two arguments concurred to this decision. From an international viewpoint, an acknowledged framework for packaged water regulation provided by the Codex Alimentarius Commission of the World Health Organization and the Food and Agriculture Organization of the United Nations was revised and approved in 2008⁹. A legislative disposition regulating different features on bottled water such as limits for hazardous chemical substances was approved in Brazil at 2005¹.

A form was specially elaborated for the data extraction. The first author carried out the data extraction and the second revised the form filling and checked the content. The included articles were analyzed according to the following logical categories: study place; number of samples; number of brands; collecting time of samples; covered area; analytical method for measuring fluoride concentration (electrometric and colorimetric); reference criterion for values' assessment and also agreement between labelling and observed fluoride amount. Risk of bias was not assessed as one of the objectives was to analyze major methodological features. The narrative synthesis was organized based on the mentioned logical categories.

RESULTS

Figure 1 shows the searching flowchart. Seventy-eight eligible records were identified from 622 ones, after applying pre-defined exclusion criteria to the title/abstract. Twenty-two articles were included after removing of duplicates, full text evaluation, and hand-searching of reference lists in the included articles. Out of them, six were from Brazil¹⁰⁻¹⁵ four from Iran¹⁶⁻¹⁹ and two from India^{20,21}, Saudi Arabian^{22,23}, and United States of America^{24,25}. The remaining comprised one for each country: Algeria²⁶; Malaysia²⁷; Niger²⁸; Australian²⁹; Poland³⁰; and Ghana³¹. Table 1 shows the studies' characteristics according to the country,

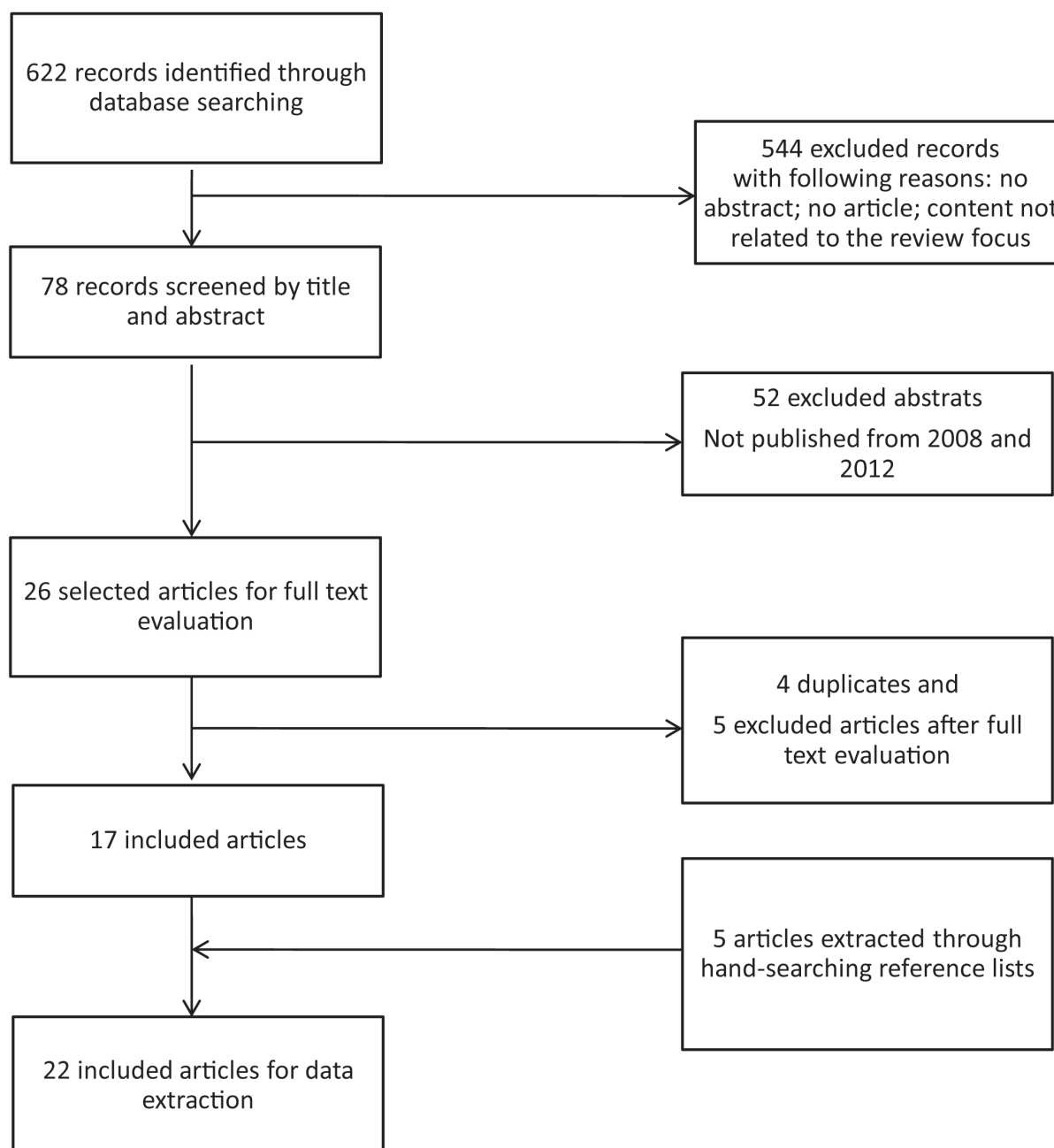


Figure 1. Flowchart of selection of included studies for the review

Table 1. Characteristics of the included studies according to the country, covered area, collecting time, analytical method, number of samples and brands and reference criterion

Ref	First / Second Author	Year	Collecting time	Country	Covered area	analytical method	samples	brands	reference criterion
10	Grec et al.	2008	12 months or more	Brazil	city of São Paulo	electrometric	229	35	local rule (São Paulo City Law 12.623/98)
11	Souza et al.	2009	1 to 60 days	Brazil	cities of João Pessoa, PB and São Luís, MA	electrometric	56	20	Galagan and Vermillion, 1957
12	Terreri et al.	2009	6 to 11 months	Brazil	city of São José do Rio Preto	electrometric	39	ni	Regional rule (São Paulo State Health Department Ordinance SS-250/1995)
13	Bulcão and Rebelo	2009	6 to 11 months	Brazil	city of Manaus	electrometric	45	15	national rule (Brazilian Health Surveillance Agency RDC 274/2005)
14	Castro et al.	2011	1 to 60 days	Brazil	city of Campo Alegre de Lourdes	electrometric	ni	7	national rule (Brazilian Health Ministry Ordinance 518/2004)
15	Sayed et al.	2011	6 to 11 months	Brazil	city of Ponta Grossa	electrometric	50	5	national rule (Brazilian Health Surveillance Agency RDC 274/2005)
16	Dobaradaran et al.	2008	1 to 60 days	Iran	city of Tehran,	spectrophotometric*	41	17	not informed
17	Amanlou et al.	2010	1 to 60 days	Iran	city of Tehran	electrometric	108	18	international agency recommendation (WHO 1996)
18	Miranzadeh et al.	2011	6 a 11m	Iran	country	electrometric	78	24	international agency recommendation (WHO 2004) and national rule (ISIRI 2002)
19	Moslemi et al.	2011	two diferent seasons	Iran	city of Tehran	electrometric	ni	8	not informed
20	Thippeswamy et al.	2010	not informed	India	city of Davangere	electrometric	30	10	national agency recommendation (US-FDA year not informed)
21	Gupta and Kumar	2012	not informed	India	city of Angra	electrometric	45	15	international agency recommendation (not identified)
22	Aldrees and Al-Manea	2010	not informed	Saudi Arabia	city of Riyadh	electrometric	45	15	national agency recommendation (ADA 2002)
23	Khan and Chohan	2010	12 months or more	Saudi Arabia	city of Riyadh	electrometric	ni	21	international agency recommendation (WHO 2006)
24	Quock and Chan	2009	not informed	Unites States	Greater Houston metropolitan area of Texas	electrometric	105	ni	national agency recommendation (ADA 2002)
25	Steinmetz et al.	2011	not informed	USA	city of Indianapolis	electrometric	458	20	national agency recommendation (ADA, year not informed)
26	Bengarez et al.	2012	not informed	Algeria	country	electrometric	ni	29	international agency recommendation (WHO 2004)
27	Azlan et al.	2012	1 to 60 days	Malaysia	country	electrometric	24	22	international agency recommendation (WHO 2006)
28	Ajayi et al.	2008	1 to 60 days	Niger	Ibadan, Oyo	spectrophotometric*	10	3	international agency recommendation (WHO 1995)
29	Mills et al.	2010	12 months or more	Australian	country	electrometric	300	ni	national rule (ABWI 2005)
30	Szymaczek and Opydob	2009	not informed	Poland	city of Poznan	electrometric	30	10	national agency recommendation (ADA 2007)
31	Oyelude and Ahenkorah	2012	12 months or more	Gana	city of Bolgatanga	spectrophotometric*	96	4	international agency recommendation (WHO 2011)

*with SPADNS reagent; WHO-World Health Organization; ADA-American Dental Association; ISIRI-Institute of Standards and Industrial Research of Iran; US-FDA- United States Food and Drugs Administration; ABWI-Australasian Bottle Water Institute

covered area, collecting time, analytical method, number of samples and brands and reference criterion.

Among the studies from Brazil, two referred to cities at Southeast region^{10,12}, two were from Northeast region^{11,14}, and the two remaining were from South¹⁵ and North¹³ regions.

In relation to sampling, 15 (68.2%) studies informed both the number of samples and brands whereas three informed only the number of samples and three only the number of brands. The average number of samples was 99.4 ranging from ten²⁸ to 458²⁵ samples. The average number of brands was 16.1 ranging from three²⁸ to 35¹⁰. Considering these 15 studies, the ratio between samples and brands was in average 5.8 ranging from 1.1²⁷ to 24.0³¹ samples for each brand under analysis.

Seven (31.8%) articles did not mention the timeframe related to the sample collecting. Among those that described the period, six collected samples from one to sixty days; four between six to eleven months and four collected during twelve months or more. Samples of one study¹⁹ were collected in two different seasons.

Regarding the covered area, four (18.2%) studies only examined brands and samples from different country areas (Algeria, Malaysia, Iran, Australian). The majority (81.8%) examined products collected in only a city or metropolitan area of the country.

The ion-selective electrode technique was utilized in 19 (86.4%) studies. The spectrophotometric method with SPADNS reagent was used in three studies^{16,28,31}.

The reference criterion for assessment was not mentioned or was inconsistently mentioned (e.g. using not applicable criterion) in three studies^{12,14,16}. One study¹¹ assessed the fluoride values based on a criterion proposed in 1957 by Galagan and Vermillion. Seventeen (77.3%) researches assessed the outcomes using a sound criterion. One study¹⁰ utilized legislation locally approved; four examined based on pertinent national regulation^{13,15,26,29}; and the thirteen remaining studies employed recommendations from international agencies such as World Health Organization (WHO) and European Communities; or from USA agencies such as *American Dental Association*, *Environmental Protection Agency* and *Food and Drug Administration*. The more mentioned supporting recommendation was based on WHO that indicates until 1.5 mg/L of fluoride as a safe potable water. Figure 2 shows standards related to labelling approved by some agencies cited in the included articles.

The values of fluoride concentration measured in the sample and those informed in the label were compared in ten (45.5%) studies. Significant discrepancies were noted in nine of them. Out of ten studies, six were undertaken in countries with national legislation on the issue and all of them presented the mentioned discrepancy. Differences were negligible in only one study³⁰.

From the viewpoint of public health surveillance, 19 (86.4%) studies mentioned explicitly the needed of control on fluoride concentration in bottled water due to its risk for human dentition. Mention related to this aspect was not observed in only three researches^{24,27,31}.

Source	Condition	Labelling
Codex Standard for Natural Mineral Waters http://www.codexalimentarius.net/		
	If the product contains more than 1 mg/L of fluoride	"contains fluoride".
	If the product contains more than 1.5 mg/L of fluoride	"The product is not suitable for infants and children under the age of seven years"
European Communities Commission Directive 2009/54/ http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32009L0054&from=EN		
	Fluoride content greater than 1 mg/L	"contains fluoride"
European Communities Commission Directive 2003/40/ http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32003L0040&from=EN		
	Natural mineral waters with a fluoride concentration exceeding 1,5 mg/L	"contains more than 1,5 mg/l of fluoride: not suitable for regular consumption by infants and children under 7 years of age"
U.S. Food and Drug Administration http://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/labelingnutrition/ucm064919.htm		
	if the bottled water contains from 0.6 mg/L to 1.0 mg/L - Excluding bottled water products specifically marketed for use by infants	"Drinking fluoridated water may reduce the risk of tooth decay"
Brazilian Health Surveillance Agency http://portal.anvisa.gov.br/wps/wcm/connect/9b898900474592b89b15df3fbc4c6735/RDC_274_2005.pdf?MOD=AJPERES		
	If the product contains more than 1 mg/L of fluoride	"contains fluoride"
	If the product contains more than 2 mg/L of fluoride	"The product is not suitable for infants and children up to seven years of age"
	If the product contains more than 2 mg/L of fluoride	"The daily intake of the product is not suitable: contains fluoride above of 2 mg/L"

Figure 2. Standards related to labelling approved by some agencies cited in the included articles

DISCUSSION

The consumption of bottled water has increased in the last years and the fluoride concentration monitoring is important for prevention and control of dental caries and dental fluorosis in populations. This need was acknowledged by the majority of the included studies due to the risk for human dentition.

Owing to the focus of this study directed to public health surveillance, the present review was restricted to the period between 2008 and 2012. Although limited to five years, articles from the world's five main continents were identified and some relevant theoretical and methodological features emerged from the analysis.

Overall an international framework for packaged water regulation is provided by the Codex Alimentarius Commission of the World Health Organization and the Food and Agriculture Organization of the United Nations⁹. The Codex Alimentarius Commission has developed a standard for natural mineral waters. It describes the product and its compositional and quality factors, including prescribed treatments, limits for certain chemicals, hygiene, packaging and labelling³². Moreover, some countries have proper legislation. It is worth noting that a city (São Paulo city) has specific law regulating the issue³³.

The main contribution of this systematic review is that the found results showed significant discrepancies between the measured fluoride concentration and the informed amount in the product's label independently of the existence of specific legislations. Besides, it constitutes an irregularity; this situation may induce the public to consume a product with the intention of obtaining some benefit that the bottle water could not really provide. This finding reinforces the warnings raised by several researchers and also reveals the needs of a periodical checking in order to confirm the accomplishment of the legislation^{10,14,17,18,20-23,25,26,29}.

Furthermore, the parameters that define hazard to health and instruct the content of labelling were diverse and should be revised as many of them can represent exposure to dental fluorosis of esthetic significance for the children. European communities tolerate bottled water up to 5.0 mg/L of fluoride as a maximum acceptable and recommend a sentence of caution in the label for the consumption of products that contain more than 1.5 mg F/L by children under seven years of age. The Codex Alimentarius Commission makes the same recommendation⁹. The FDA does not require bottled water manufacturers to list the fluoride content on the label, but does require that fluoride additives to be listed. Imported bottled water to which no fluoride is added shall not contain fluoride in excess of 1.4 mg F/L whereas that to which fluoride is added shall not contain fluoride in excess of 0.8 mg F/L. Fluoride levels of bottled water packaged in the United States shall be based on the annual average of maximum

daily air temperatures at the location where the bottled water is sold at retail. Brazilian Health Surveillance Agency do not have a value from which the fluoride level of bottled water is considered unsafe and unacceptable, but requires for products containing more than 2 mg F/L that a sentence shall be showed in the product's label warning all people for the damage in case of daily intake¹.

According to a research that examined review studies published between 2000 and 2009³⁴, it is worth to note that children under eight years of age will remain at risk for dental fluorosis if these recommendations were maintained. The prevalence of fluorosis of esthetic significance was estimated to be 10.0% (95% CI: 5.0; 17.9) and 12.5% (95% CI: 7.0; 21.5) for child/adolescent population exposed to 0.7 and 1.0 mg F/L in the drinking water, respectively. Therefore, some specialists have claimed the review of the quality standards for mineral water commercialized in Brazil¹²⁻¹⁴. An exception within this general picture is the São Paulo city, one of the world's most populated cities where the public supply water has been fluoridated since 1985. The City Council approved in 1998 a legislation that prohibits the commercialization of bottle water with concentration above 0.8 mg F/L^{10,33}.

Some methodological features can be highlighted after the examining of the studies. For measuring the fluoride concentration, the ion-selective electrode technique was more employed corroborating some studies that underline its advantages compared to other analytical techniques^{35,36}. Although the World Health Organization and several U. S. associations concerned to water quality (American Public Health Association, American Water Works Association, Water Environment Federation) have considered the possibility of more than one method, the overall preference has fallen on the ion-selective electrode technique, which is suitable for fluoride concentrations from 0.1 to more than 10 mg/L. The SPADNS method has an analytical range of 0 to 1.40 mg F/L with virtually instantaneous color development. In spite of both methods are able to produce reliable results since the responsible by the analysis understands the limitations of each one, the most used method presents higher selectivity and better linearity than the spectrophotometric method^{35,36}. On the other hand, not all studies informed the number of samples and brands investigated; some of them did not mention also the timeframe related to the sample collecting and the majority examined brands obtained in only a city or metropolitan area of a country. These limitations affect the coverage of monitoring activities and could compromise its utility and representativeness, two main attributes under a perspective from surveillance. Therewith an important room for improvement of the methodological procedures emerges mainly if the focus is directed to public health surveillance.

CONCLUSION

The results show that legislation is necessary but not sufficient. They reinforce the warnings raised by several researchers and show the relevancy of fluoride concentration surveillance in bottled water. The parameters that define hazard to health

and instruct the content of labelling were diverse and should be revised as many of them can represent avoidable exposure to dental fluorosis of esthetic significance for the children. Moreover, there is an important room for improvement of the methodological procedures in further studies.

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