

COMITÉ **D'ÉTHIQUE** DE SANTÉ PUBLIQUE

Opinion on a project to fluoridate drinking water

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Comité d'éthique de santé publique

March 2012



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Translated by the National Collaborating Centre for Environmental Health (NCCEH) in partnership with the Institut national de santé publique du Québec through a financial contribution from the Public Health Agency of Canada through the NCCEH. The views expressed herein do not necessarily represent the views of the Agency or the Centre.

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LEGAL DEPOSIT – 1st QUARTER 2012 BIBLIOTHÈQUE ET ARCHIVES NATIONALES DU QUÉBEC LIBRARY AND ARCHIVES CANADA ISBN: 978-2-550-62315-1 (FRENCH PDF) ISBN: 978-2-550-64362-3 (PDF)

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ABOUT THE COMITÉ D'ÉTHIQUE DE SANTÉ PUBLIQUE

The Comité d'éthique de santé publique (CESP – Public Health Ethics Committee) is a committee established by the Institut national de santé publique du Québec (INSPQ – National Public Health Institute of Québec), under its incorporating act (RSQ, chapter I-13.1.1), which defines its mandate and composition. The committee reports to the INSPQ's Board of Directors, which appoints its members and sets the terms of its operation. However, the CESP is solely responsible for the opinions it issues and the ethics review process it uses.

The Comité d'éthique de santé publique plays an advisory role, providing opinions to public health authorities and operates under a mandate that is both broad and specific in scope. Broadly, the CESP responds to requests it may receive regarding any ethical issues raised by the implementation of the Public Health Act, including activities or actions undertaken as part of the national program or regional and local public health action plans. More specifically, the CESP systematically examines the proposed surveillance plans or surveys on health and social issues submitted to it by the Minister or public health directors as part of their responsibilities for ongoing surveillance of the health status of the population and of health determinants.

The CESP examines the ethical dimension of the issues or projects submitted to it, in the light of the values and standards that are relevant in the specific context of these projects. It identifies potential conflicts or tensions between different values or between values and standards and facilitates decision-making by supporting project managers and proposing courses of action.

The Comité d'éthique de santé publique is made up of the following members:

- Ethicist (1): André Lacroix, Chair
- Representatives from the public (3): Nicole Girard, Laurent Lebel and Sally Phan
- Public health director (1): Dr. Philippe Lessard
- Public health professionals (2): Madeleine Breton and Jill E. Torrie
- Lawyer(1): Yves Chabot, Vice-Chair

EXECUTIVE SUMMARY

This opinion relates to a project submitted by the National Public Health Director to amend the Regulation respecting the quality of drinking water of the Ministère du Développement durable, de l'Environnement et des Parcs (MDDEP – Ministry of Sustainable Development, Environment and Parks) to include a mandatory minimum standard for fluoride of 0.7 mg/l for all Québec municipalities with populations of 5,000 or more.

Tooth decay and its consequences are a major public health concern affecting the entire Québec population. By way of illustration, tooth decay affects 42% of the province's kindergarten children. In addition, Québec children have 40% more cavities than their counterparts in Ontario and the United States. In Québec, dental treatment costs exceed \$2 billion.

The fluoridation of drinking water is presented in the literature as one of the safest, most effective, economical and equitable ways of reducing tooth decay. It has a greater impact on disadvantaged populations, and thus helps reduce health inequalities. The negative effects of fluoridation on health and the environment are not significant enough to outweigh the benefits.

However, the fluoridation of a population's water supply system will inevitably run counter to the wishes of part of that population. To force people to live more healthily against their will is certainly not a trivial matter. It is therefore important to explore ways to mitigate the consequences of such a measure on the free choice of individuals.

In conclusion, the CESP takes the view that the benefits of fluoridation outweigh its potential negative effects on health and the environment and that such benefits justify impinging on the freedom of choice of people who do not wish to have their water fluoridated. This opinion offers ways to mitigate these negative consequences on target populations; these include informing and consulting the public and inviting it to participate in the process leading to the change in regulations on the quality of drinking water.

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1 BACKGROUND

This opinion of the Comité d'éthique de santé publique (CESP) concerns a project submitted by the National Public Health Director to amend the Regulation respecting the quality of drinking water of the Ministère du Développement durable, de l'Environnement et des Parcs (MDDEP – Ministry of Sustainable Development, Environment and Parks) to include a mandatory minimum standard for fluoride of 0.7 mg/l for all Québec municipalities with populations of 5,000 or more. This is the recommended concentration in the scientific opinion issued by the Institut national de santé publique du Québec (INSPQ – National Public Health Institute of Québec) (Levy, 2007). The project submitted to the CESP is part of a national strategy promoting the fluoridation of drinking water, which is aimed at building support, mobilizing partners and informing the public in order to encourage the adoption of the proposed regulatory measure.

The first reason cited by the proponents for their initiative is that tooth decay is a chronic disease affecting a large proportion of the population of Québec. Indeed, the province is particularly prone to this problem, and children in Québec have 40% more cavities than those in Ontario and the United States (Brodeur, Olivier, Benigeri, Bedos, & Williamson, 2001). The proponents attribute the poorer dental health of Québec's population to the fact that drinking water is fluoridated much less frequently in Québec, with just 3% of the population having access to fluoridated water compared to 70% in Ontario, for example¹. In addition, the costs of dental treatment (public and private) are estimated to be approximately \$2 billion per year in Québec alone. Thus, it seems clear that tooth decay remains a major health problem, despite its reduction over the last 30 years.

Brantford, Ontario was the first Canadian city to fluoridate its drinking water, in 1945. In Québec, drinking water has been fluoridated to varying degrees since 1955. In the 1970s, the government of Québec undertook a water fluoridation program. In 1975, the Public Health Protection Act was amended to require that the water's natural fluoride content be analyzed and, if necessary, that fluoride be added to reach a threshold considered optimal for preventing tooth decay (at that time, the threshold was set at 1.2 mg/l). The Act proved difficult to enforce, primarily due to the fact that the Ministère de la Santé et des Services sociaux (MSSS – Ministry of Health and Social Services) had no practical means for doing so. In 2001, the Public Health Act removed the requirement for fluoridation while maintaining the measures to promote and support it. In 2010, an estimated 3% of the population had access to fluoridated water compared to 7% in 2006 and 12% in 1993. Thus, there has been a decrease in access to fluoridated water, resulting from the cessation of fluoridation in some municipalities¹.

During a tour of Québec municipalities undertaken by the National Public Health Director in 2008-2009, a number of mayors expressed their reluctance to pay the political price of a decision to fluoridate their water. Indeed, pressure from organized groups against fluoridation has proved particularly effective at the municipal level, as evidenced by the debates that took place in Québec City and Gatineau. From this perspective, it would fall to the government to assume responsibility for the fluoridation of drinking water vis-à-vis the public, through the proposed project.

These figures have been provided by the proponents.

It is proposed that the MDDEP Regulation respecting the quality of drinking water be amended in the light of these various contextual factors. By making this choice, the government would arm itself with the means to ensure the fluoridation of water, through site visits by inspectors, while fulfilling its obligations with respect to overall water quality.

1.1 OBJECTIVES OF THE PROJECT

The health objective of the project is to improve oral health through public access to fluoridated drinking water at a minimum standard of 0.7 mg/l. The project is part of a national strategy to promote water fluoridation, by mobilizing both the public and a wide array of partners around this measure.

It is proposed to make the fluoridation of drinking water mandatory through regulation, using a phased approach:

- Short term: fluoridation of drinking water in Québec's 10 largest cities (population of 100,000 or more), reaching 47% of the total population;
- Medium term: fluoridation of drinking water in the 10 next largest cities (populations of 50,000 or more), reaching 56% of the total population;
- Long term: fluoridation of drinking water in towns with a population of 5,000 or more, reaching 75% of the total population.

1.2 REFERENCES TO THE FLUORIDATION OF DRINKING WATER IN KEY PUBLIC HEALTH DOCUMENTS

The measures set out in sections 57 to 59 of the Public Health Act (Chapter VI: Health Promotion and Prevention, Part II: Fluoridation of drinking water) (RSQ, chapter S-2.2, 2001) provide that the Minister may set regulatory standards as to how the quality of drinking water fluoridation is to be monitored, i.e. standards regarding the optimal concentration of fluoride for the prevention of tooth decay. The Minister may provide grants to any owner of a drinking water treatment plant who applies for one to cover the costs of fluoridation, and make these grants subject to any conditions deemed appropriate. An owner who implements water fluoridation must monitor water quality (the concentration of fluoride) based on the standards set by the Minister. To this end, the Regulation establishing the optimal fluoride concentration for the prevention of tooth decay, added to the Act in 2004, sets the concentration of fluoride in drinking water at 0.7 mg/l.

The National Public Health Program (Ministère de la Santé et des Services sociaux (MSSS), 2008, p. 47) establishes two objectives for reducing oral disease:

- Reduce the average number of decayed, missing or filled tooth surfaces by 40% in children under 18;
- Reduce the prevalence of periodontal disease (gingivitis and destructive periodontal disease) in people aged 18 or over.

Two types of activities are to be deployed to achieve these objectives:

- Activities aimed at changing environmental factors "... relating to the promotion, development and implementation of policies, laws and regulations encouraging the adoption of healthy lifestyles" (MSSS, 2006, p. 48) — in this case, encouraging municipalities to fluoridate their drinking water;
- Activities aimed at influencing individual factors: "application of dental sealants in schools, for children aged 5 to 15 at risk for tooth decay" and "individualized preventative care in schools so that children from kindergarten through Grade 2 who meet the criteria for risk of dental decay receive two topical fluoride applications per year and participate in oral health education activities."

The *Plan d'action de santé dentaire publique 2005-2012* (PASDP – Public Dental Health Action Plan) (MSSS, 2006) sets out the following two objectives on fluoridation, which echo the strategy developed in the project under consideration:

- By 2008, 100% of the owners of drinking water treatment plants in municipalities with populations of 5,000 or more will have been contacted to urge them to proceed with fluoridation in accordance with the provisions set out in the Public Health Act.
- By 2012, 50% of the population of Québec will have access to drinking water with an optimal fluoride concentration of 0.7 mg/l.

1.3 SCIENTIFIC BASIS OF THE PROJECT

The various issues related to water fluoridation, its contribution to dental health and its safety for human health and the environment have been the subject of much debate in Québec and elsewhere. Before formulating an opinion on this project, the CESP had to examine these aspects of fluoridation, given their central importance to the debate.

Fluorine is found in various forms in nature, most frequently in the form of salts, called fluorides (Groupe scientifique sur l'eau, 2007). Fluorides also occur naturally in varying concentrations in drinking water from both public and private sources. In public systems where fluoridation is not practised, the maximum level observed is 0.5 mg/l. In private wells, concentrations range from 4 mg/l to 28 mg/l, but the Québec average varies from 0.07 to 0.2 mg/l (Groupe scientifique sur l'eau, 2007). Fluorides are also present in certain foods such as tea.

1.3.1 Prevalence of dental health problems

According to the PASDP (MSSS, 2006, p. 17), tooth decay affects 42% of kindergarten children (for 1996-1999) and nearly half the tooth surfaces of adults aged 35 to 44 who have at least one tooth. Oral health problems affect the entire population (all ages and social classes). The problem is also associated with inequalities: the poorest segments of the population have a significantly higher incidence of oral health problems compared to the socio-economically advantaged. An exploratory study conducted by researchers from the INSPQ in disadvantaged areas of Montréal found that 50 to 70% of preschool children were affected by tooth decay (Levy, 2007). Finally, in Canada, it was estimated that the direct costs (public and private) of

dental treatments were \$9.9 billion in 2006 (Levy, 2007) for people requiring treatment. In Québec, this amount is about \$2 billion.

1.3.2 Health impact of drinking water fluoridation

In many publications on the subject, the fluoridation of drinking water is presented as one of the safest, most effective, economical and equitable ways to reduce tooth decay. For example, a major literature review (referred to below as the University of York review) confirms the effectiveness of fluoridation (DMFT index — decayed, missing and filled teeth — lower in children who have access to fluoridated water, and more children without tooth decay) (McDonagh et al., 2000). The effectiveness of fluoridation was reaffirmed by a more recent review conducted for the government of Australia (National Health and Medical Research Council, 2007).

Water fluoridation is an effective way to combat tooth decay, particularly in children. Fluoride strengthens the crown of the tooth during its formation. This means children are more likely to benefit from water fluoridation than the rest of the population. In addition, given that oral hygiene in children is largely dependent on their parents, access to fluoridated water may compensate to some degree for the adverse conditions to which they may be exposed involuntarily (e.g. dental hygiene, diet, use of services, etc.).

As mentioned above, individuals from economically disadvantaged groups are disproportionately affected by tooth decay, primarily because they visit the dentist less frequently and brush their teeth less often (Burt, 2002). Artificial fluoridation of drinking water is a particularly effective preventative measure against tooth decay for these groups. As a result, it could be argued that fluoridation is a public health measure that helps reduce social inequalities in health.

However, some caveats are expressed in the literature regarding the extent of the benefits associated with fluoridation. According to the University of York review, it is difficult to determine the degree of reduction in the DMFT index that can be attributed to the fluoridation of drinking water: the average extent of changes in the DMFT index varied from 0.5 to 4.4, with a median of 2.25. The authors also express surprise at the dearth of quality studies on a public health measure that is so well-known and widespread.

In addition, over time, the benefits attributable to the fluoridation of water become increasingly difficult to distinguish from other measures for preventing tooth decay, since there is a general improvement in dental health. Indeed, the prevalence of tooth decay has fallen substantially over the past 30 years. This decrease, which has been observed in all western countries, regardless of whether they fluoridate their water, is attributable firstly to greater public awareness of the importance of good oral health and dental hygiene, and secondly, to the fact that other preventative measures involving fluoride — e.g. the use of fluoride toothpaste and the topical application of fluoride — are becoming more accessible and more widespread.

What, then, is the contribution of drinking water fluoridation in the reduction of tooth decay in a context of overall decreased prevalence of dental caries? Given the situation in western countries, some experts now believe it is no longer necessary (Pizzo, Piscopo, Pizzo, & Giuliani,

2007). In other words, the fluoridation of water is dependent on the relative weakness in the adoption of other preventative dental hygiene measures. In fact, as Burt has pointed out, the cessation of water fluoridation in some areas (including parts of Canada) has not been accompanied by an increase in the DMFT index, either among disadvantaged groups in the population or in general (Burt, 2002). He emphasizes, however, that the benefits attributable to fluoridation generally remain observable despite the increasingly common use of alternative means to fight tooth decay in the population.

The finding of a continuous overall improvement in oral health in the population is not shared by all researchers. In a well-known Québec study (Brodeur, Olivier, Benigeri, Bedos, & Williamson, 2001), the authors anticipated that the decline in tooth decay was reaching a plateau. There are recent studies showing that these gains appear to have levelled off, a situation partly due to the fact that the prevalence of tooth decay was increasing slightly in some population groups (Dye & Thornton-Evans, 2010).

1.3.3 Problems associated with drinking water fluoridation

The consumption of fluoridated water can cause dental fluorosis if it contributes to overexposure to fluoride. This problem develops during tooth formation and is usually characterized by permanent hypopigmentation of the enamel or, in lay terms, by the appearance of whitish spots (Groupe scientifique sur l'eau, 2007). In more severe cases, the spots are more pronounced and clearly visible. According to the University of York review, the prevalence of dental fluorosis "of aesthetic concern" is 12.5% for a population exposed to 1 mg/l of fluoride in drinking water. Children aged 1 to 3 years are most likely to develop this condition (Groupe scientifique sur l'eau, 2007). Dental fluorosis in general, including cases that are not described as being of aesthetic concern, has a prevalence of 48% for a population exposed to 1 mg/l of fluoride in drinking water. While this is primarily an aesthetic issue, the potential psychological consequences should not be minimized, particularly among young people concerned about their appearance.

Skeletal fluorosis is a fairly rare problem that primarily affects the elderly (Groupe scientifique sur l'eau, 2007). Despite the emphasis on this type of problem in anti-fluoridation literature, the University of York review found no statistically significant relationship between fluoride in drinking water and skeletal fluorosis (McDonagh et al., 2000). Moreover, according to the authors, the artificial fluoridation of drinking water does not seem to have any other adverse effect on health (cancer or otherwise). The Australian review on the subject (National Health and Medical Research Council, 2007) yielded essentially the same findings.

Finally, evaluations of the environmental impact of fluoridation have not demonstrated that it has had any significant detrimental effects. Fluorides added to water in the proposed concentrations do not tend to accumulate in groundwater and have no adverse effects on animals and plants (Pollick, 2004).

1.4 ETHICAL CONSIDERATIONS

In their submission form, the proponents outline some ethical concerns they expect to arise out of their project. In essence, these are as follows:

Since fluorine has preventative and therapeutic properties that reduce the incidence of tooth decay, some people consider the fluoridation of drinking water to be a form of medication imposed without their informed consent.

Others feel that drinking water fluoridation deprives them of the freedom to choose to have easy access to and consume water with low fluoride content. These people are opposed to being forced to drink fluoridated water, regardless of their risk of tooth decay.

For many, merely expressing the intention to add a product to their drinking water is abhorrent — even if the product is a mineral already present, and often in much greater amounts than those being prescribed to prevent tooth decay. These people believe we are already adding enough chemicals to our water to make it potable, and the addition of fluoride only reduces its purity or quality.

The proponents have also explained how ethics, understood here to be the pursuit of social justice, was taken into account in their project.

The distribution of tooth decay is very uneven across the population and varies greatly depending on socio-economic status and level of education. Fluoridation is the most convenient and least expensive way to reach high-risk groups (and the entire population) to reduce social inequalities in terms of oral and general health.

Finally, the proponents asked the CESP to address the following two questions:

Faced with the reluctance of most Québec municipalities to adopt water fluoridation, a population-based public health measure that is recognized around the world and strongly supported by the Ministère de la Santé et des Services sociaux (MSSS), is the government of Québec morally entitled to compel cities to fluoridate their water through legislation?

Also, if they refuse to fluoridate drinking water despite the favourable opinions of public health authorities, are these cities harming the health of their citizens, and are they morally responsible?

2 DELIBERATIONS OF THE COMITÉ D'ÉTHIQUE DE SANTÉ PUBLIQUE

Through its normal deliberation process, the CESP identified specific ethical issues arising from the review of the plan submitted to it. These are discussed in this section.

2.1 Understanding the situation

The fluoridation of drinking water is considered to be the most effective measure for preventing oral health problems and, notably, for reducing health inequalities associated with the socioeconomic status of certain population groups. Although less pronounced, this effect persists even in the context of all the other factors that have contributed to an overall improvement in oral health over the past 50 years.

Despite this improvement, oral health in Québec is not as good as it is in the other provinces. The rate of exposure to fluoridated water is also among the lowest in Canada.

In a context in which the number of municipalities that fluoridate their water is decreasing, current measures to promote fluoridation face significant limitations. Municipal authorities, responsible for the treatment of drinking water, do not want to assume responsibility for the decision to fluoridate, claiming that responsibility lies with public health at the ministerial level and not with local governments. This position is influenced by pressures from anti-fluoridation groups.

Under these circumstances, public health authorities are proposing an amendment to the regulation on drinking water in order to apply a mandatory minimum standard for fluoride in drinking water in all Québec municipalities with populations of 5,000 or more. The implementation of this measure would be financially supported by the MSSS and the monitoring of the implementation would be taken on by the MDDEP. Finally, the measure would be phased in gradually, applying successively to municipalities based on their population size, as part of a national strategy to promote fluoridation. The level of fluorine in water would be set at 0.7 mg/l, which is considered optimal for promoting health while minimizing the risk of dental fluorosis.

After reviewing the main components of the plan submitted to it, the CESP is of the view that water fluoridation is a source of public good with particular benefits for the socioeconomically disadvantaged and for children, given that they depend on the preventative behaviours of their parents.

The recommended standard has been revised to account for other potential exposures to fluoride (toothpastes and other fluoridated products) to avoid exposing individuals to excessive doses that could cause dental fluorosis. It therefore seems unlikely that the plan would cause health problems. It also seems implausible that it would have adverse effects on the environment.

Finally, needless to say, the fluoridation of drinking water has sparked impassioned debates, and this reality must be considered in any discussion of the ethical aspects of the issue. The universal nature of the planned measure imposes a serious constraint on individual preferences

regarding the fluoridation of water. Groups opposing it often do so in the name of individual freedom and respect for the environment. The CESP conducted its deliberations with this understanding of the plan. The highlights of the discussion are presented in the next section.

2.2 FORMULATING THE ETHICAL PROBLEM

2.2.1 The question retained by the Comité

Regarding the legitimacy of the measure being considered, the CESP settled on a question that cut across several of the concerns and one of the questions posed by the proponents. The Comité agreed on the following question:

Is it justifiable, in the interest of public health, to impose the fluoridation of drinking water on Québec municipalities with populations of 5,000 or more, against the wishes of part of the population, in order to reduce tooth decay in the general population, especially among children and the most disadvantaged in our society?

2.2.2 Identification, prioritization and discussion of relevant values

The CESP developed its opinion by identifying and prioritizing the primary values brought out by the case before it. As identified by the Committee, the values and their respective definitions (in alphabetical order), are as follows:

- Accountability: the willingness to act in accordance with assigned tasks and mandates (institutional accountability).
- Autonomy: the ability to make choices for oneself.
- Beneficence: the desire to improve the health of the population, including that of children from socioeconomically disadvantaged backgrounds.
- Citizen participation: the importance given to the population's involvement in the decision-making process.
- Freedom of choice: the ability to exercise one's choice without constraint.
- Non-maleficence: the desire to avoid causing health problems.
- Respect for the environment: the importance given to the protection of natural environments.
- Social justice and equity: balance in the distribution of resources based on the needs of those concerned, in order to reduce social inequalities in health.
- Transparency: the act of making information available so that people can understand the decision-making process.

The CESP then set about ranking these values to determine their relative importance. Through this exercise, the foundations of the Comité's view were laid, in that its opinion would be guided by the predominant values and the associated tensions that may arise from them. The Comité therefore considered only the most important values identified in the project; the others are not addressed here.

The CESP believes the most important values to consider in establishing a regulation requiring the fluoridation of drinking water are beneficence and equity (or social justice). The first is achieved by improving the population's oral health. The three major systematic reviews of the literature conclude that drinking water fluoridation is beneficial for the oral health of the populations targeted by this measure. This positive impact is measurable, notwithstanding that fluorides are widely available from other sources, such as toothpastes or topical applications. The expected improvement in health from this project is relatively large: the goal is to reduce tooth decay and associated treatment and rehabilitation costs by 20 to 40%.

Disadvantaged groups are disproportionately affected by a variety of oral health problems. Equity refers to the notion that fluoridation of drinking water, as a universally accessible measure, offers these groups the greatest benefit. From a public health perspective guided by a concern for social justice, fluoridation is understood to be a measure that helps reduce social inequalities in health.

In the decision-making process, it is important to ensure that the proposed regulatory action will not cause harm to human health (non-maleficence) or to the environment (respect for the environment). Any adverse effects of fluoridation must be limited. From a health standpoint, the recommended standard for fluoride concentration in drinking water (0.7 mg/l) was determined to be the optimal threshold for preventing tooth decay while minimizing the risk of dental fluorosis in the population. Given the prevalence of oral health problems and associated costs, the benefits of fluoridation would be proportionally greater than the risk of dental fluorosis. From an environmental standpoint, and given the importance the public attaches to water in general, the proposed regulatory action is far from trivial. It is not a matter of adding a product to water to make it potable, but of ensuring that water contains the optimal amount of fluoride to prevent oral health problems. Nevertheless, it has not been demonstrated that the fluoridation of drinking water at the recommended doses has any significant environmental impact.

In general terms, then, the legitimacy of the measure is based on the fact that the expected benefits of the proposed action, in terms of oral health and the reduction of social inequalities associated with poor oral health outweigh any foreseeable negative consequences. The proposed standard, which has been set taking into account other types of fluoride exposure (dental hygiene products, for example) reduces the risk of dental fluorosis and is not associated with a demonstrable risk to the environment. From this perspective, the values of non-maleficence and respect for the environment would be ranked lower than beneficence and equity. Nonetheless, in order to ensure that the benefits of fluoridation outweigh any potential negative consequences, the adoption of such a legislative measure should be accompanied by the establishment or maintenance of scientific monitoring activities so that the standard, or even the measure itself, can be reviewed if necessary.

Finally, freedom of choice has also been identified as an important value in the project. The proposed regulatory action would eventually apply to the entire population of targeted municipalities, or 75% of Québec's population. This population mass would then be supplied with fluoridated water, regardless of individual preference. In the specific context of the project, freedom of choice refers to the fact that part of the population does not wish to have its water fluoridated, or is opposed to it outright.

A regulatory measure such as fluoridation must necessarily constrain individual choice. This constraint may be felt with varying degrees of intensity within the population and among its various constituent groups. The universal and imposed nature of a measure that affects a resource as essential as water undoubtedly explains the intensity of public debate.

Given the public controversy surrounding the fluoridation of drinking water, it is foreseeable that the proposal being discussed here will meet with opposition from a segment of the population. However, data collected through Canada-wide and Québec studies shows that support for drinking water fluoridation is around 60% (Quiñonez & Locker, 2009; SOM Research and Survey, 2010). Thus, public opinion regarding fluoridation appears to be fairly positive both in Canada and in Québec. The fact remains that any plan contemplating compulsory fluoridation will need to be publicly rationalized. From this perspective, the argument that people should be free to have unfluoridated water is not merely an obstacle to be circumvented in order to promote public health, but rather an important factor to be considered when assessing the social acceptability of the project.

What options are there for mitigating the possible negative consequences — particularly the restriction on freedom of access to water that has not been treated with fluoride — arising from the imposition of fluoridation?

First of all, it is clear that along with the proposed measure, information must be provided to the public. Indeed, should the government choose to impose fluoridation on Québec municipalities with populations of 5,000 or more, it has a concomitant responsibility to supply information that will enable citizens to understand the decision. These obligations have already been taken on with the adoption of the national strategy to promote the fluoridation of drinking water. In view of the principles that generally apply to communication in such contexts, it is essential that any drinking water fluoridation campaign in Québec be founded on principles of honesty, accuracy, transparency, timely communication and dialogue.

In addition, public consultations could be part of the process in implementing this regulatory action. Public health authorities could invite citizens to participate in forums at which they would share their opinions and concerns. These forums could take various forms, but essentially, they would provide opportunities for participants to become informed and correct any misapprehensions they may have about fluoridation. This brings us to a discussion of the ways in which the public could actively participate in the development and implementation of health policies like the one we are addressing here. Participation may take various forms, from advisory panels where the results of deliberations directly influence decision-making, to formal plebiscites. Many North American jurisdictions already require that a referendum on fluoridation be held before such a measure can be introduced.

It should also be stated that the artificial fluoridation of drinking water is generally considered to be an irreversible measure, and this is the assumption we have made to this point. However, it seems there are some fairly simple solutions to this problem. Activated alumina defluoridation filters can be purchased at a relatively low cost². Indeed, such filters are regularly used to defluoridate water in which natural fluoride levels are too high. It is therefore relatively easy for

² For a total of around \$100 to \$300 (FilterWater.com).

people who do not wish to drink fluoridated water to filter it. On the other hand, it would certainly be more difficult for people who wish to have fluoridated water in a municipality that does not offer it to fluoridate it themselves at home. In view of this, it may be possible for government authorities to offer support to those who wish to opt out of drinking water fluoridation measures if it is determined, for example, that a plebiscite would be too costly, or too prone to various kinds of problems. However, it should be kept in mind that publicizing such opt-out options could cast doubt on the safety of fluoridation.

In summary, beneficence and equity emerge as the most important and influential values when responding to the question under consideration. They are mutually reinforcing, since beneficence includes concern for the dental health of people from lower socioeconomic backgrounds. These values can therefore be adduced to justify fluoridation. The recommended standard for fluoride levels reduces the potential risk of adverse effects on health or the environment. Consequently, the values of non-maleficence and respect for the environment can be reflected in the proposal. However, the value of individual freedom is difficult to reconcile with a universally applicable regulation, particularly in a context where opposition to fluoridation is expressed publicly. In fact, fluoridation is a classic case in public health ethics, where there is an inverse relationship between beneficence, reflected in a significant improvement in the health of the population, and concern for the individual freedoms of those who make up that population. The CESP's position is formulated in such a way as to take this fact into consideration, offering possible options for mitigating the negative consequences of such a measure.

3 THE CESP'S RESPONSE TO THE QUESTION ADDRESSED

In response to the question under review, the Comité d'éthique de santé publique finds it legitimate, from an ethical perspective, to require fluoridation of drinking water in Québec municipalities with populations of 5,000 or more in order to reduce tooth decay, especially among children and the socioeconomically disadvantaged. As explained in this opinion, the Comité considers this measure to be legitimate to the extent that it respects the values of non-maleficence and respect for the environment. Ways to mitigate any negative consequences such a measure could have on individual freedom are presented.

REFERENCES

Banoczy, J., Petersen, P., & Rugg-Gunn, A. (2009). *Milk Fluoridation for the Prevention of Dental Caries*. Geneva: WHO.

Brodeur, J.-M., Olivier, M., Benigeri, M., Bedos, C., & Williamson, S. (2001). Étude 1998-1999 sur la santé buccodentaire des élèves québécois de 5-6 ans et de 7-8 ans. Québec: Ministère de la Santé et des Services sociaux.

Burt, B. (2002). Fluoridation and Social Equity. *Journal of Public Health Dentistry, 62* (4), 195-200.

Dye, B., & Thornton-Evans, G. (2010). Trends in Oral Health by Poverty Status as Measured by Healthy People 2010 Objectives. *Public Health Reports, 125* (6), 817-830.

FilterWater.com. (n.d.). *FilterWater.com*. Consulted on november 25th, 2010 from http://www.filterwater.com.

Groupe scientifique sur l'eau. (2007). Fiche fluorures. In G. s. l'eau, *Fiches synthèses sur l'eau potable et la santé humaine* (p. 155). Québec: INSPQ.

Lévy, M., Corbeil, F., Fortin, C., Lamarre, J-R., Lavallière, A., et al. (2007). Fluoration de l'eau : analyse des bénéfices et des risques pour la santé. Institut national de santé publique du Québec, Québec.

McDonagh, M., Whiting, P., Bradley, M., Cooper, J., Sutton, A., Chestnutt, I., et al. (2000). A Systematic Review of the Efficacy and Safety of Water Fluoridation. York: NHS Centre for Reviews and Dissemination.

National Health and Medical Research Council. (2007). A Systematic Review of the Efficacy and Safety of Water Fluoridation. Canberra: Australian Government.

Petersen, P. E., & Lennon, M. A. (2004). Effective Use of Fluorides for the Prevention of Dental Caries in the 21st Century: the WHO Approach. *Community Dentistry and Oral Epidemiology*, 32, 319-321.

Pizzo, G., Piscopo, M., Pizzo, I., & Giuliana, G. (2007). Community Water Fluoridation and Caries Prevention: a Critical Review. *Clinical Oral Investigations*, 11 (3).

Pollick, H. (2004). Water Fluoridation and the Environment. *International Journal of Occupational and Environmental Health, 10,* 343-350.

Quiñonez, C., & Locker, D. (2009). Public Opinions on Community Water Fluoridation. *Canadian Journal of Public Health, 100* (2), 96-100.

SOM Recherche et Sondage. (2010). Évaluation portant sur les campagnes sociétales 2009-2010 destinées aux 25 ans et plus (volet quantitatif). Québec: SOM Recherche et Sondage.

Tramini, P. (2005). Salt Fluoridation in France since 1986. *Schweiz Monatsschr Zahnmed, 115* (8), 656-658.

Publication N°: 1422

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